## 2 SYNOPSIS

Abbreviations are defined in the list of abbreviations located at the end of the Synopsis.

**SPONSOR:** Merck Sharp & Dohme LLC, Rahway, NJ, USA (hereafter called the Sponsor or MSD)

**COMPOUND NAME:** Vibostolimab (MK-7684A)

**PROTOCOL TITLE:** A Phase 3, Randomized, Double-blind, Active-Comparator-Controlled Clinical Study of Adjuvant MK-7684A (Vibostolimab with Pembrolizumab) Versus Adjuvant Pembrolizumab in Participants with High-risk Stage II-IV Melanoma (KEYVIBE-010)

The following terms may be used interchangeably in this report:

- Participant and subject
- Intervention and treatment and medication
- Study and trial

**STUDY IDENTIFIERS:**

| | | | |
|---|---|---|---|
| IND: 161,909 | EudraCT: Not applicable | WHO/UTN: Not applicable | NCT: NCT 05665595 |
| jRCT: 2031230099 | EU CT: 2022-501417-31 | | |

**STUDY PHASE:** Phase 3

**INDICATION**: Melanoma

**STUDY CENTERS:** This study was conducted at 205 centers in 26 countries.

**STUDY STATUS:** This study is an ongoing study and this report is based on IA1.

| | |
|---|---|
| First Participant First Visit | 19-JAN-2023 |
| Data Cutoff | 06-MAR-2024 |
| Last Data Available | Not applicable |
| Database Lock Date | 10-APR-2024 |

## METHODOLOGY:

KEYVIBE-010 is a Phase 3, randomized, double-blind, active-controlled, parallel-group, multicenter, efficacy, and safety study of adjuvant MK-7684A (Arm A, a coformulation of vibostolimab with pembrolizumab) versus adjuvant MK-3475 (Arm B, pembrolizumab monotherapy) in approximately 1560 participants 12 years of age and older with resected high-risk (Stage IIB-IV) melanoma. Participants must not have received any prior systemic therapy for melanoma beyond surgical resection. Eligible participants were randomized 1:1 to receive treatment with either MK-7684A or MK-3475 (hereafter referred to as pembro). Randomization was stratified according to the participant's disease risk (IIB/IIC/IIIA/IIIB vs IIIC/IIID/IV) and by the region (Asia vs rest of the word). The primary endpoint of the study is RFS, and key secondary endpoints include DMFS and OS. AEs were monitored throughout the study and graded in severity according to the guidelines outlined in the NCI CTCAE v5.0. Periodic eDMC participant safety monitoring reviews were conducted during the trial.

As prespecified by the protocol, at IA1, the eDMC reviewed available data and recommended the discontinuation of the MK-7684A arm. All ongoing participants receiving MK-7684A treatment were provided the option to continue on pembro monotherapy for a total of 17 cycles of study treatment or until disease progression, whichever occurs first. Enrollment was completed prior to the IA1 eDMC meeting. The study treatments are shown below.

| Arm Name | Intervention Name | Unit Dose Strength(s) | Dosage Level(s) | Route of Administration | Regimen/Treatment Period | Use |
|---|---|---|---|---|---|---|
| Arm A (Protocol Amendment 04: Arm A discontinued) | MK-7684A | MK-7684 200 mg + pembrolizumab 200 mg/ 20 mL vial | 200 mg /200 mg) | IV Infusion | Q3W (Day 1 of each cycle) for 17 cycles or until discontinuation criteria are met | Test Product |
| Arm B | Pembrolizumab | 25 mg/mL | Adults: 200 mg Adolescents≥40 kg:2 mg/kg (up to max of 200 mg) | IV Infusion | Q3W (Day 1 of each cycle) for 17 cycles or until discontinuation criteria are met, whichever occurs first | Comparator |

IV=intravenous; Q3W=every 3 weeks.
MK-7684A is a coformulation of vibostolimab (MK-7684) with pembrolizumab.

## ELIGIBILITY CRITERIA:

Participants eligible for inclusion in the study had surgically resected and histologically confirmed diagnosis of Stage IIB and IIC (pathological or clinical), III, or IV cutaneous melanoma per AJCC eighth edition guidelines. A therapeutic lymph node dissection defined as an anatomically complete lymphadenectomy of the involved nodal basin for macroscopic disease was required for macroscopic disease. Participants that received any prior systemic therapy for melanoma beyond surgical resection, or evidence of metastatic disease on imaging after resection as determined by investigator assessment, were not eligible for inclusion in the study.

## OBJECTIVES AND ENDPOINTS:

| **Primary Objective** | **Primary Endpoint** |
|---|---|
| To compare MK-7684A to pembrolizumab with respect to RFS<br>Hypothesis (H1): MK-7684A is superior to pembrolizumab with respect to RFS as assessed by investigator. | RFS: time from randomization to any recurrence (local, locoregional, regional or distant) as assessed by investigator, or death due to any cause, whichever occurs first. |
| **Secondary Objectives** | **Secondary Endpoints** |
| To compare MK-7684A to pembrolizumab with respect to DMFS.<br>Hypothesis (H2): MK-7684A is superior to pembrolizumab with respect to DMFS as assessed by investigator. | DMFS: The time from randomization to appearance of a distant metastasis as assessed by investigator or death due to any cause, whichever occurs first. A distant metastasis refers to cancer that has spread from the original (primary) tumor to distant organs or distant lymph nodes. |
| To compare MK-7684A to pembrolizumab with respect to OS.<br>Hypothesis (H3): MK-7684A is superior to pembrolizumab with respect to overall survival. | OS: The time from randomization to death due to any cause. |
| To evaluate the safety and tolerability of MK-7684A and pembrolizumab | Adverse event<br>Study intervention discontinuation due to AEs |
| To evaluate MK-7684A to pembrolizumab with respect to mean change from baseline in global health status/QoL, physical functioning, and role functioning using the EORTC-QLQ-C30 | Change in score from baseline evaluated by:<br>Global health status/QoL score (Items 29 and 30)<br>Physical functioning score (Items 1-5)<br>Role functioning score (Items 6 and 7) |

**NUMBER OF PARTICIPANTS (planned and analyzed):**

Approximately 1560 participants were planned to be randomized in the study. Enrollment (LPI 01-MAY-2024) was completed prior to eDMC meeting. As of the DCO date (06-MAR-2024) for this report:

- There were 1504 participants screened and 1402 participants randomized [Table 2-4] [Table 2-5]
- In the ITT population, 1402 participants were included for analysis (n=701 in the MK-7684A group, n=701 in the pembro group) [Table 2-4]
- In the APaT population, 1398 participants were included for analysis (n=698 in MK-7684A group, n=700 in the pembro group) [Table 2-4] [Table 2-6]

**STATISTICAL AND ANALYSIS METHODS:**

The ITT population, which included all randomized participants, served as the population for primary efficacy analyses. The primary hypothesis was evaluated by comparing MK-7684A to pembro with respect to the RFS HR at IA1 (prespecified futility analysis at ~111 RFS events). A stratified Cox proportional hazard model with Efron's method of tie handling was used to assess the magnitude of the treatment difference (ie, HR) between the treatment arms. The HR and its 95% CI from the stratified Cox model with Efron's method of tie handling and with a single treatment covariate were reported.

Safety analyses were conducted in the APaT population, which consisted of all randomized participants who received at least 1 dose of study intervention. The overall safety evaluation included summary tables by treatment group of the number and percentage of participants with at least 1 AE, drug-related AE, serious AE, serious drug-related AE, Grade 3-5 AE, discontinuation from study intervention due to an AE, and AE resulting in death.

No changes were made to the planned analysis of the study.

**RESULTS:**

**Participant Disposition:**

- Overall, in the ITT population, 29 (2.1%) participants completed study treatment, 1113 (79.6%) participants were ongoing, and 256 (18.3%) participants discontinued the study, nearly half due to an AE (127 [9.1%]) [Table 2-1].
  - In the MK-7684A group: 701 randomized, 698 treated, 9 (1.3%) completed treatment, 158 (22.6%) discontinued treatment, 531 (76.1%) ongoing on treatment, 9 (1.3%) discontinued the study, 692 (98.7%) ongoing in the study [Table 2-1]
  - In the pembro group: 701 randomized, 700 treated, 20 (2.9%) completed treatment, 98 (14.0%) discontinued treatment, 582 (83.1%) ongoing on treatment, 3 (0.4%) discontinued the study, 698 (99.6%) ongoing in the study [Table 2-1]

Table 2-1
Disposition of Participant
(ITT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Participant in population | 701 | | 701 | | 1402 | |
| **Trial Disposition** | | | | | | |
| Discontinued | 9 | (1.3) | 3 | (0.4) | 12 | (0.9) |
| Death | 6 | (0.9) | 1 | (0.1) | 7 | (0.5) |
| Lost To Follow-Up | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Withdrawal By Subject | 2 | (0.3) | 2 | (0.3) | 4 | (0.3) |
| Ongoing | 692 | (98.7) | 698 | (99.6) | 1390 | (99.1) |
| **Subject Study Medication Disposition** | | | | | | |
| Started | 698 | | 700 | | 1398 | |
| Completed | 9 | (1.3) | 20 | (2.9) | 29 | (2.1) |
| Discontinued | 158 | (22.6) | 98 | (14.0) | 256 | (18.3) |
| Adverse Event | 88 | (12.6) | 39 | (5.6) | 127 | (9.1) |
| Clinical Progression | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Excluded Medication | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Lost To Follow-Up | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Non-Study Anti-Cancer Therapy | 3 | (0.4) | 2 | (0.3) | 5 | (0.4) |
| Physician Decision | 5 | (0.7) | 3 | (0.4) | 8 | (0.6) |
| Pregnancy | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Protocol Violation | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Recurrence/Relapse | 48 | (6.9) | 43 | (6.1) | 91 | (6.5) |
| Withdrawal By Subject | 10 | (1.4) | 8 | (1.1) | 18 | (1.3) |
| Ongoing | 531 | (76.1) | 582 | (83.1) | 1113 | (79.6) |

If the overall count of participant is calculated and displayed within a section in the first row, then it is used as the denominator for the percentage calculation. Otherwise, participant in population is used as the denominator for the percentage calculation.

Each subject is counted once for Study Medication Disposition.

Status not Recorded is for subjects that are continuing in trial or on treatment.

Database Cutoff Date: 06MAR2024.

Source: [P010V01MK7684a: adam-adsl]

**Demographics and Baseline Characteristics:**

The data presented below are based on the ITT analysis population [Table 2-7].

- **Overall Median Age (Range):** 61 years (21 to 93 years)
- **Gender:** 829 (59.1%) male, 573 (40.9%) female
- **Ethnicity:** 1171 (83.5%) not Hispanic or Latino, 157 (11.2%) Hispanic or Latino, 74 (5.3%) not reported/unknown
- **Race:** 4 (0.3%) American Indian, 273 (19.5%) Asian, 5 (0.4%) black or African American, 6 (0.4%) multiple, 4 (0.3%) Native Hawaiian or other Pacific Islander, 1107 (79.0%) white, 3 (0.2%) missing

**Extent of Exposure:**

In the APaT population, the extent of exposure was similar in both treatment groups. The median duration of exposure to MK-7684A versus pembro was 85 days (1 to 358) versus 87.5 days (1 to 352), respectively. The median number of administrations for both MK-7684A and pembro was 5 (range: 1 to 17) [Table 2-8].

**Efficacy:**

- The median follow-up duration in the ITT population was similar between groups; the MK-7684A group was 4.2 months (range: 0.0, 13.4) and the pembro group was 4.2 months (range: 0.0, 13.3) [Table 2-9].
- RFS HR was 1.25 (95% CI: 0.87, 1.80), which met the prespecified criterion for declaring futility (RFS HR ≥0.95) [Table 2-2].
- The RFS rates by KM estimation from Month 1 to Month 4 were similar between groups [Table 2-10]. KM estimate curves of RFS in each group are provided in [Figure 2-1].

Table 2-2
Analysis of Recurrence-Free Survival (Primary Censoring Rule)
ITT Population

| Treatment | N | Number of Events (%) | Person-month | Event Rate/ 100 Person-months | Median RFS [a] (months) (95% CI) | RFS Rate at 6 months in % [a] (95% CI) |
|---|---|---|---|---|---|---|
| MK-7684A Q3W | 701 | 67 (9.6) | 2238.8 | 3.0 | NR (NR, NR) | 80.3 (74.9, 84.7) |
| Pembrolizumab (MK-3475) Q3W | 701 | 52 (7.4) | 2268.2 | 2.3 | NR (NR, NR) | 85.4 (80.8, 88.9) |
| **Pairwise Comparisons** | | | | | Hazard Ratio[b] (95% CI)[b] | |
| MK-7684A Q3W vs. Pembrolizumab (MK-3475) Q3W | | | | | 1.25 (0.87, 1.80) | |

[a] From product-limit (Kaplan-Meier) method for censored data.

[b] Based on Cox regression model with Efron's method of tie handling with treatment as a covariate stratified by melanoma risk-based stage (IIB/IIC/clinical IIB and IIC/IIIA/IIIB vs IIIC/IIID/IV) and region (Asia vs ROW).

NR = Not reached.

Recurrence-free survival is defined as time from randomization to the date of first recurrence of melanoma at any site (local, in-transit or regional lymph nodes or distant recurrence) or death due to any cause, whichever occurs first.

Database Cutoff Date: 06MAR2024.

Source: [P010V01MK7684a: adam-adsl; adtte]

**Safety:**

- As expected for a comparison of coformulation with 2 immune-oncology therapies (MK-7684A) vs monotherapy (pembro), there were higher incidences (overall and drug-related) of AEs, Grade 3-5 AEs, SAEs, AEs leading to discontinuation of study treatment, and AEOSIs in the MK-7684A group vs pembro monotherapy group [Table 2-3] [Table 2-23].
- The majority (81.0%) of participants in KEYVIBE-010 study had at least 1 AE (82.2% in MK-7684A group; 79.7% in the pembro group), 10.3% of participants had an AE that led to treatment discontinuation (13.9% in MK-7684A group; 6.7% in the pembro group), and 9.4% (12.5% in MK-7684A group; 6.3% in the pembro group) of participants discontinued due to drug-related AEs [Table 2-3].
- The most common AEs (incidence ≥10%) in the MK-7684A group were pruritis (25.6%), rash (24.5%), fatigue (18.8%), hyperthyroidism (12.6%), and arthralgia (10.7%). The most common AEs (incidence ≥10%) in the pembro group were fatigue (20.7%), pruritis (13.0%), hyperthyroidism (11.4%), rash (10.9%), and diarrhea (10.3%) [Table 2-11]. A summary of all AEs by SOC and PT (MedDRA V26.1) is provided in [Table 2-12].
- The majority (70.0%) of participants had at least 1 drug-related AE (74.1% in the MK-7684A group; 66.0% in the pembro group) [Table 2-13]. The most common drug-related AEs (incidence ≥10%) in the MK-7684A group were pruritis (23.8%), rash (23.2%), fatigue (15.9%), and hyperthyroidism (12.2%). The most common drug-related AEs (incidence ≥10%) in the pembro group were fatigue (16.6%), pruritis (12.3%), and hyperthyroidism (11.1%) [Table 2-13]. A summary of all drug-related AEs by SOC and PT (MedDRA V26.1) is shown in [Table 2-14].
- Overall, Grade 3-5 AEs were experienced by 16.4% of participants. There were more Grade 3-5 AEs reported in the MK-7684A group compared with pembro group (21.9% versus 10.9%) [Table 2-3]. The most common Grade 3-5 AEs (incidence ≥1%) in the MK-7684A group were adrenal insufficiency (1.9%), hepatitis (1.6%), rash (1.3%), hypertension (1.1%), and rash maculopapular (1.1%). The most common Grade 3-5 AE (incidence ≥1%) in the pembro group was ALT increased (1.3%) [Table 2-15]. A summary of all Grade 3-5 AEs by SOC and PT (MedDRA V26.1) are shown in [Table 2-16].
- Drug-related Grade 3-5 AEs were experienced by 11.4% of participants (15.9% in the MK-7684A group; 6.9% in the pembro group) [Table 2-17]. The most common drug-related Grade 3-5 AEs (incidence ≥1%) in the MK-7684A group were adrenal insufficiency (1.9%), hepatitis (1.6%), rash (1.3%), and rash maculopapular (1.0%). The most common drug-related Grade 3-5 AE (incidence ≥1%) in the pembro group was ALT increased (1.0%).
- Four (0.3%) participants had an AE resulting in death [Table 2-3], 3 in the MK-7684A group and 1 in the pembro group. In the MK-7684A group, 2 of the 3 deaths were considered drug-related by the investigator (myocarditis and myasthenia gravis). In the pembro group, the 1 death was considered drug-related by the investigator (myositis) [Table 2-3] [Table 2-18].

- More participants in the MK-7684A group underwent dose interruption (23.1% vs 15.7%) [Table 2-3] and discontinuation (13.9% vs 6.7%) [Table 2-19] due to an AE. Overall, discontinuations due to a drug-related AE were 9.4% (12.5% in the MK-7684A group; 6.3% in the pembro group) [Table 2-20].
- Overall, 11.9% participants experienced at least 1 SAE (15.6% in MK-7684A vs 8.1% in the pembro group) [Table 2-3]. The most common SAE (incidence ≥1.0%) in the MK-7 684A group was adrenal insufficiency (2.0%). There were no SAEs reported in the pembro group with an incidence ≥1.0% [Table 2-21]. Drug-related SAEs were experienced in 7.4% of participants (10.6% in the MK-7684A group; 4.3% in the pembro group) and are provided by decreasing incidence in [Table 2-22].
- Overall, 27.2% of participants had at least 1 AEOSI (30.4% in MK-7684A; 24.0% in the pembro group) [Table 2-23]. The majority of the AEOSI reported in both treatment groups were Grade 1-2 (18.5% in the MK-7684A group; 20.3% in the pembro group). There were more Grade 3-4 AEOSI in the MK-7684A group compared with pembro group [Table 2-24]. The most common AEOSI in the MK-7 684A group (incidence ≥1%) were hyperthyroidism (12.6%), hypothyroidism (9.6%), adrenal insufficiency (3.3%), hepatitis (2.1%), hypophysitis (1.4%), infusion-related reaction (1.4%), rash (1.3%), rash maculopapular (1.1%), and pneumonitis (1.0%). The most common AEOSI in the pembro group (incidence ≥1%) were hyperthyroidism (11.4%), hypothyroidism (9.1%), gastritis (1.3%), adrenal insufficiency (1.0%), hepatitis (1.0%), and pneumonitis (1.0%)[Table 2-25]. AEOSI episodes were managed with systemic corticosteroids and standard clinical practice measures [Table 2-26], and a summary of outcome for participants with AEOSI is provided in [Table 2-27].

Table 2-3
Adverse Event Summary
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Participants in population | 698 | | 700 | | 1,398 | |
| with one or more adverse events | 574 | (82.2) | 558 | (79.7) | 1,132 | (81.0) |
| with no adverse event | 124 | (17.8) | 142 | (20.3) | 266 | (19.0) |
| with drug-related[a] adverse events | 517 | (74.1) | 462 | (66.0) | 979 | (70.0) |
| with toxicity grade 3-5 adverse events | 153 | (21.9) | 76 | (10.9) | 229 | (16.4) |
| with toxicity grade 3-5 drug-related adverse events | 111 | (15.9) | 48 | (6.9) | 159 | (11.4) |
| with serious adverse events | 109 | (15.6) | 57 | (8.1) | 166 | (11.9) |
| with serious drug-related adverse events | 74 | (10.6) | 30 | (4.3) | 104 | (7.4) |
| with dose modification[b] due to an adverse event | 229 | (32.8) | 145 | (20.7) | 374 | (26.8) |
| with dose interrupted due to an adverse event | 161 | (23.1) | 110 | (15.7) | 271 | (19.4) |
| who died | 3 | (0.4) | 1 | (0.1) | 4 | (0.3) |
| who died due to a drug-related adverse event | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| discontinued drug due to an adverse event | 97 | (13.9) | 47 | (6.7) | 144 | (10.3) |
| discontinued drug due to a drug-related adverse event | 87 | (12.5) | 44 | (6.3) | 131 | (9.4) |
| discontinued drug due to a serious adverse event | 38 | (5.4) | 18 | (2.6) | 56 | (4.0) |
| discontinued drug due to a serious drug-related adverse event | 34 | (4.9) | 18 | (2.6) | 52 | (3.7) |

[a] Determined by the investigator to be related to the drug.

[b] Defined as an action taken of drug interrupted or drug withdrawn.

Non-serious adverse events up to 30 days of last treatment and serious adverse events up to 90 days of last treatment are included.

MedDRA V26.1 preferred terms "Neoplasm progression", "Malignant neoplasm progression" and "Disease progression" not related to the drug are excluded.

Grades are based on NCI CTCAE version 5.

06MAR2024

Source: [P010V01MK7684a: adam-adsl; adae]

## CONCLUSIONS:

### Efficacy

Based on the IA1 results from KEYVIBE-010, the following efficacy results were observed:

- The primary endpoint of RFS met the prespecified criterion for declaring futility (RFS HR ≥0.95).
- As of the DCO, the median RFS was not reached in the MK-7684A group nor in the pembro group. The HR was 1.25 (95% CI: 0.87, 1.80).

### Safety

Based on the IA1 results from KEYVIBE-010, the following safety conclusions can be made:

- As expected for a comparison of a coformulation with 2 immune-oncology therapies (MK-7684A vs monotherapy pembro), there were higher incidences of AEs, Grade 3-5 AEs, SAEs, AEs leading to discontinuation of study treatment, and AEOSIs in the MK-7684A group vs pembro monotherapy group.
- MK-7684A has a generally manageable safety profile in the adjuvant treatment of patients with high-risk Stage II-IV melanoma.
- The types and severity of AEOSI in both treatment groups are generally similar, of low grade (Grade 1-2), and were managed with systemic corticosteroid and standard clinical practice measures.

## LIST OF ABBREVIATIONS:

| Abbreviation/Term | Definition |
|---|---|
| AE | Adverse event |
| AEOSI | Adverse event of special interest |
| AJCC | American Joint Committee on Cancer |
| ALT | Alanine aminotransferase |
| APaT | All-participants-as-treated |
| CI | Confidence interval |
| CSR | Clinical study report |
| DCO | Data cutoff |
| DMFS | Distant metastasis free survival |
| eDMC | External data monitoring committee |
| EORTC-QLQ-30 | European Organization for Research and Treatment of Cancer Quality of Life Questionnaire 30 |
| GCP | Good clinical practice |
| HR | Hazard ratio |
| IA1 | Interim analysis 1 |
| ICH | International Council for Harmonisation (of Technical Requirements for Pharmaceuticals for Human Use) |
| IEC | Independent ethics committee |
| ITT | Intent-to-treat |
| IV | Intravenous |
| KM | Kaplan-Meier |
| MedDRA | Medical Dictionary for Regulatory Activities |
| NCI CTCAE | National Cancer Institute Common Terminology Criteria for Adverse Events |
| OS | Overall survival |
| pembro | Pembrolizumab |
| PT | Preferred term |
| Q3W | Every 3 weeks |
| QoL | Quality of life |
| RFS | Recurrence-free survival |

| Abbreviation/Term | Definition |
|---|---|
| SAE | Serious adverse event |
| SOC | System organ class |

**PUBLICATION(S):** As of the date of this report, there are no publications based on this study.

**REPORT DATE:** 16-OCT-2024

**REVISED REPORT DATE:** Not applicable.

## ADDITIONAL TABLES:

Table 2-4
Study Population

| | MK-7684A Q3W | Pembrolizumab (MK-3475) Q3W | Total |
|---|---|---|---|
| Number of Participants Screened | | | 1504 |
| Number of Participants Randomized (Planned Treatment) (ITT) | 701 | 701 | 1402 |
| Number of Participants Received Treatment (Actual Treatment) (APaT) | 698 | 700 | 1398 |
| Number of Participants Randomized and Did not Receive Treatment | 3 | 1 | 4 |
| Database Cutoff Date: 06MAR2024. | | | |

Source: [P010V01MK7684a: adam-adsl]

Table 2-5
Consort Table

| | MK-7684A Q3W | Pembrolizumab (MK-3475) Q3W | Total |
|---|---|---|---|
| Participants Screened | | | 1504 |
| Participants Randomized | 701 | 701 | 1402 |
| **Participants who died** | **6** | **1** | **7** |
| Participants who did not receive treatment | 0 | 0 | 0 |
| Participants who received treatment | 6 | 1 | 7 |
| **Participants who are alive and on study** | **692** | **698** | **1390** |
| Participants who have not received treatment | 3 | 1 | 4 |
| Participants who received treatment and are on treatment | 531 | 582 | 1113 |
| Participants who discontinued study treatment | 149 | 95 | 244 |
| Participants who completed study treatment | 9 | 20 | 29 |
| **Participants who are alive but off study** | **3** | **2** | **5** |
| Participants who did not receive treatment | 0 | 0 | 0 |
| Participants who received treatment | 3 | 2 | 5 |
| 06MAR2024 | | | |

Source: [P010V01MK7684a: adam-adsl]

Table 2-6
Participants Randomized by Investigator and Treatment Group
APaT Population

| Trial-Site | Investigator Name | MK-7684A Q3W (N=698) | Pembrolizumab (MK-3475) Q3W (N=700) | Total (N=1,398) |
|---|---|---|---|---|
| 7684A-010-0004 | PPD | 2 | 2 | 4 |
| 7684A-010-0102 | | 1 | 1 | 2 |
| 7684A-010-0103 | | 4 | 4 | 8 |
| 7684A-010-0107 | | 2 | 2 | 4 |
| 7684A-010-0108 | | 2 | 1 | 3 |
| 7684A-010-0109 | | 2 | 2 | 4 |
| 7684A-010-0110 | | 0 | 1 | 1 |
| 7684A-010-0111 | | 3 | 4 | 7 |
| 7684A-010-0113 | | 0 | 1 | 1 |
| 7684A-010-0119 | | 4 | 3 | 7 |
| 7684A-010-0123 | | 5 | 1 | 6 |
| 7684A-010-0124 | | 2 | 2 | 4 |
| 7684A-010-0125 | | 1 | 3 | 4 |
| 7684A-010-0127 | | 1 | 0 | 1 |
| 7684A-010-0130 | | 3 | 5 | 8 |
| 7684A-010-0131 | | 1 | 0 | 1 |
| 7684A-010-0132 | | 1 | 0 | 1 |
| 7684A-010-0135 | | 4 | 6 | 10 |
| 7684A-010-0138 | | 5 | 0 | 5 |
| 7684A-010-0142 | | 4 | 6 | 10 |
| 7684A-010-0145 | | 1 | 0 | 1 |
| 7684A-010-0200 | | 1 | 1 | 2 |
| 7684A-010-0204 | | 3 | 0 | 3 |
| 7684A-010-0206 | | 2 | 4 | 6 |
| 7684A-010-0209 | | 5 | 2 | 7 |
| 7684A-010-0211 | | 2 | 7 | 9 |
| 7684A-010-0212 | | 2 | 5 | 7 |
| 7684A-010-0252 | | 8 | 2 | 10 |
| 7684A-010-0255 | | 6 | 2 | 8 |
| 7684A-010-0256 | | 4 | 4 | 8 |
| 7684A-010-0258 | | 4 | 3 | 7 |

Participants Randomized by Investigator and Treatment Group
APaT Population

| Trial-Site | Investigator Name | MK-7684A Q3W (N=698) | Pembrolizumab (MK-3475) Q3W (N=700) | Total (N=1,398) |
|---|---|---|---|---|
| 7684A-010-0259 | PPD | 9 | 3 | 12 |
| 7684A-010-0262 | | 2 | 5 | 7 |
| 7684A-010-0300 | | 0 | 1 | 1 |
| 7684A-010-0302 | | 5 | 7 | 12 |
| 7684A-010-0303 | | 9 | 8 | 17 |
| 7684A-010-0305 | | 6 | 7 | 13 |
| 7684A-010-0308 | | 1 | 0 | 1 |
| 7684A-010-0352 | | 1 | 0 | 1 |
| 7684A-010-0355 | | 3 | 1 | 4 |
| 7684A-010-0357 | | 1 | 0 | 1 |
| 7684A-010-0358 | | 1 | 1 | 2 |
| 7684A-010-0600 | | 2 | 2 | 4 |
| 7684A-010-0601 | | 7 | 5 | 12 |
| 7684A-010-0602 | | 2 | 0 | 2 |
| 7684A-010-0604 | | 6 | 6 | 12 |
| 7684A-010-0605 | | 1 | 0 | 1 |
| 7684A-010-0606 | | 2 | 2 | 4 |
| 7684A-010-0650 | | 1 | 5 | 6 |
| 7684A-010-0652 | | 0 | 1 | 1 |
| 7684A-010-0653 | | 0 | 1 | 1 |
| 7684A-010-0654 | | 1 | 0 | 1 |
| 7684A-010-0655 | | 2 | 0 | 2 |
| 7684A-010-0656 | | 1 | 1 | 2 |
| 7684A-010-0700 | | 2 | 3 | 5 |
| 7684A-010-0702 | | 1 | 4 | 5 |
| 7684A-010-0705 | | 1 | 0 | 1 |
| 7684A-010-0706 | | 2 | 1 | 3 |
| 7684A-010-0707 | | 0 | 1 | 1 |
| 7684A-010-0708 | | 4 | 1 | 5 |

Participants Randomized by Investigator and Treatment Group
APaT Population

| Trial-Site | Investigator Name | MK-7684A Q3W (N=698) | Pembrolizumab (MK-3475) Q3W (N=700) | Total (N=1,398) |
|---|---|---|---|---|
| 7684A-010-0713 | PPD | 3 | 4 | 7 |
| 7684A-010-0714 | | 1 | 2 | 3 |
| 7684A-010-0750 | | 5 | 1 | 6 |
| 7684A-010-0751 | | 4 | 1 | 5 |
| 7684A-010-0752 | | 7 | 8 | 15 |
| 7684A-010-0754 | | 3 | 2 | 5 |
| 7684A-010-0756 | | 5 | 8 | 13 |
| 7684A-010-0757 | | 1 | 1 | 2 |
| 7684A-010-0758 | | 6 | 7 | 13 |
| 7684A-010-0759 | | 5 | 5 | 10 |
| 7684A-010-0761 | | 5 | 3 | 8 |
| 7684A-010-0762 | | 6 | 4 | 10 |
| 7684A-010-0765 | | 5 | 2 | 7 |
| 7684A-010-0766 | | 3 | 6 | 9 |
| 7684A-010-0767 | | 1 | 2 | 3 |
| 7684A-010-0900 | | 0 | 2 | 2 |
| 7684A-010-0950 | | 3 | 2 | 5 |
| 7684A-010-0951 | | 5 | 3 | 8 |
| 7684A-010-0952 | | 2 | 4 | 6 |
| 7684A-010-0953 | | 4 | 4 | 8 |
| 7684A-010-0954 | | 8 | 4 | 12 |
| 7684A-010-0955 | | 1 | 0 | 1 |
| 7684A-010-1000 | | 7 | 4 | 11 |
| 7684A-010-1001 | | 1 | 0 | 1 |
| 7684A-010-1002 | | 7 | 3 | 10 |
| 7684A-010-1003 | | 5 | 4 | 9 |
| 7684A-010-1004 | | 3 | 4 | 7 |
| 7684A-010-1005 | | 4 | 2 | 6 |

Participants Randomized by Investigator and Treatment Group
APaT Population

| Trial-Site | Investigator Name | MK-7684A Q3W (N=698) | Pembrolizumab (MK-3475) Q3W (N=700) | Total (N=1,398) |
|---|---|---|---|---|
| 7684A-010-1006 | PPD | 0 | 2 | 2 |
| 7684A-010-1008 | | 3 | 5 | 8 |
| 7684A-010-1011 | | 5 | 3 | 8 |
| 7684A-010-1050 | | 15 | 11 | 26 |
| 7684A-010-1051 | | 8 | 9 | 17 |
| 7684A-010-1053 | | 2 | 5 | 7 |
| 7684A-010-1054 | | 3 | 2 | 5 |
| 7684A-010-1056 | | 6 | 3 | 9 |
| 7684A-010-1060 | | 5 | 3 | 8 |
| 7684A-010-1061 | | 3 | 5 | 8 |
| 7684A-010-1063 | | 1 | 2 | 3 |
| 7684A-010-1064 | | 0 | 1 | 1 |
| 7684A-010-1065 | | 1 | 3 | 4 |
| 7684A-010-1150 | | 2 | 1 | 3 |
| 7684A-010-1151 | | 3 | 4 | 7 |
| 7684A-010-1152 | | 2 | 3 | 5 |
| 7684A-010-1154 | | 3 | 6 | 9 |
| 7684A-010-1155 | | 13 | 7 | 20 |
| 7684A-010-1158 | | 4 | 2 | 6 |
| 7684A-010-1159 | | 3 | 6 | 9 |
| 7684A-010-1160 | | 2 | 1 | 3 |
| 7684A-010-1161 | | 4 | 3 | 7 |
| 7684A-010-1200 | | 2 | 6 | 8 |
| 7684A-010-1201 | | 6 | 0 | 6 |
| 7684A-010-1202 | | 0 | 7 | 7 |

# Participants Randomized by Investigator and Treatment Group
## APaT Population

| Trial-Site | Investigator Name | MK-7684A Q3W (N=698) | Pembrolizumab (MK-3475) Q3W (N=700) | Total (N=1,398) |
|---|---|---|---|---|
| 7684A-010-1203 | PPD | 2 | 8 | 10 |
| 7684A-010-1204 | | 1 | 6 | 7 |
| 7684A-010-1205 | | 5 | 1 | 6 |
| 7684A-010-1252 | | 3 | 0 | 3 |
| 7684A-010-1253 | | 0 | 1 | 1 |
| 7684A-010-1300 | | 19 | 23 | 42 |
| 7684A-010-1301 | | 2 | 5 | 7 |
| 7684A-010-1303 | | 2 | 4 | 6 |
| 7684A-010-1304 | | 3 | 4 | 7 |
| 7684A-010-1305 | | 0 | 2 | 2 |
| 7684A-010-1306 | | 2 | 3 | 5 |
| 7684A-010-1307 | | 7 | 2 | 9 |
| 7684A-010-1308 | | 0 | 3 | 3 |
| 7684A-010-1353 | | 0 | 1 | 1 |
| 7684A-010-1357 | | 3 | 4 | 7 |
| 7684A-010-1358 | | 3 | 4 | 7 |
| 7684A-010-1359 | | 2 | 1 | 3 |
| 7684A-010-1360 | | 1 | 2 | 3 |
| 7684A-010-1361 | | 1 | 0 | 1 |
| 7684A-010-1363 | | 5 | 6 | 11 |
| 7684A-010-1400 | | 2 | 0 | 2 |
| 7684A-010-1401 | | 2 | 0 | 2 |
| 7684A-010-1405 | | 1 | 3 | 4 |
| 7684A-010-1450 | | 18 | 22 | 40 |
| 7684A-010-1451 | | 6 | 9 | 15 |
| 7684A-010-1453 | | 4 | 6 | 10 |
| 7684A-010-1455 | | 2 | 6 | 8 |
| 7684A-010-1456 | | 5 | 7 | 12 |
| 7684A-010-1457 | | 6 | 6 | 12 |
| 7684A-010-1458 | | 3 | 4 | 7 |
| 7684A-010-1460 | | 34 | 25 | 59 |

# Participants Randomized by Investigator and Treatment Group
## APaT Population

| Trial-Site | Investigator Name | MK-7684A Q3W (N=698) | Pembrolizumab (MK-3475) Q3W (N=700) | Total (N=1,398) |
|---|---|---|---|---|
| 7684A-010-1462 | PPD | 9 | 5 | 14 |
| 7684A-010-1464 | | 6 | 5 | 11 |
| 7684A-010-1465 | | 0 | 2 | 2 |
| 7684A-010-1501 | | 6 | 7 | 13 |
| 7684A-010-1508 | | 28 | 32 | 60 |
| 7684A-010-1509 | | 2 | 8 | 10 |
| 7684A-010-1510 | | 5 | 6 | 11 |
| 7684A-010-1511 | | 1 | 0 | 1 |
| 7684A-010-1551 | | 1 | 1 | 2 |
| 7684A-010-1552 | | 1 | 3 | 4 |
| 7684A-010-1600 | | 3 | 2 | 5 |
| 7684A-010-1601 | | 12 | 8 | 20 |
| 7684A-010-1602 | | 1 | 7 | 8 |
| 7684A-010-1650 | | 20 | 23 | 43 |
| 7684A-010-1651 | | 0 | 3 | 3 |
| 7684A-010-1652 | | 1 | 2 | 3 |
| 7684A-010-1653 | | 3 | 4 | 7 |
| 7684A-010-1655 | | 9 | 5 | 14 |
| 7684A-010-1657 | | 0 | 1 | 1 |
| 7684A-010-1658 | | 9 | 10 | 19 |
| 7684A-010-1659 | | 16 | 17 | 33 |
| 7684A-010-1660 | | 1 | 1 | 2 |
| 7684A-010-1661 | | 6 | 6 | 12 |
| 7684A-010-1662 | | 5 | 3 | 8 |
| 7684A-010-1664 | | 9 | 8 | 17 |
| 7684A-010-1665 | | 4 | 3 | 7 |
| 7684A-010-1666 | | 1 | 0 | 1 |
| 7684A-010-1667 | | 8 | 6 | 14 |
| 7684A-010-1668 | | 8 | 8 | 16 |
| 7684A-010-1669 | | 1 | 4 | 5 |
| 7684A-010-1673 | | 1 | 4 | 5 |
| 7684A-010-1674 | | 1 | 0 | 1 |

Participants Randomized by Investigator and Treatment Group
APaT Population

| Trial-Site | Investigator Name | MK-7684A Q3W (N=698) | Pembrolizumab (MK-3475) Q3W (N=700) | Total (N=1,398) |
|---|---|---|---|---|
| 7684A-010-1750 | PPD | 4 | 1 | 5 |
| 7684A-010-1751 | | 1 | 2 | 3 |
| 7684A-010-1752 | | 2 | 2 | 4 |
| 7684A-010-1753 | | 5 | 1 | 6 |

N = Number of participants randomized in the treatment group.
Database Cutoff Date: 06MAR2024.

Source: [P010V01MK7684a: adam-adsl]

Table 2-7
Participant Characteristics
(ITT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Participants in population | 701 | | 701 | | 1,402 | |
| **Sex** | | | | | | |
| Male | 419 | (59.8) | 410 | (58.5) | 829 | (59.1) |
| Female | 282 | (40.2) | 291 | (41.5) | 573 | (40.9) |
| **Age (Years)** | | | | | | |
| 18 - 64 | 419 | (59.8) | 427 | (60.9) | 846 | (60.3) |
| ≥ 65 | 282 | (40.2) | 274 | (39.1) | 556 | (39.7) |
| Mean | 59.0 | | 59.2 | | 59.1 | |
| SD | 13.8 | | 13.9 | | 13.9 | |
| Median | 61.0 | | 61.0 | | 61.0 | |
| Range | 21 to 93 | | 21 to 88 | | 21 to 93 | |
| **Race** | | | | | | |
| American Indian Or Alaska Native | 3 | (0.4) | 1 | (0.1) | 4 | (0.3) |
| Asian | 134 | (19.1) | 139 | (19.8) | 273 | (19.5) |
| Black Or African American | 3 | (0.4) | 2 | (0.3) | 5 | (0.4) |
| Multiple | 4 | (0.6) | 2 | (0.3) | 6 | (0.4) |
| American Indian Or Alaska Native, Black Or African American | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| American Indian Or Alaska Native, White | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Black Or African American, White | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Native Hawaiian Or Other Pacific Islander | 2 | (0.3) | 2 | (0.3) | 4 | (0.3) |
| White | 553 | (78.9) | 554 | (79.0) | 1,107 | (79.0) |
| Missing | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| **Ethnicity** | | | | | | |
| Hispanic Or Latino | 84 | (12.0) | 73 | (10.4) | 157 | (11.2) |
| Not Hispanic Or Latino | 585 | (83.5) | 586 | (83.6) | 1,171 | (83.5) |
| Not Reported | 29 | (4.1) | 37 | (5.3) | 66 | (4.7) |
| Unknown | 3 | (0.4) | 5 | (0.7) | 8 | (0.6) |
| **ECOG** | | | | | | |
| 0 | 585 | (83.5) | 590 | (84.2) | 1,175 | (83.8) |
| 1 | 116 | (16.5) | 111 | (15.8) | 227 | (16.2) |

# Participant Characteristics
# (ITT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| **LPS Status** | | | | | | |
| Not Applicable | 701 | (100.0) | 701 | (100.0) | 1,402 | (100.0) |
| **KPS Status** | | | | | | |
| Not Applicable | 701 | (100.0) | 701 | (100.0) | 1,402 | (100.0) |
| **T-Stage** | | | | | | |
| T0 | 38 | (5.4) | 32 | (4.6) | 70 | (5.0) |
| T1 | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| T1a | 21 | (3.0) | 25 | (3.6) | 46 | (3.3) |
| T1b | 21 | (3.0) | 22 | (3.1) | 43 | (3.1) |
| T2 | 0 | (0.0) | 3 | (0.4) | 3 | (0.2) |
| T2a | 91 | (13.0) | 78 | (11.1) | 169 | (12.1) |
| T2b | 28 | (4.0) | 24 | (3.4) | 52 | (3.7) |
| T3 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| T3a | 71 | (10.1) | 88 | (12.6) | 159 | (11.3) |
| T3b | 133 | (19.0) | 123 | (17.5) | 256 | (18.3) |
| T4 | 1 | (0.1) | 2 | (0.3) | 3 | (0.2) |
| T4a | 90 | (12.8) | 93 | (13.3) | 183 | (13.1) |
| T4b | 182 | (26.0) | 181 | (25.8) | 363 | (25.9) |
| TX | 20 | (2.9) | 26 | (3.7) | 46 | (3.3) |
| Missing | 1 | (0.1) | 3 | (0.4) | 4 | (0.3) |
| **Nodal Involvement** | | | | | | |
| N0 | 214 | (30.5) | 208 | (29.7) | 422 | (30.1) |
| N1 | 5 | (0.7) | 4 | (0.6) | 9 | (0.6) |
| N1a | 177 | (25.2) | 199 | (28.4) | 376 | (26.8) |
| N1b | 60 | (8.6) | 65 | (9.3) | 125 | (8.9) |
| N1c | 55 | (7.8) | 46 | (6.6) | 101 | (7.2) |
| N2 | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| N2a | 56 | (8.0) | 45 | (6.4) | 101 | (7.2) |
| N2b | 40 | (5.7) | 50 | (7.1) | 90 | (6.4) |
| N2c | 14 | (2.0) | 18 | (2.6) | 32 | (2.3) |
| N3a | 10 | (1.4) | 4 | (0.6) | 14 | (1.0) |
| N3b | 30 | (4.3) | 22 | (3.1) | 52 | (3.7) |
| N3c | 21 | (3.0) | 23 | (3.3) | 44 | (3.1) |
| NX | 16 | (2.3) | 14 | (2.0) | 30 | (2.1) |

Participant Characteristics
(ITT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Missing | 1 | (0.1) | 3 | (0.4) | 4 | (0.3) |
| **Metastatic Staging** | | | | | | |
| M0 | 662 | (94.4) | 662 | (94.4) | 1,324 | (94.4) |
| M1a(0) | 6 | (0.9) | 3 | (0.4) | 9 | (0.6) |
| M1a | 21 | (3.0) | 21 | (3.0) | 42 | (3.0) |
| M1b(0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| M1b | 8 | (1.1) | 6 | (0.9) | 14 | (1.0) |
| M1c | 1 | (0.1) | 4 | (0.6) | 5 | (0.4) |
| Missing | 2 | (0.3) | 3 | (0.4) | 5 | (0.4) |
| **Stratification** | | | | | | |
| RISK-BASED STAGING IIB/IIC/CLINICAL IIB AND IIC/IIIA/IIIB + ASIA | 66 | (9.4) | 68 | (9.7) | 134 | (9.6) |
| RISK-BASED STAGING IIB/IIC/CLINICAL IIB AND IIC/IIIA/IIIB + ROW | 361 | (51.5) | 359 | (51.2) | 720 | (51.4) |
| RISK-BASED STAGING IIIC/IIID/IV + ASIA | 67 | (9.6) | 67 | (9.6) | 134 | (9.6) |
| RISK-BASED STAGING IIIC/IIID/IV + ROW | 207 | (29.5) | 207 | (29.5) | 414 | (29.5) |
| **Stratification Risk-based Staging** | | | | | | |
| IIB/IIC/clinical IIB and IIC/IIIA/IIIB | 427 | (60.9) | 427 | (60.9) | 854 | (60.9) |
| IIIC/IIID/IV | 274 | (39.1) | 274 | (39.1) | 548 | (39.1) |
| **Overall Cancer Stage** | | | | | | |
| IIB | 118 | (16.8) | 111 | (15.8) | 229 | (16.3) |
| IIC | 85 | (12.1) | 87 | (12.4) | 172 | (12.3) |
| IIIA | 77 | (11.0) | 69 | (9.8) | 146 | (10.4) |
| IIIB | 141 | (20.1) | 159 | (22.7) | 300 | (21.4) |
| IIIC | 223 | (31.8) | 222 | (31.7) | 445 | (31.7) |
| IIID | 19 | (2.7) | 15 | (2.1) | 34 | (2.4) |
| IV | 37 | (5.3) | 36 | (5.1) | 73 | (5.2) |
| Missing | 1 | (0.1) | 2 | (0.3) | 3 | (0.2) |
| **Overall Cancer Stage Group** | | | | | | |

Participant Characteristics
(ITT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| IIB/C and IIIA/B | 421 | (60.1) | 426 | (60.8) | 847 | (60.4) |
| IIIC/D and IV | 279 | (39.8) | 273 | (38.9) | 552 | (39.4) |
| Missing | 1 | (0.1) | 2 | (0.3) | 3 | (0.2) |
| **Geographic Region** | | | | | | |
| Asia | 133 | (19.0) | 135 | (19.3) | 268 | (19.1) |
| Rest of the World | 568 | (81.0) | 566 | (80.7) | 1,134 | (80.9) |

SD=Standard deviation.
06MAR2024

Source: [P010V01MK7684a: adam-adsl]

Table 2-8
Summary of Drug Exposure
(APaT Population)

| | MK-7684A Q3W (N=698) | Pembrolizumab (MK-3475) Q3W (N=700) | Total (N=1398) |
|---|---|---|---|
| **Number of Days on Therapy** | | | |
| n | 698 | 700 | 1398 |
| Mean (SD) | 99.5 (80.7) | 112.7 (88.8) | 106.1 (85.1) |
| Median | 85 | 87.5 | 85 |
| Range | 1 to 358 | 1 to 352 | 1 to 358 |
| **Number of Administrations** | | | |
| n | 698 | 700 | 1398 |
| Mean (SD) | 5.5 (3.7) | 6.2 (4.1) | 5.8 (3.9) |
| Median | 5 | 5 | 5 |
| Range | 1 to 17 | 1 to 17 | 1 to 17 |
| Number of Days on Therapy is calculated as last dose date - first dose date +1.<br>Database Cutoff Date: 06MAR2024 | | | |

Source: [P010V01MK7684a: adam-adsl; adexsum]

Table 2-9
Summary of Follow-up Duration
(ITT Population)

| Follow-up duration (months)[a] | MK-7684A Q3W (N=701) | Pembrolizumab (MK-3475) Q3W (N=701) | Total (N=1402) |
|---|---|---|---|
| Median (Range) | 4.2 (0.0, 13.4) | 4.2 (0.0, 13.3) | 4.2 (0.0, 13.4) |
| Mean (SD) | 4.6 (3.2) | 4.6 (3.2) | 4.6 (3.2) |

[a] Follow-up duration is defined as the time from randomization to the date of death or the database cutoff date if the participant is still alive.

Database Cutoff Date: 06MAR2024

Source: [P010V01MK7684a: adam-adsl]

Table 2-10
Recurrence-Free Survival Rate Over Time
(ITT Population)

| | MK-7684A Q3W (N=701) % (95% CI)[a] | Pembrolizumab (MK-3475) Q3W (N=701) % (95% CI)[a] |
|---|---|---|
| **Recurrence-Free Survival rate at time point** | | |
| 1 months | 99.2 (97.8, 99.7) | 99.6 (98.4, 99.9) |
| 2 months | 98.1 (96.3, 99.0) | 97.5 (95.7, 98.6) |
| 3 months | 91.2 (88.0, 93.6) | 91.1 (87.9, 93.5) |
| 4 months | 88.5 (84.6, 91.4) | 88.7 (84.9, 91.6) |
| 5 months | 85.6 (81.2, 89.0) | 87.9 (83.9, 90.9) |
| 6 months | 80.3 (74.9, 84.7) | 85.4 (80.8, 88.9) |

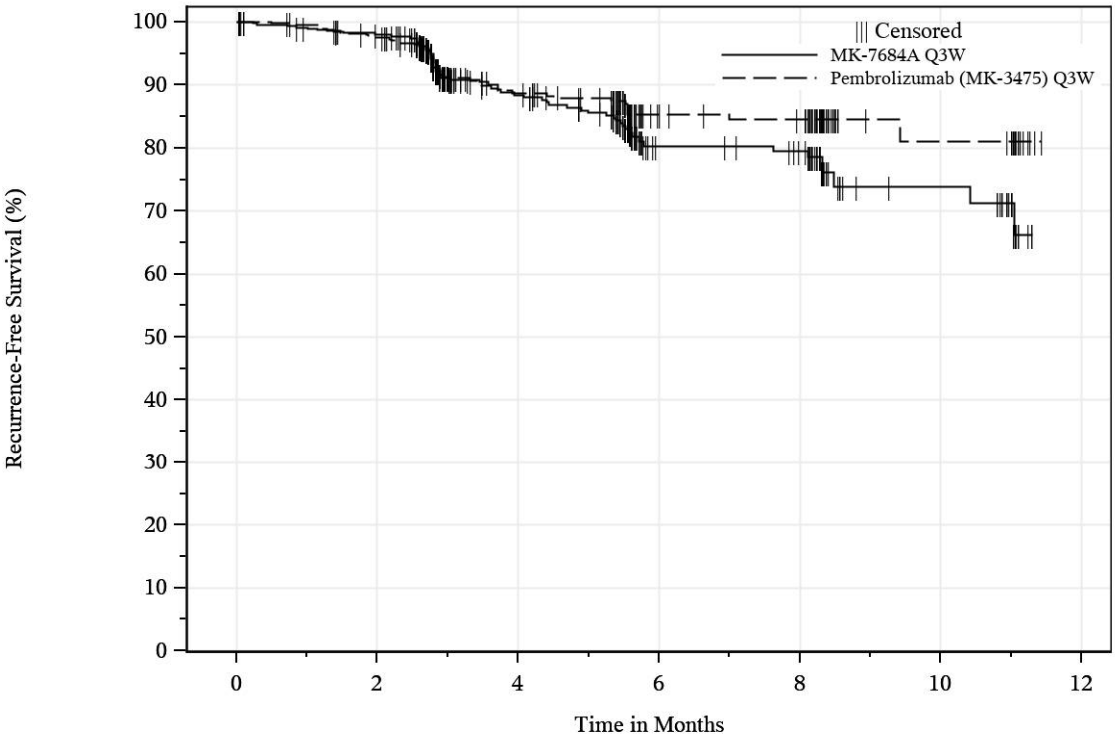
[a] From product-limit (Kaplan-Meier) method for censored data.

Recurrence-free survival is defined as time from randomization to the date of first recurrence of melanoma at any site (local, in-transit or regional lymph nodes or distant recurrence) or death due to any cause, whichever occurs first.

Database Cutoff Date: 06MAR2024.

Source: [P010V01MK7684a: adam-adsl; adtte

Figure 2-1
Kaplan-Meier Estimates of Recurrence-Free Survival (Primary Censoring Rule)
ITT Population




**At Risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| MK-7684A Q3W | 701 | 458 | 220 | 97 | 91 | 28 | 0 |
| Pembrolizumab (MK-3475) Q3W | 701 | 468 | 220 | 101 | 96 | 23 | 0 |

06MAR2024

Source: [P010V01MK7684a: adam-adsl; adtte]

Table 2-11
Participants With Adverse Events by Decreasing Incidence
(Incidence ≥ 5% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Participants in population | 698 | | 700 | | 1,398 | |
| with one or more adverse events | 574 | (82.2) | 558 | (79.7) | 1,132 | (81.0) |
| with no adverse events | 124 | (17.8) | 142 | (20.3) | 266 | (19.0) |
| Pruritus | 179 | (25.6) | 91 | (13.0) | 270 | (19.3) |
| Rash | 171 | (24.5) | 76 | (10.9) | 247 | (17.7) |
| Fatigue | 131 | (18.8) | 145 | (20.7) | 276 | (19.7) |
| Hyperthyroidism | 88 | (12.6) | 80 | (11.4) | 168 | (12.0) |
| Arthralgia | 75 | (10.7) | 69 | (9.9) | 144 | (10.3) |
| Alanine aminotransferase increased | 69 | (9.9) | 69 | (9.9) | 138 | (9.9) |
| Hypothyroidism | 67 | (9.6) | 64 | (9.1) | 131 | (9.4) |
| Diarrhoea | 66 | (9.5) | 72 | (10.3) | 138 | (9.9) |
| Aspartate aminotransferase increased | 65 | (9.3) | 52 | (7.4) | 117 | (8.4) |
| Headache | 61 | (8.7) | 48 | (6.9) | 109 | (7.8) |
| Rash maculo-papular | 50 | (7.2) | 22 | (3.1) | 72 | (5.2) |
| Nausea | 47 | (6.7) | 58 | (8.3) | 105 | (7.5) |
| Cough | 43 | (6.2) | 35 | (5.0) | 78 | (5.6) |
| Asthenia | 35 | (5.0) | 19 | (2.7) | 54 | (3.9) |

Every participant is counted a single time for each applicable row and column.
A specific adverse event appears on this report only if its incidence in one or more of the columns meets the incidence criterion in the report title, after rounding.
Grades are based on NCI CTCAE version 5
Non-serious adverse events up to 30 days of last treatment and serious adverse events up to 90 days of last treatment are included.
MedDRA V26.1 preferred terms "Neoplasm progression", "Malignant neoplasm progression" and "Disease progression" not related to the drug are excluded.
06MAR2024

Source: [P010V01MK7684a: adam-adsl; adae]

Table 2-12
Participants With Adverse Events by System Organ Class and Preferred Term
(Incidence ≥ 5% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Participants in population | 698 | | 700 | | 1,398 | |
| with one or more adverse events | 574 | (82.2) | 558 | (79.7) | 1,132 | (81.0) |
| with no adverse events | 124 | (17.8) | 142 | (20.3) | 266 | (19.0) |
| **Blood and lymphatic system disorders** | **53** | **(7.6)** | **44** | **(6.3)** | **97** | **(6.9)** |
| **Endocrine disorders** | **152** | **(21.8)** | **128** | **(18.3)** | **280** | **(20.0)** |
| Hyperthyroidism | 88 | (12.6) | 80 | (11.4) | 168 | (12.0) |
| Hypothyroidism | 67 | (9.6) | 64 | (9.1) | 131 | (9.4) |
| **Gastrointestinal disorders** | **166** | **(23.8)** | **202** | **(28.9)** | **368** | **(26.3)** |
| Diarrhoea | 66 | (9.5) | 72 | (10.3) | 138 | (9.9) |
| Nausea | 47 | (6.7) | 58 | (8.3) | 105 | (7.5) |
| **General disorders and administration site conditions** | **238** | **(34.1)** | **221** | **(31.6)** | **459** | **(32.8)** |
| Asthenia | 35 | (5.0) | 19 | (2.7) | 54 | (3.9) |
| Fatigue | 131 | (18.8) | 145 | (20.7) | 276 | (19.7) |
| **Infections and infestations** | **183** | **(26.2)** | **162** | **(23.1)** | **345** | **(24.7)** |
| **Injury, poisoning and procedural complications** | **31** | **(4.4)** | **42** | **(6.0)** | **73** | **(5.2)** |
| **Investigations** | **181** | **(25.9)** | **170** | **(24.3)** | **351** | **(25.1)** |
| Alanine aminotransferase increased | 69 | (9.9) | 69 | (9.9) | 138 | (9.9) |
| Aspartate aminotransferase increased | 65 | (9.3) | 52 | (7.4) | 117 | (8.4) |
| **Metabolism and nutrition disorders** | **111** | **(15.9)** | **104** | **(14.9)** | **215** | **(15.4)** |
| **Musculoskeletal and connective tissue disorders** | **163** | **(23.4)** | **153** | **(21.9)** | **316** | **(22.6)** |
| Arthralgia | 75 | (10.7) | 69 | (9.9) | 144 | (10.3) |
| **Nervous system disorders** | **115** | **(16.5)** | **98** | **(14.0)** | **213** | **(15.2)** |
| Headache | 61 | (8.7) | 48 | (6.9) | 109 | (7.8) |

Participants With Adverse Events by System Organ Class and Preferred Term
(Incidence ≥ 5% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| **Psychiatric disorders** | **56** | **(8.0)** | **33** | **(4.7)** | **89** | **(6.4)** |
| **Respiratory, thoracic and mediastinal disorders** | **89** | **(12.8)** | **74** | **(10.6)** | **163** | **(11.7)** |
| Cough | 43 | (6.2) | 35 | (5.0) | 78 | (5.6) |
| **Skin and subcutaneous tissue disorders** | **402** | **(57.6)** | **225** | **(32.1)** | **627** | **(44.8)** |
| Pruritus | 179 | (25.6) | 91 | (13.0) | 270 | (19.3) |
| Rash | 171 | (24.5) | 76 | (10.9) | 247 | (17.7) |
| Rash maculo-papular | 50 | (7.2) | 22 | (3.1) | 72 | (5.2) |
| **Vascular disorders** | **34** | **(4.9)** | **36** | **(5.1)** | **70** | **(5.0)** |

Every participant is counted a single time for each applicable row and column.
A system organ class or specific adverse event appears on this report only if its incidence in one or more of the columns meets the incidence criterion in the report title, after rounding.
Grades are based on NCI CTCAE version 5
Non-serious adverse events up to 30 days of last treatment and serious adverse events up to 90 days of last treatment are included.
MedDRA V26.1 preferred terms "Neoplasm progression", "Malignant neoplasm progression" and "Disease progression" not related to the drug are excluded.
06MAR2024

Source: [P010V01MK7684a: adam-adsl; adae]

Table 2-13
Participants With Drug-Related Adverse Events by Decreasing Incidence
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Participants in population | 698 | | 700 | | 1,398 | |
| with one or more adverse events | 517 | (74.1) | 462 | (66.0) | 979 | (70.0) |
| with no adverse events | 181 | (25.9) | 238 | (34.0) | 419 | (30.0) |
| Pruritus | 166 | (23.8) | 86 | (12.3) | 252 | (18.0) |
| Rash | 162 | (23.2) | 65 | (9.3) | 227 | (16.2) |
| Fatigue | 111 | (15.9) | 116 | (16.6) | 227 | (16.2) |
| Hyperthyroidism | 85 | (12.2) | 78 | (11.1) | 163 | (11.7) |
| Hypothyroidism | 63 | (9.0) | 60 | (8.6) | 123 | (8.8) |
| Aspartate aminotransferase increased | 53 | (7.6) | 40 | (5.7) | 93 | (6.7) |
| Arthralgia | 52 | (7.4) | 47 | (6.7) | 99 | (7.1) |
| Alanine aminotransferase increased | 51 | (7.3) | 55 | (7.9) | 106 | (7.6) |
| Rash maculo-papular | 44 | (6.3) | 22 | (3.1) | 66 | (4.7) |
| Diarrhoea | 35 | (5.0) | 34 | (4.9) | 69 | (4.9) |
| Asthenia | 32 | (4.6) | 13 | (1.9) | 45 | (3.2) |
| Nausea | 31 | (4.4) | 35 | (5.0) | 66 | (4.7) |
| Headache | 28 | (4.0) | 22 | (3.1) | 50 | (3.6) |
| Myalgia | 26 | (3.7) | 21 | (3.0) | 47 | (3.4) |
| Adrenal insufficiency | 22 | (3.2) | 7 | (1.0) | 29 | (2.1) |
| Pyrexia | 20 | (2.9) | 3 | (0.4) | 23 | (1.6) |
| Dry skin | 19 | (2.7) | 8 | (1.1) | 27 | (1.9) |
| Eczema | 17 | (2.4) | 2 | (0.3) | 19 | (1.4) |
| Dermatitis | 16 | (2.3) | 6 | (0.9) | 22 | (1.6) |
| Blood bilirubin increased | 15 | (2.1) | 14 | (2.0) | 29 | (2.1) |
| Chills | 15 | (2.1) | 2 | (0.3) | 17 | (1.2) |
| Decreased appetite | 15 | (2.1) | 10 | (1.4) | 25 | (1.8) |
| Dry mouth | 15 | (2.1) | 18 | (2.6) | 33 | (2.4) |
| Gamma-glutamyltransferase increased | 14 | (2.0) | 8 | (1.1) | 22 | (1.6) |
| Rash pruritic | 14 | (2.0) | 2 | (0.3) | 16 | (1.1) |
| Eosinophilia | 13 | (1.9) | 6 | (0.9) | 19 | (1.4) |
| Hepatitis | 13 | (1.9) | 6 | (0.9) | 19 | (1.4) |
| Blood creatine phosphokinase increased | 11 | (1.6) | 9 | (1.3) | 20 | (1.4) |
| Lymphocyte count decreased | 11 | (1.6) | 3 | (0.4) | 14 | (1.0) |
| Weight decreased | 11 | (1.6) | 2 | (0.3) | 13 | (0.9) |
| Anaemia | 10 | (1.4) | 7 | (1.0) | 17 | (1.2) |
| Blood thyroid stimulating hormone increased | 10 | (1.4) | 6 | (0.9) | 16 | (1.1) |

Participants With Drug-Related Adverse Events by Decreasing Incidence
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Hyperglycaemia | 10 | (1.4) | 9 | (1.3) | 19 | (1.4) |
| Hypophysitis | 10 | (1.4) | 2 | (0.3) | 12 | (0.9) |
| Infusion related reaction | 10 | (1.4) | 4 | (0.6) | 14 | (1.0) |
| Arthritis | 9 | (1.3) | 11 | (1.6) | 20 | (1.4) |
| Blood alkaline phosphatase increased | 9 | (1.3) | 4 | (0.6) | 13 | (0.9) |
| Cough | 9 | (1.3) | 7 | (1.0) | 16 | (1.1) |
| Influenza like illness | 9 | (1.3) | 6 | (0.9) | 15 | (1.1) |
| Pneumonitis | 7 | (1.0) | 7 | (1.0) | 14 | (1.0) |
| Vomiting | 7 | (1.0) | 8 | (1.1) | 15 | (1.1) |
| White blood cell count decreased | 7 | (1.0) | 4 | (0.6) | 11 | (0.8) |
| Blood glucose increased | 6 | (0.9) | 1 | (0.1) | 7 | (0.5) |
| Erythema | 6 | (0.9) | 4 | (0.6) | 10 | (0.7) |
| Hyponatraemia | 6 | (0.9) | 1 | (0.1) | 7 | (0.5) |
| Myocarditis | 6 | (0.9) | 1 | (0.1) | 7 | (0.5) |
| Rash papular | 6 | (0.9) | 0 | (0.0) | 6 | (0.4) |
| Vitiligo | 6 | (0.9) | 4 | (0.6) | 10 | (0.7) |
| Back pain | 5 | (0.7) | 6 | (0.9) | 11 | (0.8) |
| Blood creatinine increased | 5 | (0.7) | 6 | (0.9) | 11 | (0.8) |
| Blood thyroid stimulating hormone decreased | 5 | (0.7) | 5 | (0.7) | 10 | (0.7) |
| Colitis | 5 | (0.7) | 6 | (0.9) | 11 | (0.8) |
| Dizziness | 5 | (0.7) | 2 | (0.3) | 7 | (0.5) |
| Dyshidrotic eczema | 5 | (0.7) | 0 | (0.0) | 5 | (0.4) |
| Immune-mediated enterocolitis | 5 | (0.7) | 1 | (0.1) | 6 | (0.4) |
| Bile acids increased | 4 | (0.6) | 7 | (1.0) | 11 | (0.8) |
| Blood lactate dehydrogenase increased | 4 | (0.6) | 5 | (0.7) | 9 | (0.6) |
| C-reactive protein increased | 4 | (0.6) | 0 | (0.0) | 4 | (0.3) |
| Constipation | 4 | (0.6) | 8 | (1.1) | 12 | (0.9) |
| Cortisol decreased | 4 | (0.6) | 0 | (0.0) | 4 | (0.3) |
| Drug eruption | 4 | (0.6) | 2 | (0.3) | 6 | (0.4) |
| Dry eye | 4 | (0.6) | 7 | (1.0) | 11 | (0.8) |
| Eosinophil count increased | 4 | (0.6) | 1 | (0.1) | 5 | (0.4) |
| Glomerular filtration rate decreased | 4 | (0.6) | 2 | (0.3) | 6 | (0.4) |
| Hypertriglyceridaemia | 4 | (0.6) | 7 | (1.0) | 11 | (0.8) |
| Psoriasis | 4 | (0.6) | 6 | (0.9) | 10 | (0.7) |
| Rash erythematous | 4 | (0.6) | 0 | (0.0) | 4 | (0.3) |
| Thyroiditis | 4 | (0.6) | 6 | (0.9) | 10 | (0.7) |

Participants With Drug-Related Adverse Events by Decreasing Incidence
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Type 1 diabetes mellitus | 4 | (0.6) | 4 | (0.6) | 8 | (0.6) |
| Abdominal distension | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Abdominal pain | 3 | (0.4) | 4 | (0.6) | 7 | (0.5) |
| Abdominal pain upper | 3 | (0.4) | 3 | (0.4) | 6 | (0.4) |
| Amylase increased | 3 | (0.4) | 2 | (0.3) | 5 | (0.4) |
| Bilirubin conjugated increased | 3 | (0.4) | 6 | (0.9) | 9 | (0.6) |
| Dermatitis acneiform | 3 | (0.4) | 3 | (0.4) | 6 | (0.4) |
| Dysphonia | 3 | (0.4) | 1 | (0.1) | 4 | (0.3) |
| Encephalopathy | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Feeling cold | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Gastritis | 3 | (0.4) | 6 | (0.9) | 9 | (0.6) |
| Gastrooesophageal reflux disease | 3 | (0.4) | 2 | (0.3) | 5 | (0.4) |
| Glucocorticoid deficiency | 3 | (0.4) | 1 | (0.1) | 4 | (0.3) |
| Hand dermatitis | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Hypercholesterolaemia | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Hyperuricaemia | 3 | (0.4) | 1 | (0.1) | 4 | (0.3) |
| Hypoalbuminaemia | 3 | (0.4) | 2 | (0.3) | 5 | (0.4) |
| Immune-mediated dermatitis | 3 | (0.4) | 2 | (0.3) | 5 | (0.4) |
| Immune-mediated hypophysitis | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Insomnia | 3 | (0.4) | 3 | (0.4) | 6 | (0.4) |
| Lichenoid keratosis | 3 | (0.4) | 1 | (0.1) | 4 | (0.3) |
| Lipase increased | 3 | (0.4) | 2 | (0.3) | 5 | (0.4) |
| Lymphopenia | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Neutropenia | 3 | (0.4) | 2 | (0.3) | 5 | (0.4) |
| Night sweats | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Oedema peripheral | 3 | (0.4) | 4 | (0.6) | 7 | (0.5) |
| Pain in extremity | 3 | (0.4) | 5 | (0.7) | 8 | (0.6) |
| Rash macular | 3 | (0.4) | 4 | (0.6) | 7 | (0.5) |
| Serum amyloid A protein increased | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Skin exfoliation | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Skin lesion | 3 | (0.4) | 2 | (0.3) | 5 | (0.4) |
| Stomatitis | 3 | (0.4) | 3 | (0.4) | 6 | (0.4) |
| Taste disorder | 3 | (0.4) | 1 | (0.1) | 4 | (0.3) |
| Uveitis | 3 | (0.4) | 1 | (0.1) | 4 | (0.3) |
| Vertigo | 3 | (0.4) | 2 | (0.3) | 5 | (0.4) |
| Xerosis | 3 | (0.4) | 3 | (0.4) | 6 | (0.4) |
| Adrenal disorder | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |

Participants With Drug-Related Adverse Events by Decreasing Incidence
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Anxiety | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Autoimmune thyroiditis | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Chest discomfort | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Chest pain | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Dehydration | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Diabetes mellitus | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Dyspnoea | 2 | (0.3) | 4 | (0.6) | 6 | (0.4) |
| Eczema nummular | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Faeces soft | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Flatulence | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Haematuria | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Hot flush | 2 | (0.3) | 2 | (0.3) | 4 | (0.3) |
| Hyperphosphataemia | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Hypophosphataemia | 2 | (0.3) | 2 | (0.3) | 4 | (0.3) |
| Hypotension | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Immune-mediated hypothyroidism | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Increased appetite | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Intertrigo | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Joint stiffness | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Lethargy | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Leukopenia | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Liver function test abnormal | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Lymphadenopathy | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Malaise | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Meningitis aseptic | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Migraine | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Mucosal inflammation | 2 | (0.3) | 2 | (0.3) | 4 | (0.3) |
| Muscular weakness | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Musculoskeletal pain | 2 | (0.3) | 4 | (0.6) | 6 | (0.4) |
| Myositis | 2 | (0.3) | 2 | (0.3) | 4 | (0.3) |
| Neurodermatitis | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Non-cardiac chest pain | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Pain | 2 | (0.3) | 2 | (0.3) | 4 | (0.3) |
| Palmar-plantar erythrodysaesthesia syndrome | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Paraesthesia | 2 | (0.3) | 4 | (0.6) | 6 | (0.4) |
| Peripheral swelling | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |

Participants With Drug-Related Adverse Events by Decreasing Incidence
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Platelet count decreased | 2 | (0.3) | 3 | (0.4) | 5 | (0.4) |
| Polymyalgia rheumatica | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Proteinuria | 2 | (0.3) | 5 | (0.7) | 7 | (0.5) |
| Pulmonary mass | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Rash pustular | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Seborrhoeic dermatitis | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Sinus tachycardia | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Skin hypopigmentation | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Skin toxicity | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Tachycardia | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Tremor | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Tri-iodothyronine free increased | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Troponin T increased | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| White blood cells urine positive | 2 | (0.3) | 3 | (0.4) | 5 | (0.4) |
| Acrochordon | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Acute generalised exanthematous pustulosis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Acute kidney injury | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Acute myocardial infarction | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Administration site extravasation | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Adrenocorticotropic hormone deficiency | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Ageusia | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Anal pruritus | 1 | (0.1) | 2 | (0.3) | 3 | (0.2) |
| Appetite disorder | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Arrhythmia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Arteriosclerosis coronary artery | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Asthma | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Autoimmune arthritis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Autoimmune haemolytic anaemia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Autoimmune hepatitis | 1 | (0.1) | 2 | (0.3) | 3 | (0.2) |
| Blepharitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Blood corticotrophin decreased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Blood potassium decreased | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Blood pressure increased | 1 | (0.1) | 2 | (0.3) | 3 | (0.2) |
| Blood urea increased | 1 | (0.1) | 3 | (0.4) | 4 | (0.3) |
| Bone pain | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Cardiac failure | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |

Participants With Drug-Related Adverse Events by Decreasing Incidence
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Cardiovascular disorder | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Conjunctivitis | 1 | (0.1) | 3 | (0.4) | 4 | (0.3) |
| Costochondritis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Dermatitis allergic | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Dermatitis atopic | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Dermatitis bullous | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Dermatitis psoriasiform | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Device related infection | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Diabetic ketoacidosis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Disturbance in attention | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Diverticulitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Drug hypersensitivity | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Drug reaction with eosinophilia and systemic symptoms | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Dysgeusia | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Dyspepsia | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Dysphagia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Ear pain | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Eczema eyelids | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Encephalitis autoimmune | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Epistaxis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Erectile dysfunction | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Erythema multiforme | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Erythema nodosum | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Extrasystoles | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Eye pruritus | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Eye swelling | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Facial paresis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Febrile neutropenia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Feeling of body temperature change | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Folliculitis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Functional gastrointestinal disorder | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Gastroenteritis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| General physical health deterioration | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Groin pain | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Guillain-Barre syndrome | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Haemoglobin decreased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |

Participants With Drug-Related Adverse Events by Decreasing Incidence
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Herpes zoster | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Herpes zoster oticus | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Hyperaesthesia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Hyperhidrosis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Hyperlipidaemia | 1 | (0.1) | 2 | (0.3) | 3 | (0.2) |
| Hypernatraemia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Hyperpyrexia | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Hypertension | 1 | (0.1) | 5 | (0.7) | 6 | (0.4) |
| Hypertransaminasaemia | 1 | (0.1) | 2 | (0.3) | 3 | (0.2) |
| Hypoglycaemia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Hypokalaemia | 1 | (0.1) | 2 | (0.3) | 3 | (0.2) |
| Hypoproteinaemia | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Hypoxia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Immune thrombocytopenia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Immune-mediated arthritis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Immune-mediated hepatitis | 1 | (0.1) | 4 | (0.6) | 5 | (0.4) |
| Immune-mediated myositis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Influenza | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Iridocyclitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Joint range of motion decreased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Leukocytosis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Leukoderma | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Lip dry | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Listless | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Meningitis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Muscle spasms | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Muscle tightness | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Musculoskeletal stiffness | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Myasthenia gravis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Myelitis transverse | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Neuralgia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Neutrophil count increased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Occipital neuralgia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Onychoclasis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Oral candidiasis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Otitis externa | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Palpitations | 1 | (0.1) | 4 | (0.6) | 5 | (0.4) |

Participants With Drug-Related Adverse Events by Decreasing Incidence
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Peripheral sensory neuropathy | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Persistent depressive disorder | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Petechiae | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Photophobia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Photopsia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Pneumonia | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Pollakiuria | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Post herpetic neuralgia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Pruritus allergic | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Pruritus genital | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Purpura | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Renal impairment | 1 | (0.1) | 2 | (0.3) | 3 | (0.2) |
| Rhinitis allergic | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| S100 protein increased | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Sarcoidosis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Scleritis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Seborrhoea | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Secondary adrenocortical insufficiency | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Sinus congestion | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Skin discolouration | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Skin disorder | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Skin plaque | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Sleep disorder | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Stevens-Johnson syndrome | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Supraventricular tachycardia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Syncope | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Synovitis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Systemic inflammatory response syndrome | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Thrombocytopenia | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Thyroid function test abnormal | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Thyroxine decreased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Thyroxine free decreased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Thyroxine free increased | 1 | (0.1) | 2 | (0.3) | 3 | (0.2) |
| Transaminases increased | 1 | (0.1) | 2 | (0.3) | 3 | (0.2) |
| Tri-iodothyronine free decreased | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Tri-iodothyronine increased | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |

Participants With Drug-Related Adverse Events by Decreasing Incidence
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Type 2 diabetes mellitus | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Upper respiratory tract infection | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Urinary occult blood positive | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Urinary tract infection | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Urinary tract inflammation | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Urobilinogen urine increased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Urticaria | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Vasculitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Vision blurred | 1 | (0.1) | 2 | (0.3) | 3 | (0.2) |
| Visual impairment | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Weight increased | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Wheezing | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Xeroderma | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Null | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Abdominal pain lower | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Abnormal faeces | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| Acne | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Aggression | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Alopecia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Angular cheilitis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Anorectal discomfort | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Appendix disorder | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Atrial fibrillation | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| Attention deficit hyperactivity disorder | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Blood bilirubin unconjugated increased | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Blood triglycerides increased | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Blood urine present | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Breath odour | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Bronchial wall thickening | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Bronchitis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Burning sensation | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Carpal tunnel syndrome | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| Cystoid macular oedema | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Defaecation urgency | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Dyspnoea exertional | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Ear pruritus | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Exercise tolerance decreased | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |

Participants With Drug-Related Adverse Events by Decreasing Incidence
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Eye pain | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Fasciitis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Gastritis erosive | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Glutamate dehydrogenase increased | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Grip strength decreased | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Haemorrhoids | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Head discomfort | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Hepatic function abnormal | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| Hepatitis C | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Hepatotoxicity | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Hypercalcaemia | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| Hypercreatininaemia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Hyperparathyroidism | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Hypertonia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Hypoacusis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Hypocalcaemia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Hypomagnesaemia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| IIIrd nerve paresis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Immune-mediated hyperthyroidism | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Immune-mediated myocarditis | 0 | (0.0) | 3 | (0.4) | 3 | (0.2) |
| Immune-mediated nephritis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Inflammation | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Intercostal neuralgia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Intermenstrual bleeding | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Irritability | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Irritable bowel syndrome | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Keratitis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Liver function test increased | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Macule | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Mouth ulceration | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Mucosal dryness | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Myoglobin blood increased | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| Nephritis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Neuritis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Neuropathy peripheral | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Neutrophil count decreased | 0 | (0.0) | 3 | (0.4) | 3 | (0.2) |
| Neutrophilia | 0 | (0.0) | 3 | (0.4) | 3 | (0.2) |

Participants With Drug-Related Adverse Events by Decreasing Incidence
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Ocular hyperaemia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Ocular hypertension | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Optic neuropathy | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Oral dysaesthesia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Oral lichen planus | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Periarthritis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Peripheral coldness | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Persistent postural-perceptual dizziness | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Polymyositis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Polyserositis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Productive cough | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Radiculopathy | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Restlessness | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Rheumatoid arthritis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Rhinitis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Sarcoid-like reaction | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| Seasonal allergy | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| Septic shock | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Sinus bradycardia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Sinusitis | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| Skin depigmentation | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Spinal pain | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Supraventricular extrasystoles | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Swelling | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| Temperature intolerance | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Tendonitis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Thrombocytosis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Trichoglossia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Troponin I increased | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Troponin increased | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Tubulointerstitial nephritis | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| Upper-airway cough syndrome | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Vogt-Koyanagi-Harada disease | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |

Participants With Drug-Related Adverse Events by Decreasing Incidence
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Xerophthalmia | 0 | (0.0) | 4 | (0.6) | 4 | (0.3) |

Every participant is counted a single time for each applicable row and column.
Grades are based on NCI CTCAE version 5
Non-serious adverse events up to 30 days of last treatment and serious adverse events up to 90 days of last treatment are included.
MedDRA V26.1 preferred terms "Neoplasm progression", "Malignant neoplasm progression" and "Disease progression" not related to the drug are excluded.
06MAR2024

Source: [P010V01MK7684a: adam-adsl; adae]

Table 2-14
Participants With Drug-Related Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Participants in population | 698 | | 700 | | 1,398 | |
| with one or more adverse events | 517 | (74.1) | 462 | (66.0) | 979 | (70.0) |
| with no adverse events | 181 | (25.9) | 238 | (34.0) | 419 | (30.0) |
| **Blood and lymphatic system disorders** | **32** | **(4.6)** | **19** | **(2.7)** | **51** | **(3.6)** |
| Anaemia | 10 | (1.4) | 7 | (1.0) | 17 | (1.2) |
| Autoimmune haemolytic anaemia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Eosinophilia | 13 | (1.9) | 6 | (0.9) | 19 | (1.4) |
| Febrile neutropenia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Immune thrombocytopenia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Leukocytosis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Leukopenia | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Lymphadenopathy | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Lymphopenia | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Neutropenia | 3 | (0.4) | 2 | (0.3) | 5 | (0.4) |
| Neutrophilia | 0 | (0.0) | 3 | (0.4) | 3 | (0.2) |
| Thrombocytopenia | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Thrombocytosis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| **Cardiac disorders** | **13** | **(1.9)** | **14** | **(2.0)** | **27** | **(1.9)** |
| Acute myocardial infarction | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Arrhythmia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Arteriosclerosis coronary artery | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Atrial fibrillation | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| Cardiac failure | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Cardiovascular disorder | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Extrasystoles | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Immune-mediated myocarditis | 0 | (0.0) | 3 | (0.4) | 3 | (0.2) |
| Myocarditis | 6 | (0.9) | 1 | (0.1) | 7 | (0.5) |
| Palpitations | 1 | (0.1) | 4 | (0.6) | 5 | (0.4) |
| Sinus bradycardia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Sinus tachycardia | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Supraventricular extrasystoles | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Supraventricular tachycardia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Tachycardia | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |

Participants With Drug-Related Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| **Ear and labyrinth disorders** | **4** | **(0.6)** | **4** | **(0.6)** | **8** | **(0.6)** |
| Ear pain | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Ear pruritus | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Hypoacusis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Vertigo | 3 | (0.4) | 2 | (0.3) | 5 | (0.4) |
| **Endocrine disorders** | **143** | **(20.5)** | **123** | **(17.6)** | **266** | **(19.0)** |
| Adrenal disorder | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Adrenal insufficiency | 22 | (3.2) | 7 | (1.0) | 29 | (2.1) |
| Adrenocorticotropic hormone deficiency | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Autoimmune thyroiditis | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Glucocorticoid deficiency | 3 | (0.4) | 1 | (0.1) | 4 | (0.3) |
| Hyperparathyroidism | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Hyperthyroidism | 85 | (12.2) | 78 | (11.1) | 163 | (11.7) |
| Hypophysitis | 10 | (1.4) | 2 | (0.3) | 12 | (0.9) |
| Hypothyroidism | 63 | (9.0) | 60 | (8.6) | 123 | (8.8) |
| Immune-mediated hyperthyroidism | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Immune-mediated hypophysitis | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Immune-mediated hypothyroidism | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Secondary adrenocortical insufficiency | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Thyroiditis | 4 | (0.6) | 6 | (0.9) | 10 | (0.7) |
| **Eye disorders** | **15** | **(2.1)** | **19** | **(2.7)** | **34** | **(2.4)** |
| Blepharitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Cystoid macular oedema | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Dry eye | 4 | (0.6) | 7 | (1.0) | 11 | (0.8) |
| Eczema eyelids | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Eye pain | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Eye pruritus | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Eye swelling | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Iridocyclitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Keratitis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Ocular hyperaemia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Ocular hypertension | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Optic neuropathy | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |

Participants With Drug-Related Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| **Eye disorders** | **15** | **(2.1)** | **19** | **(2.7)** | **34** | **(2.4)** |
| Photophobia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Photopsia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Scleritis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Uveitis | 3 | (0.4) | 1 | (0.1) | 4 | (0.3) |
| Vision blurred | 1 | (0.1) | 2 | (0.3) | 3 | (0.2) |
| Visual impairment | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Vogt-Koyanagi-Harada disease | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Xerophthalmia | 0 | (0.0) | 4 | (0.6) | 4 | (0.3) |
| **Gastrointestinal disorders** | **94** | **(13.5)** | **109** | **(15.6)** | **203** | **(14.5)** |
| Abdominal distension | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Abdominal pain | 3 | (0.4) | 4 | (0.6) | 7 | (0.5) |
| Abdominal pain lower | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Abdominal pain upper | 3 | (0.4) | 3 | (0.4) | 6 | (0.4) |
| Abnormal faeces | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| Anal pruritus | 1 | (0.1) | 2 | (0.3) | 3 | (0.2) |
| Angular cheilitis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Anorectal discomfort | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Appendix disorder | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Breath odour | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Colitis | 5 | (0.7) | 6 | (0.9) | 11 | (0.8) |
| Constipation | 4 | (0.6) | 8 | (1.1) | 12 | (0.9) |
| Defaecation urgency | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Diarrhoea | 35 | (5.0) | 34 | (4.9) | 69 | (4.9) |
| Dry mouth | 15 | (2.1) | 18 | (2.6) | 33 | (2.4) |
| Dyspepsia | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Dysphagia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Faeces soft | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Flatulence | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Functional gastrointestinal disorder | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Gastritis | 3 | (0.4) | 6 | (0.9) | 9 | (0.6) |
| Gastritis erosive | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Gastrooesophageal reflux disease | 3 | (0.4) | 2 | (0.3) | 5 | (0.4) |
| Haemorrhoids | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |

Participants With Drug-Related Adverse Events by System Organ Class and Preferred Term
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(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| **Gastrointestinal disorders** | **94** | **(13.5)** | **109** | **(15.6)** | **203** | **(14.5)** |
| Immune-mediated enterocolitis | 5 | (0.7) | 1 | (0.1) | 6 | (0.4) |
| Irritable bowel syndrome | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Lip dry | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Mouth ulceration | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Nausea | 31 | (4.4) | 35 | (5.0) | 66 | (4.7) |
| Oral dysaesthesia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Oral lichen planus | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Stomatitis | 3 | (0.4) | 3 | (0.4) | 6 | (0.4) |
| Trichoglossia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Vomiting | 7 | (1.0) | 8 | (1.1) | 15 | (1.1) |
| **General disorders and administration site conditions** | **180** | **(25.8)** | **154** | **(22.0)** | **334** | **(23.9)** |
| Administration site extravasation | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Asthenia | 32 | (4.6) | 13 | (1.9) | 45 | (3.2) |
| Chest discomfort | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Chest pain | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Chills | 15 | (2.1) | 2 | (0.3) | 17 | (1.2) |
| Exercise tolerance decreased | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Fatigue | 111 | (15.9) | 116 | (16.6) | 227 | (16.2) |
| Feeling cold | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Feeling of body temperature change | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| General physical health deterioration | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Hyperpyrexia | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Inflammation | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Influenza like illness | 9 | (1.3) | 6 | (0.9) | 15 | (1.1) |
| Malaise | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Mucosal dryness | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Mucosal inflammation | 2 | (0.3) | 2 | (0.3) | 4 | (0.3) |
| Non-cardiac chest pain | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Oedema peripheral | 3 | (0.4) | 4 | (0.6) | 7 | (0.5) |
| Pain | 2 | (0.3) | 2 | (0.3) | 4 | (0.3) |
| Peripheral swelling | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Polyserositis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |

Participants With Drug-Related Adverse Events by System Organ Class and Preferred Term
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(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| **General disorders and administration site conditions** | **180** | **(25.8)** | **154** | **(22.0)** | **334** | **(23.9)** |
| Pyrexia | 20 | (2.9) | 3 | (0.4) | 23 | (1.6) |
| Swelling | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| Systemic inflammatory response syndrome | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Temperature intolerance | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Xerosis | 3 | (0.4) | 3 | (0.4) | 6 | (0.4) |
| **Hepatobiliary disorders** | **16** | **(2.3)** | **17** | **(2.4)** | **33** | **(2.4)** |
| Autoimmune hepatitis | 1 | (0.1) | 2 | (0.3) | 3 | (0.2) |
| Hepatic function abnormal | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| Hepatitis | 13 | (1.9) | 6 | (0.9) | 19 | (1.4) |
| Hepatotoxicity | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Hypertransaminasaemia | 1 | (0.1) | 2 | (0.3) | 3 | (0.2) |
| Immune-mediated hepatitis | 1 | (0.1) | 4 | (0.6) | 5 | (0.4) |
| **Immune system disorders** | **2** | **(0.3)** | **2** | **(0.3)** | **4** | **(0.3)** |
| Drug hypersensitivity | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Sarcoidosis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Seasonal allergy | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| **Infections and infestations** | **18** | **(2.6)** | **15** | **(2.1)** | **33** | **(2.4)** |
| Bronchitis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Conjunctivitis | 1 | (0.1) | 3 | (0.4) | 4 | (0.3) |
| Device related infection | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Diverticulitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Folliculitis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Gastroenteritis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Hepatitis C | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Herpes zoster | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Herpes zoster oticus | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Influenza | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Meningitis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Meningitis aseptic | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |

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| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| **Infections and infestations** | **18** | **(2.6)** | **15** | **(2.1)** | **33** | **(2.4)** |
| Oral candidiasis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Otitis externa | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Pneumonia | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Rash pustular | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Rhinitis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Septic shock | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Sinusitis | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| Upper respiratory tract infection | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Urinary tract infection | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| **Injury, poisoning and procedural complications** | **10** | **(1.4)** | **4** | **(0.6)** | **14** | **(1.0)** |
| Infusion related reaction | 10 | (1.4) | 4 | (0.6) | 14 | (1.0) |
| **Investigations** | **129** | **(18.5)** | **110** | **(15.7)** | **239** | **(17.1)** |
| Alanine aminotransferase increased | 51 | (7.3) | 55 | (7.9) | 106 | (7.6) |
| Amylase increased | 3 | (0.4) | 2 | (0.3) | 5 | (0.4) |
| Aspartate aminotransferase increased | 53 | (7.6) | 40 | (5.7) | 93 | (6.7) |
| Bile acids increased | 4 | (0.6) | 7 | (1.0) | 11 | (0.8) |
| Bilirubin conjugated increased | 3 | (0.4) | 6 | (0.9) | 9 | (0.6) |
| Blood alkaline phosphatase increased | 9 | (1.3) | 4 | (0.6) | 13 | (0.9) |
| Blood bilirubin increased | 15 | (2.1) | 14 | (2.0) | 29 | (2.1) |
| Blood bilirubin unconjugated increased | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Blood corticotrophin decreased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Blood creatine phosphokinase increased | 11 | (1.6) | 9 | (1.3) | 20 | (1.4) |
| Blood creatinine increased | 5 | (0.7) | 6 | (0.9) | 11 | (0.8) |
| Blood glucose increased | 6 | (0.9) | 1 | (0.1) | 7 | (0.5) |
| Blood lactate dehydrogenase increased | 4 | (0.6) | 5 | (0.7) | 9 | (0.6) |
| Blood potassium decreased | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Blood pressure increased | 1 | (0.1) | 2 | (0.3) | 3 | (0.2) |
| Blood thyroid stimulating hormone decreased | 5 | (0.7) | 5 | (0.7) | 10 | (0.7) |
| Blood thyroid stimulating hormone increased | 10 | (1.4) | 6 | (0.9) | 16 | (1.1) |

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|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| **Investigations** | **129** | **(18.5)** | **110** | **(15.7)** | **239** | **(17.1)** |
| Blood triglycerides increased | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Blood urea increased | 1 | (0.1) | 3 | (0.4) | 4 | (0.3) |
| Blood urine present | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| C-reactive protein increased | 4 | (0.6) | 0 | (0.0) | 4 | (0.3) |
| Cortisol decreased | 4 | (0.6) | 0 | (0.0) | 4 | (0.3) |
| Eosinophil count increased | 4 | (0.6) | 1 | (0.1) | 5 | (0.4) |
| Gamma-glutamyltransferase increased | 14 | (2.0) | 8 | (1.1) | 22 | (1.6) |
| Glomerular filtration rate decreased | 4 | (0.6) | 2 | (0.3) | 6 | (0.4) |
| Glutamate dehydrogenase increased | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Grip strength decreased | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Haemoglobin decreased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Lipase increased | 3 | (0.4) | 2 | (0.3) | 5 | (0.4) |
| Liver function test abnormal | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Liver function test increased | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Lymphocyte count decreased | 11 | (1.6) | 3 | (0.4) | 14 | (1.0) |
| Myoglobin blood increased | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| Neutrophil count decreased | 0 | (0.0) | 3 | (0.4) | 3 | (0.2) |
| Neutrophil count increased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Platelet count decreased | 2 | (0.3) | 3 | (0.4) | 5 | (0.4) |
| S100 protein increased | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Serum amyloid A protein increased | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Thyroid function test abnormal | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Thyroxine decreased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Thyroxine free decreased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Thyroxine free increased | 1 | (0.1) | 2 | (0.3) | 3 | (0.2) |
| Transaminases increased | 1 | (0.1) | 2 | (0.3) | 3 | (0.2) |
| Tri-iodothyronine free decreased | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Tri-iodothyronine free increased | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Tri-iodothyronine increased | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Troponin I increased | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Troponin T increased | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Troponin increased | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Urinary occult blood positive | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Urobilinogen urine increased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |

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|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| **Investigations** | **129** | **(18.5)** | **110** | **(15.7)** | **239** | **(17.1)** |
| Weight decreased | 11 | (1.6) | 2 | (0.3) | 13 | (0.9) |
| Weight increased | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| White blood cell count decreased | 7 | (1.0) | 4 | (0.6) | 11 | (0.8) |
| White blood cells urine positive | 2 | (0.3) | 3 | (0.4) | 5 | (0.4) |
| **Metabolism and nutrition disorders** | **55** | **(7.9)** | **41** | **(5.9)** | **96** | **(6.9)** |
| Appetite disorder | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Decreased appetite | 15 | (2.1) | 10 | (1.4) | 25 | (1.8) |
| Dehydration | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Diabetes mellitus | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Diabetic ketoacidosis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Hypercalcaemia | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| Hypercholesterolaemia | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Hypercreatininaemia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Hyperglycaemia | 10 | (1.4) | 9 | (1.3) | 19 | (1.4) |
| Hyperlipidaemia | 1 | (0.1) | 2 | (0.3) | 3 | (0.2) |
| Hypernatraemia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Hyperphosphataemia | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Hypertriglyceridaemia | 4 | (0.6) | 7 | (1.0) | 11 | (0.8) |
| Hyperuricaemia | 3 | (0.4) | 1 | (0.1) | 4 | (0.3) |
| Hypoalbuminaemia | 3 | (0.4) | 2 | (0.3) | 5 | (0.4) |
| Hypocalcaemia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Hypoglycaemia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Hypokalaemia | 1 | (0.1) | 2 | (0.3) | 3 | (0.2) |
| Hypomagnesaemia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Hyponatraemia | 6 | (0.9) | 1 | (0.1) | 7 | (0.5) |
| Hypophosphataemia | 2 | (0.3) | 2 | (0.3) | 4 | (0.3) |
| Hypoproteinaemia | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Increased appetite | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Type 1 diabetes mellitus | 4 | (0.6) | 4 | (0.6) | 8 | (0.6) |
| Type 2 diabetes mellitus | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| **Musculoskeletal and connective tissue disorders** | **98** | **(14.0)** | **89** | **(12.7)** | **187** | **(13.4)** |

Participants With Drug-Related Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| **Musculoskeletal and connective tissue disorders** | **98** | **(14.0)** | **89** | **(12.7)** | **187** | **(13.4)** |
| Arthralgia | 52 | (7.4) | 47 | (6.7) | 99 | (7.1) |
| Arthritis | 9 | (1.3) | 11 | (1.6) | 20 | (1.4) |
| Autoimmune arthritis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Back pain | 5 | (0.7) | 6 | (0.9) | 11 | (0.8) |
| Bone pain | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Costochondritis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Fasciitis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Groin pain | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Immune-mediated arthritis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Immune-mediated myositis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Joint range of motion decreased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Joint stiffness | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Muscle spasms | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Muscle tightness | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Muscular weakness | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Musculoskeletal pain | 2 | (0.3) | 4 | (0.6) | 6 | (0.4) |
| Musculoskeletal stiffness | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Myalgia | 26 | (3.7) | 21 | (3.0) | 47 | (3.4) |
| Myositis | 2 | (0.3) | 2 | (0.3) | 4 | (0.3) |
| Pain in extremity | 3 | (0.4) | 5 | (0.7) | 8 | (0.6) |
| Periarthritis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Polymyalgia rheumatica | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Polymyositis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Rheumatoid arthritis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Spinal pain | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Synovitis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Tendonitis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| **Neoplasms benign, malignant and unspecified (incl cysts and polyps)** | **1** | **(0.1)** | **0** | **(0.0)** | **1** | **(0.1)** |
| Acrochordon | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| **Nervous system disorders** | **55** | **(7.9)** | **41** | **(5.9)** | **96** | **(6.9)** |

Participants With Drug-Related Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| **Nervous system disorders** | **55** | **(7.9)** | **41** | **(5.9)** | **96** | **(6.9)** |
| Ageusia | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Burning sensation | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Carpal tunnel syndrome | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| Disturbance in attention | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Dizziness | 5 | (0.7) | 2 | (0.3) | 7 | (0.5) |
| Dysgeusia | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Encephalitis autoimmune | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Encephalopathy | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Facial paresis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Guillain-Barre syndrome | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Head discomfort | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Headache | 28 | (4.0) | 22 | (3.1) | 50 | (3.6) |
| Hyperaesthesia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Hypertonia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| IIIrd nerve paresis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Intercostal neuralgia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Lethargy | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Migraine | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Myasthenia gravis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Myelitis transverse | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Neuralgia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Neuritis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Neuropathy peripheral | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Occipital neuralgia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Paraesthesia | 2 | (0.3) | 4 | (0.6) | 6 | (0.4) |
| Peripheral sensory neuropathy | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Persistent postural-perceptual dizziness | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Post herpetic neuralgia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Radiculopathy | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Syncope | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Taste disorder | 3 | (0.4) | 1 | (0.1) | 4 | (0.3) |
| Tremor | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| **Psychiatric disorders** | **8** | **(1.1)** | **6** | **(0.9)** | **14** | **(1.0)** |

Participants With Drug-Related Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| **Psychiatric disorders** | **8** | **(1.1)** | **6** | **(0.9)** | **14** | **(1.0)** |
| Aggression | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Anxiety | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Attention deficit hyperactivity disorder | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Insomnia | 3 | (0.4) | 3 | (0.4) | 6 | (0.4) |
| Irritability | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Listless | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Persistent depressive disorder | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Restlessness | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Sleep disorder | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| **Renal and urinary disorders** | **8** | **(1.1)** | **13** | **(1.9)** | **21** | **(1.5)** |
| Acute kidney injury | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Haematuria | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Immune-mediated nephritis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Nephritis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Pollakiuria | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Proteinuria | 2 | (0.3) | 5 | (0.7) | 7 | (0.5) |
| Renal impairment | 1 | (0.1) | 2 | (0.3) | 3 | (0.2) |
| Tubulointerstitial nephritis | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| Urinary tract inflammation | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| **Reproductive system and breast disorders** | **2** | **(0.3)** | **3** | **(0.4)** | **5** | **(0.4)** |
| Erectile dysfunction | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Intermenstrual bleeding | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Pruritus genital | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| **Respiratory, thoracic and mediastinal disorders** | **26** | **(3.7)** | **20** | **(2.9)** | **46** | **(3.3)** |
| Asthma | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Bronchial wall thickening | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Cough | 9 | (1.3) | 7 | (1.0) | 16 | (1.1) |
| Dysphonia | 3 | (0.4) | 1 | (0.1) | 4 | (0.3) |
| Dyspnoea | 2 | (0.3) | 4 | (0.6) | 6 | (0.4) |

Participants With Drug-Related Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| **Respiratory, thoracic and mediastinal disorders** | **26** | **(3.7)** | **20** | **(2.9)** | **46** | **(3.3)** |
| Dyspnoea exertional | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Epistaxis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Hypoxia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Pneumonitis | 7 | (1.0) | 7 | (1.0) | 14 | (1.0) |
| Productive cough | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Pulmonary mass | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Rhinitis allergic | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Sinus congestion | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Upper-airway cough syndrome | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Wheezing | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| **Skin and subcutaneous tissue disorders** | **366** | **(52.4)** | **182** | **(26.0)** | **548** | **(39.2)** |
| Acne | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Acute generalised exanthematous pustulosis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Alopecia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Dermatitis | 16 | (2.3) | 6 | (0.9) | 22 | (1.6) |
| Dermatitis acneiform | 3 | (0.4) | 3 | (0.4) | 6 | (0.4) |
| Dermatitis allergic | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Dermatitis atopic | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Dermatitis bullous | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Dermatitis psoriasiform | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Drug eruption | 4 | (0.6) | 2 | (0.3) | 6 | (0.4) |
| Drug reaction with eosinophilia and systemic symptoms | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Dry skin | 19 | (2.7) | 8 | (1.1) | 27 | (1.9) |
| Dyshidrotic eczema | 5 | (0.7) | 0 | (0.0) | 5 | (0.4) |
| Eczema | 17 | (2.4) | 2 | (0.3) | 19 | (1.4) |
| Eczema nummular | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Erythema | 6 | (0.9) | 4 | (0.6) | 10 | (0.7) |
| Erythema multiforme | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Erythema nodosum | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Hand dermatitis | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |

Participants With Drug-Related Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| **Skin and subcutaneous tissue disorders** | **366** | **(52.4)** | **182** | **(26.0)** | **548** | **(39.2)** |
| Hyperhidrosis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Immune-mediated dermatitis | 3 | (0.4) | 2 | (0.3) | 5 | (0.4) |
| Intertrigo | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Leukoderma | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Lichenoid keratosis | 3 | (0.4) | 1 | (0.1) | 4 | (0.3) |
| Macule | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Neurodermatitis | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Night sweats | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Onychoclasis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Palmar-plantar erythrodysaesthesia syndrome | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Petechiae | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Pruritus | 166 | (23.8) | 86 | (12.3) | 252 | (18.0) |
| Pruritus allergic | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Psoriasis | 4 | (0.6) | 6 | (0.9) | 10 | (0.7) |
| Purpura | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Rash | 162 | (23.2) | 65 | (9.3) | 227 | (16.2) |
| Rash erythematous | 4 | (0.6) | 0 | (0.0) | 4 | (0.3) |
| Rash macular | 3 | (0.4) | 4 | (0.6) | 7 | (0.5) |
| Rash maculo-papular | 44 | (6.3) | 22 | (3.1) | 66 | (4.7) |
| Rash papular | 6 | (0.9) | 0 | (0.0) | 6 | (0.4) |
| Rash pruritic | 14 | (2.0) | 2 | (0.3) | 16 | (1.1) |
| Sarcoid-like reaction | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| Seborrhoea | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Seborrhoeic dermatitis | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Skin depigmentation | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Skin discolouration | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Skin disorder | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Skin exfoliation | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Skin hypopigmentation | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Skin lesion | 3 | (0.4) | 2 | (0.3) | 5 | (0.4) |
| Skin plaque | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Skin toxicity | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Stevens-Johnson syndrome | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |

Participants With Drug-Related Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| **Skin and subcutaneous tissue disorders** | **366** | **(52.4)** | **182** | **(26.0)** | **548** | **(39.2)** |
| Urticaria | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Vitiligo | 6 | (0.9) | 4 | (0.6) | 10 | (0.7) |
| Xeroderma | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| **Vascular disorders** | **6** | **(0.9)** | **8** | **(1.1)** | **14** | **(1.0)** |
| Hot flush | 2 | (0.3) | 2 | (0.3) | 4 | (0.3) |
| Hypertension | 1 | (0.1) | 5 | (0.7) | 6 | (0.4) |
| Hypotension | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Peripheral coldness | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Vasculitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| **Null** | **1** | **(0.1)** | **0** | **(0.0)** | **1** | **(0.1)** |
| Null | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |

Every participant is counted a single time for each applicable row and column.
Grades are based on NCI CTCAE version 5
Non-serious adverse events up to 30 days of last treatment and serious adverse events up to 90 days of last treatment are included.
MedDRA V26.1 preferred terms "Neoplasm progression", "Malignant neoplasm progression" and "Disease progression" not related to the drug are excluded.
06MAR2024

Source: [P010V01MK7684a: adam-adsl; adae]

Table 2-15
Participants With Grade 3-5 Adverse Events by Decreasing Incidence
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Participants in population | 698 | | 700 | | 1,398 | |
| with one or more adverse events | 153 | (21.9) | 76 | (10.9) | 229 | (16.4) |
| with no adverse events | 545 | (78.1) | 624 | (89.1) | 1,169 | (83.6) |
| | | | | | | |
| Adrenal insufficiency | 13 | (1.9) | 2 | (0.3) | 15 | (1.1) |
| Hepatitis | 11 | (1.6) | 4 | (0.6) | 15 | (1.1) |
| Rash | 9 | (1.3) | 0 | (0.0) | 9 | (0.6) |
| Hypertension | 8 | (1.1) | 5 | (0.7) | 13 | (0.9) |
| Rash maculo-papular | 8 | (1.1) | 0 | (0.0) | 8 | (0.6) |
| Pruritus | 6 | (0.9) | 0 | (0.0) | 6 | (0.4) |
| Alanine aminotransferase increased | 5 | (0.7) | 9 | (1.3) | 14 | (1.0) |
| Cellulitis | 5 | (0.7) | 1 | (0.1) | 6 | (0.4) |
| Pneumonia | 5 | (0.7) | 0 | (0.0) | 5 | (0.4) |
| Colitis | 4 | (0.6) | 1 | (0.1) | 5 | (0.4) |
| Hypophysitis | 4 | (0.6) | 0 | (0.0) | 4 | (0.3) |
| Type 1 diabetes mellitus | 4 | (0.6) | 3 | (0.4) | 7 | (0.5) |
| Arthritis | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Aspartate aminotransferase increased | 3 | (0.4) | 4 | (0.6) | 7 | (0.5) |
| Encephalopathy | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Gamma-glutamyltransferase increased | 3 | (0.4) | 3 | (0.4) | 6 | (0.4) |
| Hyperglycaemia | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Meningitis aseptic | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Myocarditis | 3 | (0.4) | 1 | (0.1) | 4 | (0.3) |
| Rash pruritic | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Syncope | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Anaemia | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Blood creatine phosphokinase increased | 2 | (0.3) | 3 | (0.4) | 5 | (0.4) |
| Decreased appetite | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Dermatitis | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Diabetic ketoacidosis | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Diarrhoea | 2 | (0.3) | 4 | (0.6) | 6 | (0.4) |
| Immune-mediated enterocolitis | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Immune-mediated hypophysitis | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Influenza | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Lichenoid keratosis | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Lipase increased | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Lymphocyte count decreased | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |

Participants With Grade 3-5 Adverse Events by Decreasing Incidence
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Muscular weakness | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Myositis | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Nausea | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Pulmonary embolism | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Uveitis | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Acute kidney injury | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Adrenal disorder | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Amylase increased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Anxiety | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Appendicitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Arrhythmia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Asthenia | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Atrial fibrillation | 1 | (0.1) | 2 | (0.3) | 3 | (0.2) |
| Atrial flutter | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Autoimmune haemolytic anaemia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Bacterial infection | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Beta haemolytic streptococcal infection | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Blood bilirubin increased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Bronchitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| COVID-19 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Cardiac failure congestive | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Carpal tunnel syndrome | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Cerebrovascular accident | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Chronic sinusitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Cortisol decreased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Costochondritis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Dermatitis acneiform | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Device related infection | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Diabetes mellitus | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Diarrhoea infectious | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Drug hypersensitivity | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Drug reaction with eosinophilia and systemic symptoms | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Dysphagia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Dyspnoea | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Eczema | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Encephalitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |

Participants With Grade 3-5 Adverse Events by Decreasing Incidence
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Encephalitis autoimmune | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Eosinophilia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Erysipelas | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Erythema | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Facial nerve disorder | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Febrile neutropenia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Gastroenteritis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| General physical health deterioration | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Groin infection | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Guillain-Barre syndrome | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Hypertriglyceridaemia | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Hyponatraemia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Hypothyroidism | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Hypoxia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Immune thrombocytopenia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Immune-mediated dermatitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Immune-mediated hepatitis | 1 | (0.1) | 2 | (0.3) | 3 | (0.2) |
| Immune-mediated hypothyroidism | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Immune-mediated myositis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Incarcerated umbilical hernia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Intra-abdominal haematoma | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Iridocyclitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Jaundice cholestatic | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Leukopenia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Lymphopenia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Meningitis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Meningoencephalitis viral | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Migraine | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Myalgia | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Myasthenia gravis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Myelitis transverse | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Nephritis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Neutropenia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Pancreatitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Pneumonia legionella | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Pneumonia viral | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Pneumonitis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |

Participants With Grade 3-5 Adverse Events by Decreasing Incidence
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Polymyalgia rheumatica | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Psoriasis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Pulmonary artery thrombosis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Pyelonephritis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Pyrexia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Rash papular | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Retinal detachment | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Scleritis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Septic shock | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Skin laceration | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Stevens-Johnson syndrome | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Systemic inflammatory response syndrome | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Transaminases increased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Troponin I increased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Upper respiratory tract infection | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Urosepsis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Vasculitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Vertigo | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Visual impairment | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| White blood cell count decreased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Wound infection | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Basal cell carcinoma | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Blood alkaline phosphatase increased | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Bowen's disease | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Cardiac failure | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Conjunctivitis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Cough | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Dehydration | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Dengue fever | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Fall | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| Fatigue | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| Gastritis erosive | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Haemorrhage intracranial | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Headache | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Hepatitis C | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Hypertransaminasaemia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |

Participants With Grade 3-5 Adverse Events by Decreasing Incidence
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Hypokalaemia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Immune-mediated myocarditis | 0 | (0.0) | 3 | (0.4) | 3 | (0.2) |
| Immune-mediated nephritis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Myocardial infarction | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Neuritis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Neutrophil count decreased | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Optic neuropathy | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Persistent postural-perceptual dizziness | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Pneumocystis jirovecii pneumonia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Polymyositis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Presyncope | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Proteinuria | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Pulmonary hypertension | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Rhabdomyolysis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Right ventricular failure | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Skin graft necrosis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Skin infection | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| Soft tissue disorder | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Spinal fracture | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Subdural haemorrhage | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Tubulointerstitial nephritis | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| Type 2 diabetes mellitus | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Ureterolithiasis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Urinary tract infection | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Ventricular tachycardia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Vogt-Koyanagi-Harada disease | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |

Every participant is counted a single time for each applicable row and column.
Grades are based on NCI CTCAE version 5
Non-serious adverse events up to 30 days of last treatment and serious adverse events up to 90 days of last treatment are included.
MedDRA V26.1 preferred terms "Neoplasm progression", "Malignant neoplasm progression" and "Disease progression" not related to the drug are excluded.
06MAR2024

Source: [P010V01MK7684a: adam-adsl; adae]

Table 2-16
Participants With Grade 3-5 Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Participants in population | 698 | | 700 | | 1,398 | |
| with one or more adverse events | 153 | (21.9) | 76 | (10.9) | 229 | (16.4) |
| with no adverse events | 545 | (78.1) | 624 | (89.1) | 1,169 | (83.6) |
| **Blood and lymphatic system disorders** | **5** | **(0.7)** | **0** | **(0.0)** | **5** | **(0.4)** |
| Anaemia | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Autoimmune haemolytic anaemia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Eosinophilia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Febrile neutropenia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Immune thrombocytopenia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Leukopenia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Lymphopenia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Neutropenia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| **Cardiac disorders** | **6** | **(0.9)** | **10** | **(1.4)** | **16** | **(1.1)** |
| Arrhythmia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Atrial fibrillation | 1 | (0.1) | 2 | (0.3) | 3 | (0.2) |
| Atrial flutter | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Cardiac failure | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Cardiac failure congestive | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Immune-mediated myocarditis | 0 | (0.0) | 3 | (0.4) | 3 | (0.2) |
| Myocardial infarction | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Myocarditis | 3 | (0.4) | 1 | (0.1) | 4 | (0.3) |
| Right ventricular failure | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Ventricular tachycardia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| **Ear and labyrinth disorders** | **1** | **(0.1)** | **0** | **(0.0)** | **1** | **(0.1)** |
| Vertigo | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| **Endocrine disorders** | **22** | **(3.2)** | **2** | **(0.3)** | **24** | **(1.7)** |
| Adrenal disorder | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Adrenal insufficiency | 13 | (1.9) | 2 | (0.3) | 15 | (1.1) |
| Hypophysitis | 4 | (0.6) | 0 | (0.0) | 4 | (0.3) |
| Hypothyroidism | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Immune-mediated hypophysitis | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |

Participants With Grade 3-5 Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| **Endocrine disorders** | **22** | **(3.2)** | **2** | **(0.3)** | **24** | **(1.7)** |
| Immune-mediated hypothyroidism | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| **Eye disorders** | **4** | **(0.6)** | **2** | **(0.3)** | **6** | **(0.4)** |
| Iridocyclitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Optic neuropathy | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Retinal detachment | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Scleritis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Uveitis | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Visual impairment | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Vogt-Koyanagi-Harada disease | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| **Gastrointestinal disorders** | **12** | **(1.7)** | **6** | **(0.9)** | **18** | **(1.3)** |
| Colitis | 4 | (0.6) | 1 | (0.1) | 5 | (0.4) |
| Diarrhoea | 2 | (0.3) | 4 | (0.6) | 6 | (0.4) |
| Dysphagia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Gastritis erosive | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Immune-mediated enterocolitis | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Incarcerated umbilical hernia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Intra-abdominal haematoma | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Nausea | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Pancreatitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| **General disorders and administration site conditions** | **4** | **(0.6)** | **4** | **(0.6)** | **8** | **(0.6)** |
| Asthenia | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Fatigue | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| General physical health deterioration | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Pyrexia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Systemic inflammatory response syndrome | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| **Hepatobiliary disorders** | **12** | **(1.7)** | **7** | **(1.0)** | **19** | **(1.4)** |
| Hepatitis | 11 | (1.6) | 4 | (0.6) | 15 | (1.1) |
| Hypertransaminasaemia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |

Participants With Grade 3-5 Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| **Hepatobiliary disorders** | **12** | **(1.7)** | **7** | **(1.0)** | **19** | **(1.4)** |
| Immune-mediated hepatitis | 1 | (0.1) | 2 | (0.3) | 3 | (0.2) |
| Jaundice cholestatic | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| **Immune system disorders** | **1** | **(0.1)** | **0** | **(0.0)** | **1** | **(0.1)** |
| Drug hypersensitivity | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| **Infections and infestations** | **30** | **(4.3)** | **11** | **(1.6)** | **41** | **(2.9)** |
| Appendicitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Bacterial infection | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Beta haemolytic streptococcal infection | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Bronchitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| COVID-19 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Cellulitis | 5 | (0.7) | 1 | (0.1) | 6 | (0.4) |
| Chronic sinusitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Conjunctivitis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Dengue fever | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Device related infection | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Diarrhoea infectious | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Encephalitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Erysipelas | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Gastroenteritis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Groin infection | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Hepatitis C | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Influenza | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Meningitis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Meningitis aseptic | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Meningoencephalitis viral | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Pneumocystis jirovecii pneumonia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Pneumonia | 5 | (0.7) | 0 | (0.0) | 5 | (0.4) |
| Pneumonia legionella | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Pneumonia viral | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Pyelonephritis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Septic shock | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Skin infection | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |

Participants With Grade 3-5 Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| **Infections and infestations** | **30** | **(4.3)** | **11** | **(1.6)** | **41** | **(2.9)** |
| Upper respiratory tract infection | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Urinary tract infection | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Urosepsis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Wound infection | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| **Injury, poisoning and procedural complications** | **1** | **(0.1)** | **5** | **(0.7)** | **6** | **(0.4)** |
| Fall | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| Skin graft necrosis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Skin laceration | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Spinal fracture | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Subdural haemorrhage | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| **Investigations** | **19** | **(2.7)** | **14** | **(2.0)** | **33** | **(2.4)** |
| Alanine aminotransferase increased | 5 | (0.7) | 9 | (1.3) | 14 | (1.0) |
| Amylase increased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Aspartate aminotransferase increased | 3 | (0.4) | 4 | (0.6) | 7 | (0.5) |
| Blood alkaline phosphatase increased | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Blood bilirubin increased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Blood creatine phosphokinase increased | 2 | (0.3) | 3 | (0.4) | 5 | (0.4) |
| Cortisol decreased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Gamma-glutamyltransferase increased | 3 | (0.4) | 3 | (0.4) | 6 | (0.4) |
| Lipase increased | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Lymphocyte count decreased | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Neutrophil count decreased | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Transaminases increased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Troponin I increased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| White blood cell count decreased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| **Metabolism and nutrition disorders** | **13** | **(1.9)** | **9** | **(1.3)** | **22** | **(1.6)** |
| Decreased appetite | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Dehydration | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Diabetes mellitus | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Diabetic ketoacidosis | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |

Participants With Grade 3-5 Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| **Metabolism and nutrition disorders** | **13** | **(1.9)** | **9** | **(1.3)** | **22** | **(1.6)** |
| Hyperglycaemia | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Hypertriglyceridaemia | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Hypokalaemia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Hyponatraemia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Type 1 diabetes mellitus | 4 | (0.6) | 3 | (0.4) | 7 | (0.5) |
| Type 2 diabetes mellitus | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| **Musculoskeletal and connective tissue disorders** | **10** | **(1.4)** | **7** | **(1.0)** | **17** | **(1.2)** |
| Arthritis | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Costochondritis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Immune-mediated myositis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Muscular weakness | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Myalgia | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Myositis | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Polymyalgia rheumatica | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Polymyositis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Rhabdomyolysis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Soft tissue disorder | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| **Neoplasms benign, malignant and unspecified (incl cysts and polyps)** | **0** | **(0.0)** | **2** | **(0.3)** | **2** | **(0.1)** |
| Basal cell carcinoma | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Bowen's disease | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| **Nervous system disorders** | **14** | **(2.0)** | **6** | **(0.9)** | **20** | **(1.4)** |
| Carpal tunnel syndrome | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Cerebrovascular accident | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Encephalitis autoimmune | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Encephalopathy | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Facial nerve disorder | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Guillain-Barre syndrome | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Haemorrhage intracranial | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Headache | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |

Participants With Grade 3-5 Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| **Nervous system disorders** | **14** | **(2.0)** | **6** | **(0.9)** | **20** | **(1.4)** |
| Migraine | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Myasthenia gravis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Myelitis transverse | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Neuritis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Persistent postural-perceptual dizziness | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Presyncope | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Syncope | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| **Psychiatric disorders** | **1** | **(0.1)** | **0** | **(0.0)** | **1** | **(0.1)** |
| Anxiety | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| **Renal and urinary disorders** | **2** | **(0.3)** | **5** | **(0.7)** | **7** | **(0.5)** |
| Acute kidney injury | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Immune-mediated nephritis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Nephritis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Proteinuria | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Tubulointerstitial nephritis | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| Ureterolithiasis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| **Respiratory, thoracic and mediastinal disorders** | **4** | **(0.6)** | **4** | **(0.6)** | **8** | **(0.6)** |
| Cough | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Dyspnoea | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Hypoxia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Pneumonitis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Pulmonary artery thrombosis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Pulmonary embolism | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Pulmonary hypertension | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| **Skin and subcutaneous tissue disorders** | **34** | **(4.9)** | **1** | **(0.1)** | **35** | **(2.5)** |
| Dermatitis | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Dermatitis acneiform | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Drug reaction with eosinophilia and systemic symptoms | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |

Participants With Grade 3-5 Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| **Skin and subcutaneous tissue disorders** | **34** | **(4.9)** | **1** | **(0.1)** | **35** | **(2.5)** |
| Eczema | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Erythema | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Immune-mediated dermatitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Lichenoid keratosis | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Pruritus | 6 | (0.9) | 0 | (0.0) | 6 | (0.4) |
| Psoriasis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Rash | 9 | (1.3) | 0 | (0.0) | 9 | (0.6) |
| Rash maculo-papular | 8 | (1.1) | 0 | (0.0) | 8 | (0.6) |
| Rash papular | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Rash pruritic | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Stevens-Johnson syndrome | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| **Vascular disorders** | **9** | **(1.3)** | **5** | **(0.7)** | **14** | **(1.0)** |
| Hypertension | 8 | (1.1) | 5 | (0.7) | 13 | (0.9) |
| Vasculitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |

Every participant is counted a single time for each applicable row and column.
Grades are based on NCI CTCAE version 5
Non-serious adverse events up to 30 days of last treatment and serious adverse events up to 90 days of last treatment are included.
MedDRA V26.1 preferred terms "Neoplasm progression", "Malignant neoplasm progression" and "Disease progression" not related to the drug are excluded.
06MAR2024

Source: [P010V01MK7684a: adam-adsl; adae]

Table 2-17
Participants With Drug-Related Grade 3-5 Adverse Events by Decreasing Incidence (Incidence > 0% in One or More Treatment Groups) (APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Participants in population | 698 | | 700 | | 1,398 | |
| with one or more adverse events | 111 | (15.9) | 48 | (6.9) | 159 | (11.4) |
| with no adverse events | 587 | (84.1) | 652 | (93.1) | 1,239 | (88.6) |
| | | | | | | |
| Adrenal insufficiency | 13 | (1.9) | 2 | (0.3) | 15 | (1.1) |
| Hepatitis | 11 | (1.6) | 4 | (0.6) | 15 | (1.1) |
| Rash | 9 | (1.3) | 0 | (0.0) | 9 | (0.6) |
| Rash maculo-papular | 7 | (1.0) | 0 | (0.0) | 7 | (0.5) |
| Pruritus | 6 | (0.9) | 0 | (0.0) | 6 | (0.4) |
| Colitis | 4 | (0.6) | 1 | (0.1) | 5 | (0.4) |
| Hypophysitis | 4 | (0.6) | 0 | (0.0) | 4 | (0.3) |
| Type 1 diabetes mellitus | 4 | (0.6) | 3 | (0.4) | 7 | (0.5) |
| Alanine aminotransferase increased | 3 | (0.4) | 7 | (1.0) | 10 | (0.7) |
| Arthritis | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Encephalopathy | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Hyperglycaemia | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Myocarditis | 3 | (0.4) | 1 | (0.1) | 4 | (0.3) |
| Rash pruritic | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Aspartate aminotransferase increased | 2 | (0.3) | 4 | (0.6) | 6 | (0.4) |
| Blood creatine phosphokinase increased | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Decreased appetite | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Dermatitis | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Immune-mediated enterocolitis | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Immune-mediated hypophysitis | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Lichenoid keratosis | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Lymphocyte count decreased | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Meningitis aseptic | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Muscular weakness | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Myositis | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Nausea | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Uveitis | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Adrenal disorder | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Amylase increased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Anaemia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Arrhythmia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Asthenia | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Autoimmune haemolytic anaemia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |

Participants With Drug-Related Grade 3-5 Adverse Events by Decreasing Incidence
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Blood bilirubin increased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Cortisol decreased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Costochondritis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Dermatitis acneiform | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Device related infection | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Diabetes mellitus | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Diabetic ketoacidosis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Diarrhoea | 1 | (0.1) | 3 | (0.4) | 4 | (0.3) |
| Drug reaction with eosinophilia and systemic symptoms | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Dysphagia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Dyspnoea | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Eczema | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Encephalitis autoimmune | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Eosinophilia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Erythema | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Febrile neutropenia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Gamma-glutamyltransferase increased | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| General physical health deterioration | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Guillain-Barre syndrome | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Hyponatraemia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Hypothyroidism | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Hypoxia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Immune thrombocytopenia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Immune-mediated dermatitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Immune-mediated hepatitis | 1 | (0.1) | 2 | (0.3) | 3 | (0.2) |
| Immune-mediated hypothyroidism | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Immune-mediated myositis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Iridocyclitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Leukopenia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Lipase increased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Meningitis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Migraine | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Myalgia | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Myasthenia gravis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Myelitis transverse | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Neutropenia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |

Participants With Drug-Related Grade 3-5 Adverse Events by Decreasing Incidence
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Pneumonitis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Polymyalgia rheumatica | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Psoriasis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Pyrexia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Rash papular | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Scleritis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Stevens-Johnson syndrome | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Syncope | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Systemic inflammatory response syndrome | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Transaminases increased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Vasculitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Visual impairment | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| White blood cell count decreased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Atrial fibrillation | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Blood alkaline phosphatase increased | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Cardiac failure | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Fatigue | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| Gastritis erosive | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Hepatitis C | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Hypertension | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| Hypertransaminasaemia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Hypertriglyceridaemia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Hypokalaemia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Immune-mediated myocarditis | 0 | (0.0) | 3 | (0.4) | 3 | (0.2) |
| Immune-mediated nephritis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Neuritis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Neutrophil count decreased | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Optic neuropathy | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Persistent postural-perceptual dizziness | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Polymyositis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Proteinuria | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Septic shock | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Tubulointerstitial nephritis | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |

Participants With Drug-Related Grade 3-5 Adverse Events by Decreasing Incidence
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Vogt-Koyanagi-Harada disease | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |

Every participant is counted a single time for each applicable row and column.
Grades are based on NCI CTCAE version 5
Non-serious adverse events up to 30 days of last treatment and serious adverse events up to 90 days of last treatment are included.
MedDRA V26.1 preferred terms "Neoplasm progression", "Malignant neoplasm progression" and "Disease progression" not related to the drug are excluded.
Database Cutoff Date: 06MAR2024.

Source: [P010V01MK7684a: adam-adsl; adae]

Table 2-18
Participants With Adverse Events Resulting in Death by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Participants in population | 698 | | 700 | | 1,398 | |
| with one or more adverse events | 3 | (0.4) | 1 | (0.1) | 4 | (0.3) |
| with no adverse events | 695 | (99.6) | 699 | (99.9) | 1,394 | (99.7) |
| **Cardiac disorders** | **1** | **(0.1)** | **0** | **(0.0)** | **1** | **(0.1)** |
| Myocarditis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| **Infections and infestations** | **1** | **(0.1)** | **0** | **(0.0)** | **1** | **(0.1)** |
| Septic shock | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| **Musculoskeletal and connective tissue disorders** | **0** | **(0.0)** | **1** | **(0.1)** | **1** | **(0.1)** |
| Myositis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| **Nervous system disorders** | **1** | **(0.1)** | **0** | **(0.0)** | **1** | **(0.1)** |
| Myasthenia gravis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |

Every participant is counted a single time for each applicable row and column.
Grades are based on NCI CTCAE version 5
Non-serious adverse events up to 30 days of last treatment and serious adverse events up to 90 days of last treatment are included.
MedDRA V26.1 preferred terms "Neoplasm progression", "Malignant neoplasm progression" and "Disease progression" not related to the drug are excluded.
06MAR2024

Source: [P010V01MK7684a: adam-adsl; adae]

Table 2-19
Participants With Adverse Events Resulting in Treatment Discontinuation by Decreasing Incidence
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Participants in population | 698 | | 700 | | 1,398 | |
| with one or more adverse events | 97 | (13.9) | 47 | (6.7) | 144 | (10.3) |
| with no adverse events | 601 | (86.1) | 653 | (93.3) | 1,254 | (89.7) |
| | | | | | | |
| Hepatitis | 11 | (1.6) | 5 | (0.7) | 16 | (1.1) |
| Rash | 9 | (1.3) | 0 | (0.0) | 9 | (0.6) |
| Myocarditis | 5 | (0.7) | 0 | (0.0) | 5 | (0.4) |
| Pneumonitis | 4 | (0.6) | 4 | (0.6) | 8 | (0.6) |
| Rash maculo-papular | 4 | (0.6) | 0 | (0.0) | 4 | (0.3) |
| Alanine aminotransferase increased | 3 | (0.4) | 3 | (0.4) | 6 | (0.4) |
| Arthritis | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Rash pruritic | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Arthralgia | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Aspartate aminotransferase increased | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Dermatitis | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Encephalopathy | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Immune-mediated enterocolitis | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Immune-mediated hypophysitis | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Lichenoid keratosis | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Malignant melanoma | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Pruritus | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Acute myocardial infarction | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Adrenal insufficiency | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Anxiety | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Arrhythmia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Arteriosclerosis coronary artery | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Autoimmune haemolytic anaemia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Back pain | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Cardiac failure | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Colitis | 1 | (0.1) | 2 | (0.3) | 3 | (0.2) |
| Dermatitis atopic | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Diverticulitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Drug reaction with eosinophilia and systemic symptoms | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Dry skin | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Dyspnoea | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |

Participants With Adverse Events Resulting in Treatment Discontinuation by Decreasing Incidence
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Eczema | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Encephalitis autoimmune | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Gastritis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Guillain-Barre syndrome | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Hyperglycaemia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Hypophysitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Hypothyroidism | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Immune thrombocytopenia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Immune-mediated dermatitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Immune-mediated hepatitis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Melanoma recurrent | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Meningitis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Meningitis aseptic | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Meningoencephalitis viral | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Myasthenia gravis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Myelitis transverse | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Myositis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Nephritis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Neurodermatitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Peripheral sensory neuropathy | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Polymyalgia rheumatica | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Scleritis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Septic shock | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Stevens-Johnson syndrome | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Subdural haematoma | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Synovitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Systemic inflammatory response syndrome | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Type 1 diabetes mellitus | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Uveitis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Visual impairment | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Weight decreased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Blood creatine phosphokinase increased | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Cardiomyopathy | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Diabetic ketoacidosis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Dry mouth | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |

Participants With Adverse Events Resulting in Treatment Discontinuation by Decreasing Incidence
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Fasciitis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Fatigue | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Headache | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Hepatitis C | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Hypertransaminasaemia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Immune-mediated myocarditis | 0 | (0.0) | 3 | (0.4) | 3 | (0.2) |
| Immune-mediated myositis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Immune-mediated nephritis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Neuritis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Optic neuropathy | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Periarthritis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Persistent postural-perceptual dizziness | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Polymyositis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Psoriasis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Radiculopathy | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Restless legs syndrome | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Tubulointerstitial nephritis | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| Vogt-Koyanagi-Harada disease | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |

Every participant is counted a single time for each applicable row and column.
Grades are based on NCI CTCAE version 5
Non-serious adverse events up to 30 days of last treatment and serious adverse events up to 90 days of last treatment are included.
MedDRA V26.1 preferred terms "Neoplasm progression", "Malignant neoplasm progression" and "Disease progression" not related to the drug are excluded.
06MAR2024

Source: [P010V01MK7684a: adam-adsl; adae]

Table 2-20
Participants With Drug-Related Adverse Events Resulting in Treatment Discontinuation by Decreasing Incidence
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Participants in population | 698 | | 700 | | 1,398 | |
| with one or more adverse events | 87 | (12.5) | 44 | (6.3) | 131 | (9.4) |
| with no adverse events | 611 | (87.5) | 656 | (93.7) | 1,267 | (90.6) |
| | | | | | | |
| Hepatitis | 10 | (1.4) | 5 | (0.7) | 15 | (1.1) |
| Rash | 9 | (1.3) | 0 | (0.0) | 9 | (0.6) |
| Myocarditis | 5 | (0.7) | 0 | (0.0) | 5 | (0.4) |
| Pneumonitis | 4 | (0.6) | 4 | (0.6) | 8 | (0.6) |
| Rash maculo-papular | 4 | (0.6) | 0 | (0.0) | 4 | (0.3) |
| Alanine aminotransferase increased | 3 | (0.4) | 3 | (0.4) | 6 | (0.4) |
| Arthritis | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Rash pruritic | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Arthralgia | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Aspartate aminotransferase increased | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Dermatitis | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Encephalopathy | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Immune-mediated enterocolitis | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Immune-mediated hypophysitis | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Lichenoid keratosis | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Pruritus | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Acute myocardial infarction | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Adrenal insufficiency | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Arrhythmia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Arteriosclerosis coronary artery | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Autoimmune haemolytic anaemia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Back pain | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Cardiac failure | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Colitis | 1 | (0.1) | 2 | (0.3) | 3 | (0.2) |
| Dermatitis atopic | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Diverticulitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Drug reaction with eosinophilia and systemic symptoms | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Dry skin | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Dyspnoea | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Eczema | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Encephalitis autoimmune | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |

Participants With Drug-Related Adverse Events Resulting in Treatment Discontinuation by Decreasing Incidence
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Gastritis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Guillain-Barre syndrome | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Hyperglycaemia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Hypophysitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Hypothyroidism | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Immune thrombocytopenia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Immune-mediated dermatitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Immune-mediated hepatitis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Meningitis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Meningitis aseptic | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Myasthenia gravis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Myelitis transverse | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Myositis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Peripheral sensory neuropathy | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Polymyalgia rheumatica | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Scleritis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Stevens-Johnson syndrome | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Synovitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Systemic inflammatory response syndrome | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Type 1 diabetes mellitus | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Uveitis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Visual impairment | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Weight decreased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Diabetic ketoacidosis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Dry mouth | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Fasciitis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Fatigue | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Headache | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Hepatitis C | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Hypertransaminasaemia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Immune-mediated myocarditis | 0 | (0.0) | 3 | (0.4) | 3 | (0.2) |
| Immune-mediated myositis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Immune-mediated nephritis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Neuritis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Optic neuropathy | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |

Participants With Drug-Related Adverse Events Resulting in Treatment Discontinuation by Decreasing Incidence
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Periarthritis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Persistent postural-perceptual dizziness | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Polymyositis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Psoriasis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Radiculopathy | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Tubulointerstitial nephritis | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| Vogt-Koyanagi-Harada disease | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |

Every participant is counted a single time for each applicable row and column.
Grades are based on NCI CTCAE version 5
Non-serious adverse events up to 30 days of last treatment and serious adverse events up to 90 days of last treatment are included.
MedDRA V26.1 preferred terms "Neoplasm progression", "Malignant neoplasm progression" and "Disease progression" not related to the drug are excluded.
06MAR2024

Source: [P010V01MK7684a: adam-adsl; adae]

Table 2-21
Participants With Serious Adverse Events by Decreasing Incidence
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Participants in population | 698 | | 700 | | 1,398 | |
| with one or more adverse events | 109 | (15.6) | 57 | (8.1) | 166 | (11.9) |
| with no adverse events | 589 | (84.4) | 643 | (91.9) | 1,232 | (88.1) |
| | | | | | | |
| Adrenal insufficiency | 14 | (2.0) | 2 | (0.3) | 16 | (1.1) |
| Myocarditis | 6 | (0.9) | 1 | (0.1) | 7 | (0.5) |
| Cellulitis | 5 | (0.7) | 1 | (0.1) | 6 | (0.4) |
| Hypophysitis | 5 | (0.7) | 0 | (0.0) | 5 | (0.4) |
| Hepatitis | 4 | (0.6) | 1 | (0.1) | 5 | (0.4) |
| Immune-mediated enterocolitis | 4 | (0.6) | 1 | (0.1) | 5 | (0.4) |
| Pneumonia | 4 | (0.6) | 2 | (0.3) | 6 | (0.4) |
| Rash | 4 | (0.6) | 0 | (0.0) | 4 | (0.3) |
| Colitis | 3 | (0.4) | 2 | (0.3) | 5 | (0.4) |
| Encephalopathy | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Meningitis aseptic | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Type 1 diabetes mellitus | 3 | (0.4) | 2 | (0.3) | 5 | (0.4) |
| Diabetic ketoacidosis | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Immune-mediated hypophysitis | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Influenza | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Myositis | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Pneumonitis | 2 | (0.3) | 2 | (0.3) | 4 | (0.3) |
| Pulmonary embolism | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Rash maculo-papular | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Acute myocardial infarction | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Adrenal disorder | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Alanine aminotransferase increased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Anaemia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Anxiety | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Appendicitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Arrhythmia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Arteriosclerosis coronary artery | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Arthritis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Aspartate aminotransferase increased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Atrial fibrillation | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Atrial flutter | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Autoimmune haemolytic anaemia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Beta haemolytic streptococcal infection | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |

Participants With Serious Adverse Events by Decreasing Incidence
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Bronchitis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| COVID-19 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Cardiac failure | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Cardiac failure congestive | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Cerebrovascular accident | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Chronic sinusitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Costochondritis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Dermatitis acneiform | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Device related infection | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Diabetes mellitus | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Diarrhoea infectious | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Drug hypersensitivity | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Drug reaction with eosinophilia and systemic symptoms | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Dysphagia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Encephalitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Encephalitis autoimmune | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Erysipelas | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Facial nerve disorder | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Febrile neutropenia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Gastritis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Gastroenteritis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| General physical health deterioration | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Groin infection | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Guillain-Barre syndrome | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Hyperglycaemia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Hypothyroidism | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Immune thrombocytopenia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Immune-mediated hepatitis | 1 | (0.1) | 2 | (0.3) | 3 | (0.2) |
| Immune-mediated hypothyroidism | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Incarcerated umbilical hernia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Incisional hernia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Intra-abdominal haematoma | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Jaundice cholestatic | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Joint swelling | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Meningitis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Meningoencephalitis viral | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |

Participants With Serious Adverse Events by Decreasing Incidence
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Muscular weakness | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Myasthenia gravis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Myelitis transverse | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Nephritis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Pancreatitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Pneumonia legionella | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Pneumonia viral | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Presyncope | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Pruritus | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Pulmonary artery thrombosis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Pyelonephritis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Pyrexia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Septic shock | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Skin laceration | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Squamous cell carcinoma of skin | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Stevens-Johnson syndrome | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Syncope | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Systemic inflammatory response syndrome | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Troponin T increased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Umbilical hernia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Upper respiratory tract infection | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Urinary tract infection | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Urosepsis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Uveitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Vertigo | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Visual impairment | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Vomiting | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Wound infection | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Blood creatine phosphokinase increased | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Cataract | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Cough | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Decreased appetite | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Deep vein thrombosis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Dehydration | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Dengue fever | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Diarrhoea | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |

Participants With Serious Adverse Events by Decreasing Incidence
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Dyspnoea | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Fall | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Fatigue | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Gastritis erosive | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Gastrointestinal disorder | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Haemorrhage intracranial | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Hypertension | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Hypoglycaemia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Immune-mediated myocarditis | 0 | (0.0) | 3 | (0.4) | 3 | (0.2) |
| Immune-mediated myositis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Melanocytic naevus | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Meniscus injury | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Myocardial infarction | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Neuritis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Optic neuropathy | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Persistent postural-perceptual dizziness | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Pneumocystis jirovecii pneumonia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Polymyositis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Pulmonary hypertension | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Right ventricular failure | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Skin graft necrosis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Skin infection | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| Soft tissue disorder | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Spinal fracture | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Subdural haemorrhage | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Thrombophlebitis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Transient ischaemic attack | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Tubulointerstitial nephritis | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| Type 2 diabetes mellitus | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Ureterolithiasis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Ventricular tachycardia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |

Participants With Serious Adverse Events by Decreasing Incidence
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Vogt-Koyanagi-Harada disease | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |

Every participant is counted a single time for each applicable row and column.
Grades are based on NCI CTCAE version 5
Serious adverse events up to 90 days of last treatment are included.
MedDRA V26.1 preferred terms "Neoplasm progression", "Malignant neoplasm progression" and "Disease progression" not related to the drug are excluded.
06MAR2024

Source: [P010V01MK7684a: adam-adsl; adae]

Table 2-22
Participants With Drug-Related Serious Adverse Events by Decreasing Incidence
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Participants in population | 698 | | 700 | | 1,398 | |
| with one or more adverse events | 74 | (10.6) | 30 | (4.3) | 104 | (7.4) |
| with no adverse events | 624 | (89.4) | 670 | (95.7) | 1,294 | (92.6) |
| Adrenal insufficiency | 14 | (2.0) | 2 | (0.3) | 16 | (1.1) |
| Myocarditis | 6 | (0.9) | 1 | (0.1) | 7 | (0.5) |
| Hypophysitis | 5 | (0.7) | 0 | (0.0) | 5 | (0.4) |
| Hepatitis | 4 | (0.6) | 1 | (0.1) | 5 | (0.4) |
| Immune-mediated enterocolitis | 4 | (0.6) | 1 | (0.1) | 5 | (0.4) |
| Rash | 4 | (0.6) | 0 | (0.0) | 4 | (0.3) |
| Colitis | 3 | (0.4) | 2 | (0.3) | 5 | (0.4) |
| Encephalopathy | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Type 1 diabetes mellitus | 3 | (0.4) | 2 | (0.3) | 5 | (0.4) |
| Immune-mediated hypophysitis | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Meningitis aseptic | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Myositis | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Pneumonitis | 2 | (0.3) | 2 | (0.3) | 4 | (0.3) |
| Rash maculo-papular | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Acute myocardial infarction | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Adrenal disorder | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Alanine aminotransferase increased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Anaemia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Arrhythmia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Arteriosclerosis coronary artery | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Arthritis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Aspartate aminotransferase increased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Autoimmune haemolytic anaemia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Cardiac failure | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Costochondritis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Dermatitis acneiform | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Device related infection | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Diabetes mellitus | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Diabetic ketoacidosis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Drug reaction with eosinophilia and systemic symptoms | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Dysphagia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Encephalitis autoimmune | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |

Participants With Drug-Related Serious Adverse Events by Decreasing Incidence
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Febrile neutropenia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Gastritis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| General physical health deterioration | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Guillain-Barre syndrome | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Hyperglycaemia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Hypothyroidism | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Immune thrombocytopenia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Immune-mediated hepatitis | 1 | (0.1) | 2 | (0.3) | 3 | (0.2) |
| Immune-mediated hypothyroidism | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Meningitis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Muscular weakness | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Myasthenia gravis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Myelitis transverse | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Pruritus | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Pyrexia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Stevens-Johnson syndrome | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Systemic inflammatory response syndrome | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Troponin T increased | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Uveitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Visual impairment | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Vomiting | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Decreased appetite | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Fatigue | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Gastritis erosive | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Hypertension | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Immune-mediated myocarditis | 0 | (0.0) | 3 | (0.4) | 3 | (0.2) |
| Immune-mediated myositis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Neuritis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Optic neuropathy | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Persistent postural-perceptual dizziness | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Polymyositis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Septic shock | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Tubulointerstitial nephritis | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |

Participants With Drug-Related Serious Adverse Events by Decreasing Incidence
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Vogt-Koyanagi-Harada disease | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |

Every participant is counted a single time for each applicable row and column.
Grades are based on NCI CTCAE version 5
Non-serious adverse events up to 30 days of last treatment and serious adverse events up to 90 days of last treatment are included.
MedDRA V26.1 preferred terms "Neoplasm progression", "Malignant neoplasm progression" and "Disease progression" not related to the drug are excluded.
06MAR2024

Source: [P010V01MK7684a: adam-adsl; adae]

Table 2-23
Adverse Event Summary
AEOSI Overall
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Participants in population | 698 | | 700 | | 1,398 | |
| with one or more adverse events | 212 | (30.4) | 168 | (24.0) | 380 | (27.2) |
| with no adverse event | 486 | (69.6) | 532 | (76.0) | 1,018 | (72.8) |
| with drug-related[a] adverse events | 200 | (28.7) | 158 | (22.6) | 358 | (25.6) |
| with toxicity grade 3-5 adverse events | 83 | (11.9) | 26 | (3.7) | 109 | (7.8) |
| with toxicity grade 3-5 drug-related adverse events | 78 | (11.2) | 25 | (3.6) | 103 | (7.4) |
| with serious adverse events | 58 | (8.3) | 22 | (3.1) | 80 | (5.7) |
| with serious drug-related adverse events | 54 | (7.7) | 22 | (3.1) | 76 | (5.4) |
| with dose modification[b] due to an adverse event | 91 | (13.0) | 44 | (6.3) | 135 | (9.7) |
| with dose interrupted due to an adverse event | 48 | (6.9) | 22 | (3.1) | 70 | (5.0) |
| who died | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| who died due to a drug-related adverse event | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| discontinued drug due to an adverse event | 49 | (7.0) | 26 | (3.7) | 75 | (5.4) |
| discontinued drug due to a drug-related adverse event | 47 | (6.7) | 26 | (3.7) | 73 | (5.2) |
| discontinued drug due to a serious adverse event | 28 | (4.0) | 14 | (2.0) | 42 | (3.0) |
| discontinued drug due to a serious drug-related adverse event | 27 | (3.9) | 14 | (2.0) | 41 | (2.9) |

[a] Determined by the investigator to be related to the drug.

[b] Defined as an action taken of drug interrupted or drug withdrawn.

Grades are based on NCI CTCAE version 5.

Non-serious adverse events up to 30 days of last treatment and serious adverse events up to 90 days of last treatment are included.

06MAR2024

Source: [P010V01MK7684a: adam-adsl; adae]

Table 2-24
Participants With Adverse Events of Special Interest (AEOSI) by Maximum Toxicity Grade
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Participants in population | 698 | | 700 | | 1,398 | |
| with one or more adverse events | 212 | (30.4) | 168 | (24.0) | 380 | (27.2) |
| Grade 1 | 53 | (7.6) | 77 | (11.0) | 130 | (9.3) |
| Grade 2 | 76 | (10.9) | 65 | (9.3) | 141 | (10.1) |
| Grade 3 | 72 | (10.3) | 22 | (3.1) | 94 | (6.7) |
| Grade 4 | 9 | (1.3) | 3 | (0.4) | 12 | (0.9) |
| Grade 5 | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| with no adverse events | 486 | (69.6) | 532 | (76.0) | 1,018 | (72.8) |
| **Adrenal Insufficiency** | **24** | **(3.4)** | **7** | **(1.0)** | **31** | **(2.2)** |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Grade 2 | 11 | (1.6) | 4 | (0.6) | 15 | (1.1) |
| Grade 3 | 11 | (1.6) | 2 | (0.3) | 13 | (0.9) |
| Grade 4 | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Adrenal insufficiency | 23 | (3.3) | 7 | (1.0) | 30 | (2.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Grade 2 | 10 | (1.4) | 4 | (0.6) | 14 | (1.0) |
| Grade 3 | 11 | (1.6) | 2 | (0.3) | 13 | (0.9) |
| Grade 4 | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Secondary adrenocortical insufficiency | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Grade 2 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| **Arthritis** | **2** | **(0.3)** | **1** | **(0.1)** | **3** | **(0.2)** |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Grade 2 | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Autoimmune arthritis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Grade 2 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Immune-mediated arthritis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Grade 2 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| **Colitis** | **10** | **(1.4)** | **7** | **(1.0)** | **17** | **(1.2)** |
| Grade 1 | 1 | (0.1) | 3 | (0.4) | 4 | (0.3) |

Participants With Adverse Events of Special Interest (AEOSI) by Maximum Toxicity Grade
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| **Colitis** | **10** | **(1.4)** | **7** | **(1.0)** | **17** | **(1.2)** |
| Grade 2 | 3 | (0.4) | 2 | (0.3) | 5 | (0.4) |
| Grade 3 | 6 | (0.9) | 2 | (0.3) | 8 | (0.6) |
| Colitis | 6 | (0.9) | 6 | (0.9) | 12 | (0.9) |
| Grade 1 | 1 | (0.1) | 3 | (0.4) | 4 | (0.3) |
| Grade 2 | 1 | (0.1) | 2 | (0.3) | 3 | (0.2) |
| Grade 3 | 4 | (0.6) | 1 | (0.1) | 5 | (0.4) |
| Immune-mediated enterocolitis | 5 | (0.7) | 1 | (0.1) | 6 | (0.4) |
| Grade 2 | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Grade 3 | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| **Encephalitis** | **2** | **(0.3)** | **0** | **(0.0)** | **2** | **(0.1)** |
| Grade 3 | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Encephalitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Grade 3 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Encephalitis autoimmune | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Grade 3 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| **Gastritis** | **3** | **(0.4)** | **10** | **(1.4)** | **13** | **(0.9)** |
| Grade 1 | 1 | (0.1) | 7 | (1.0) | 8 | (0.6) |
| Grade 2 | 2 | (0.3) | 2 | (0.3) | 4 | (0.3) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Gastritis | 3 | (0.4) | 9 | (1.3) | 12 | (0.9) |
| Grade 1 | 1 | (0.1) | 7 | (1.0) | 8 | (0.6) |
| Grade 2 | 2 | (0.3) | 2 | (0.3) | 4 | (0.3) |
| Gastritis erosive | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| **Guillain-Barre Syndrome** | **1** | **(0.1)** | **0** | **(0.0)** | **1** | **(0.1)** |
| Grade 3 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Guillain-Barre syndrome | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Grade 3 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |

Participants With Adverse Events of Special Interest (AEOSI) by Maximum Toxicity Grade
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| **Haemolytic Anaemia** | **1** | **(0.1)** | **0** | **(0.0)** | **1** | **(0.1)** |
| Grade 4 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Autoimmune haemolytic anaemia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Grade 4 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| **Hepatitis** | **17** | **(2.4)** | **13** | **(1.9)** | **30** | **(2.1)** |
| Grade 1 | 3 | (0.4) | 1 | (0.1) | 4 | (0.3) |
| Grade 2 | 2 | (0.3) | 6 | (0.9) | 8 | (0.6) |
| Grade 3 | 9 | (1.3) | 5 | (0.7) | 14 | (1.0) |
| Grade 4 | 3 | (0.4) | 1 | (0.1) | 4 | (0.3) |
| Autoimmune hepatitis | 1 | (0.1) | 2 | (0.3) | 3 | (0.2) |
| Grade 1 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Grade 2 | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| Hepatitis | 15 | (2.1) | 7 | (1.0) | 22 | (1.6) |
| Grade 1 | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Grade 2 | 2 | (0.3) | 2 | (0.3) | 4 | (0.3) |
| Grade 3 | 8 | (1.1) | 3 | (0.4) | 11 | (0.8) |
| Grade 4 | 3 | (0.4) | 1 | (0.1) | 4 | (0.3) |
| Immune-mediated hepatitis | 1 | (0.1) | 4 | (0.6) | 5 | (0.4) |
| Grade 2 | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| Grade 3 | 1 | (0.1) | 2 | (0.3) | 3 | (0.2) |
| **Hyperthyroidism** | **88** | **(12.6)** | **81** | **(11.6)** | **169** | **(12.1)** |
| Grade 1 | 73 | (10.5) | 65 | (9.3) | 138 | (9.9) |
| Grade 2 | 15 | (2.1) | 16 | (2.3) | 31 | (2.2) |
| Hyperthyroidism | 88 | (12.6) | 80 | (11.4) | 168 | (12.0) |
| Grade 1 | 73 | (10.5) | 64 | (9.1) | 137 | (9.8) |
| Grade 2 | 15 | (2.1) | 16 | (2.3) | 31 | (2.2) |
| Immune-mediated hyperthyroidism | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| **Hypophysitis** | **13** | **(1.9)** | **2** | **(0.3)** | **15** | **(1.1)** |

Participants With Adverse Events of Special Interest (AEOSI) by Maximum Toxicity Grade
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| **Hypophysitis** | **13** | **(1.9)** | **2** | **(0.3)** | **15** | **(1.1)** |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Grade 2 | 7 | (1.0) | 1 | (0.1) | 8 | (0.6) |
| Grade 3 | 6 | (0.9) | 0 | (0.0) | 6 | (0.4) |
| Hypophysitis | 10 | (1.4) | 2 | (0.3) | 12 | (0.9) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Grade 2 | 6 | (0.9) | 1 | (0.1) | 7 | (0.5) |
| Grade 3 | 4 | (0.6) | 0 | (0.0) | 4 | (0.3) |
| Immune-mediated hypophysitis | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Grade 2 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Grade 3 | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| **Hypothyroidism** | **69** | **(9.9)** | **65** | **(9.3)** | **134** | **(9.6)** |
| Grade 1 | 19 | (2.7) | 24 | (3.4) | 43 | (3.1) |
| Grade 2 | 48 | (6.9) | 41 | (5.9) | 89 | (6.4) |
| Grade 3 | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Hypothyroidism | 67 | (9.6) | 64 | (9.1) | 131 | (9.4) |
| Grade 1 | 19 | (2.7) | 23 | (3.3) | 42 | (3.0) |
| Grade 2 | 47 | (6.7) | 41 | (5.9) | 88 | (6.3) |
| Grade 3 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Immune-mediated hypothyroidism | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Grade 2 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Grade 3 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| **Infusion Reactions** | **13** | **(1.9)** | **4** | **(0.6)** | **17** | **(1.2)** |
| Grade 1 | 3 | (0.4) | 4 | (0.6) | 7 | (0.5) |
| Grade 2 | 9 | (1.3) | 0 | (0.0) | 9 | (0.6) |
| Grade 3 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Drug hypersensitivity | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Grade 3 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Hypersensitivity | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |

Participants With Adverse Events of Special Interest (AEOSI) by Maximum Toxicity Grade
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Hypersensitivity | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Grade 1 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Infusion related reaction | 10 | (1.4) | 4 | (0.6) | 14 | (1.0) |
| Grade 1 | 2 | (0.3) | 4 | (0.6) | 6 | (0.4) |
| Grade 2 | 8 | (1.1) | 0 | (0.0) | 8 | (0.6) |
| **Myasthenic Syndrome** | **1** | **(0.1)** | **0** | **(0.0)** | **1** | **(0.1)** |
| Grade 5 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Myasthenia gravis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Grade 5 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| **Myelitis** | **1** | **(0.1)** | **0** | **(0.0)** | **1** | **(0.1)** |
| Grade 3 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Myelitis transverse | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Grade 3 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| **Myocarditis** | **6** | **(0.9)** | **4** | **(0.6)** | **10** | **(0.7)** |
| Grade 1 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Grade 2 | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 3 | (0.4) | 3 | (0.2) |
| Grade 4 | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Grade 5 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Immune-mediated myocarditis | 0 | (0.0) | 3 | (0.4) | 3 | (0.2) |
| Grade 3 | 0 | (0.0) | 3 | (0.4) | 3 | (0.2) |
| Myocarditis | 6 | (0.9) | 1 | (0.1) | 7 | (0.5) |
| Grade 1 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Grade 2 | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Grade 4 | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Grade 5 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| **Myositis** | **4** | **(0.6)** | **5** | **(0.7)** | **9** | **(0.6)** |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |

Participants With Adverse Events of Special Interest (AEOSI) by Maximum Toxicity Grade
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| **Myositis** | **4** | **(0.6)** | **5** | **(0.7)** | **9** | **(0.6)** |
| Grade 3 | 2 | (0.3) | 2 | (0.3) | 4 | (0.3) |
| Grade 4 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 5 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Immune-mediated myositis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Myositis | 3 | (0.4) | 2 | (0.3) | 5 | (0.4) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Grade 4 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Grade 5 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Polymyositis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Grade 4 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Rhabdomyolysis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| **Nephritis** | **1** | **(0.1)** | **4** | **(0.6)** | **5** | **(0.4)** |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Grade 3 | 1 | (0.1) | 2 | (0.3) | 3 | (0.2) |
| Grade 4 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Immune-mediated nephritis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Grade 4 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Nephritis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Grade 3 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Tubulointerstitial nephritis | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| **Pancreatitis** | **1** | **(0.1)** | **0** | **(0.0)** | **1** | **(0.1)** |
| Grade 3 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Pancreatitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Grade 3 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |

Participants With Adverse Events of Special Interest (AEOSI) by Maximum Toxicity Grade
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| **Pneumonitis** | **7** | **(1.0)** | **7** | **(1.0)** | **14** | **(1.0)** |
| Grade 1 | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Grade 2 | 4 | (0.6) | 5 | (0.7) | 9 | (0.6) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Pneumonitis | 7 | (1.0) | 7 | (1.0) | 14 | (1.0) |
| Grade 1 | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Grade 2 | 4 | (0.6) | 5 | (0.7) | 9 | (0.6) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| **Sarcoidosis** | **1** | **(0.1)** | **0** | **(0.0)** | **1** | **(0.1)** |
| Grade 1 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Sarcoidosis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Grade 1 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| **Severe Skin Reactions** | **26** | **(3.7)** | **0** | **(0.0)** | **26** | **(1.9)** |
| Grade 1 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Grade 2 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Grade 3 | 24 | (3.4) | 0 | (0.0) | 24 | (1.7) |
| Dermatitis bullous | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Grade 1 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Erythema multiforme | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Grade 2 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Pruritus | 6 | (0.9) | 0 | (0.0) | 6 | (0.4) |
| Grade 3 | 6 | (0.9) | 0 | (0.0) | 6 | (0.4) |
| Rash | 9 | (1.3) | 0 | (0.0) | 9 | (0.6) |
| Grade 3 | 9 | (1.3) | 0 | (0.0) | 9 | (0.6) |
| Rash maculo-papular | 8 | (1.1) | 0 | (0.0) | 8 | (0.6) |
| Grade 3 | 8 | (1.1) | 0 | (0.0) | 8 | (0.6) |
| Rash pruritic | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Grade 3 | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Stevens-Johnson syndrome | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Grade 3 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |

Participants With Adverse Events of Special Interest (AEOSI) by Maximum Toxicity Grade
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| **Thyroiditis** | **6** | **(0.9)** | **6** | **(0.9)** | **12** | **(0.9)** |
| Grade 1 | 3 | (0.4) | 5 | (0.7) | 8 | (0.6) |
| Grade 2 | 3 | (0.4) | 1 | (0.1) | 4 | (0.3) |
| Autoimmune thyroiditis | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Grade 2 | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Thyroiditis | 4 | (0.6) | 6 | (0.9) | 10 | (0.7) |
| Grade 1 | 3 | (0.4) | 5 | (0.7) | 8 | (0.6) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| **Type 1 Diabetes Mellitus** | **6** | **(0.9)** | **4** | **(0.6)** | **10** | **(0.7)** |
| Grade 3 | 4 | (0.6) | 4 | (0.6) | 8 | (0.6) |
| Grade 4 | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Diabetic ketoacidosis | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 4 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Type 1 diabetes mellitus | 4 | (0.6) | 4 | (0.6) | 8 | (0.6) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Grade 3 | 3 | (0.4) | 3 | (0.4) | 6 | (0.4) |
| Grade 4 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| **Uveitis** | **4** | **(0.6)** | **2** | **(0.3)** | **6** | **(0.4)** |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 3 | (0.4) | 1 | (0.1) | 4 | (0.3) |
| Iridocyclitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Grade 3 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Uveitis | 3 | (0.4) | 1 | (0.1) | 4 | (0.3) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Vogt-Koyanagi-Harada disease | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| **Vasculitis** | **1** | **(0.1)** | **0** | **(0.0)** | **1** | **(0.1)** |

Participants With Adverse Events of Special Interest (AEOSI) by Maximum Toxicity Grade
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| **Vasculitis** | **1** | **(0.1)** | **0** | **(0.0)** | **1** | **(0.1)** |
| Grade 3 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Vasculitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Grade 3 | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |

Every participant is counted a single time for each applicable specific adverse event. A participant with multiple adverse events within a bolded term is counted a single time for that bolded term.

Only the highest reported grade of a given adverse event is counted for the individual participant.

Grades are based on Grades are based on NCI CTCAE version 5.

Non-serious adverse events up to 30 days of last treatment and serious adverse events up to 90 days of last treatment are included.

MedDRA V26.1 preferred terms "Neoplasm progression", "Malignant neoplasm progression" and "Disease progression" not related to the drug are excluded.

06MAR2024

Source: [P010V01MK7684a: adam-adsl; adae]

Table 2-25
Participants With Adverse Events of Special Interest (AEOSI) by AEOSI Category and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| Participants in population | 698 | | 700 | | 1,398 | |
| with one or more adverse events | 212 | (30.4) | 168 | (24.0) | 380 | (27.2) |
| with no adverse events | 486 | (69.6) | 532 | (76.0) | 1,018 | (72.8) |
| **Adrenal Insufficiency** | **24** | **(3.4)** | **7** | **(1.0)** | **31** | **(2.2)** |
| Adrenal insufficiency | 23 | (3.3) | 7 | (1.0) | 30 | (2.1) |
| Secondary adrenocortical insufficiency | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| **Arthritis** | **2** | **(0.3)** | **1** | **(0.1)** | **3** | **(0.2)** |
| Autoimmune arthritis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Immune-mediated arthritis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| **Colitis** | **10** | **(1.4)** | **7** | **(1.0)** | **17** | **(1.2)** |
| Colitis | 6 | (0.9) | 6 | (0.9) | 12 | (0.9) |
| Immune-mediated enterocolitis | 5 | (0.7) | 1 | (0.1) | 6 | (0.4) |
| **Encephalitis** | **2** | **(0.3)** | **0** | **(0.0)** | **2** | **(0.1)** |
| Encephalitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Encephalitis autoimmune | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| **Gastritis** | **3** | **(0.4)** | **10** | **(1.4)** | **13** | **(0.9)** |
| Gastritis | 3 | (0.4) | 9 | (1.3) | 12 | (0.9) |
| Gastritis erosive | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| **Guillain-Barre Syndrome** | **1** | **(0.1)** | **0** | **(0.0)** | **1** | **(0.1)** |
| Guillain-Barre syndrome | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| **Haemolytic Anaemia** | **1** | **(0.1)** | **0** | **(0.0)** | **1** | **(0.1)** |
| Autoimmune haemolytic anaemia | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| **Hepatitis** | **17** | **(2.4)** | **13** | **(1.9)** | **30** | **(2.1)** |
| Autoimmune hepatitis | 1 | (0.1) | 2 | (0.3) | 3 | (0.2) |
| Hepatitis | 15 | (2.1) | 7 | (1.0) | 22 | (1.6) |
| Immune-mediated hepatitis | 1 | (0.1) | 4 | (0.6) | 5 | (0.4) |

Participants With Adverse Events of Special Interest (AEOSI) by AEOSI Category and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| **Hyperthyroidism** | **88** | **(12.6)** | **81** | **(11.6)** | **169** | **(12.1)** |
| Hyperthyroidism | 88 | (12.6) | 80 | (11.4) | 168 | (12.0) |
| Immune-mediated hyperthyroidism | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| **Hypophysitis** | **13** | **(1.9)** | **2** | **(0.3)** | **15** | **(1.1)** |
| Hypophysitis | 10 | (1.4) | 2 | (0.3) | 12 | (0.9) |
| Immune-mediated hypophysitis | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| **Hypothyroidism** | **69** | **(9.9)** | **65** | **(9.3)** | **134** | **(9.6)** |
| Hypothyroidism | 67 | (9.6) | 64 | (9.1) | 131 | (9.4) |
| Immune-mediated hypothyroidism | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| **Infusion Reactions** | **13** | **(1.9)** | **4** | **(0.6)** | **17** | **(1.2)** |
| Drug hypersensitivity | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Hypersensitivity | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Infusion related reaction | 10 | (1.4) | 4 | (0.6) | 14 | (1.0) |
| **Myasthenic Syndrome** | **1** | **(0.1)** | **0** | **(0.0)** | **1** | **(0.1)** |
| Myasthenia gravis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| **Myelitis** | **1** | **(0.1)** | **0** | **(0.0)** | **1** | **(0.1)** |
| Myelitis transverse | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| **Myocarditis** | **6** | **(0.9)** | **4** | **(0.6)** | **10** | **(0.7)** |
| Immune-mediated myocarditis | 0 | (0.0) | 3 | (0.4) | 3 | (0.2) |
| Myocarditis | 6 | (0.9) | 1 | (0.1) | 7 | (0.5) |
| **Myositis** | **4** | **(0.6)** | **5** | **(0.7)** | **9** | **(0.6)** |
| Immune-mediated myositis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Myositis | 3 | (0.4) | 2 | (0.3) | 5 | (0.4) |
| Polymyositis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| Rhabdomyolysis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |
| **Nephritis** | **1** | **(0.1)** | **4** | **(0.6)** | **5** | **(0.4)** |
| Immune-mediated nephritis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |

Participants With Adverse Events of Special Interest (AEOSI) by AEOSI Category and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| **Nephritis** | **1** | **(0.1)** | **4** | **(0.6)** | **5** | **(0.4)** |
| Nephritis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Tubulointerstitial nephritis | 0 | (0.0) | 2 | (0.3) | 2 | (0.1) |
| **Pancreatitis** | **1** | **(0.1)** | **0** | **(0.0)** | **1** | **(0.1)** |
| Pancreatitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| **Pneumonitis** | **7** | **(1.0)** | **7** | **(1.0)** | **14** | **(1.0)** |
| Pneumonitis | 7 | (1.0) | 7 | (1.0) | 14 | (1.0) |
| **Sarcoidosis** | **1** | **(0.1)** | **0** | **(0.0)** | **1** | **(0.1)** |
| Sarcoidosis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| **Severe Skin Reactions** | **26** | **(3.7)** | **0** | **(0.0)** | **26** | **(1.9)** |
| Dermatitis bullous | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Erythema multiforme | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Pruritus | 6 | (0.9) | 0 | (0.0) | 6 | (0.4) |
| Rash | 9 | (1.3) | 0 | (0.0) | 9 | (0.6) |
| Rash maculo-papular | 8 | (1.1) | 0 | (0.0) | 8 | (0.6) |
| Rash pruritic | 3 | (0.4) | 0 | (0.0) | 3 | (0.2) |
| Stevens-Johnson syndrome | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| **Thyroiditis** | **6** | **(0.9)** | **6** | **(0.9)** | **12** | **(0.9)** |
| Autoimmune thyroiditis | 2 | (0.3) | 0 | (0.0) | 2 | (0.1) |
| Thyroiditis | 4 | (0.6) | 6 | (0.9) | 10 | (0.7) |
| **Type 1 Diabetes Mellitus** | **6** | **(0.9)** | **4** | **(0.6)** | **10** | **(0.7)** |
| Diabetic ketoacidosis | 2 | (0.3) | 1 | (0.1) | 3 | (0.2) |
| Type 1 diabetes mellitus | 4 | (0.6) | 4 | (0.6) | 8 | (0.6) |
| **Uveitis** | **4** | **(0.6)** | **2** | **(0.3)** | **6** | **(0.4)** |
| Iridocyclitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |
| Uveitis | 3 | (0.4) | 1 | (0.1) | 4 | (0.3) |
| Vogt-Koyanagi-Harada disease | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) |

Participants With Adverse Events of Special Interest (AEOSI) by AEOSI Category and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(APaT Population)

| | MK-7684A Q3W | | Pembrolizumab (MK-3475) Q3W | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| **Vasculitis** | **1** | **(0.1)** | **0** | **(0.0)** | **1** | **(0.1)** |
| Vasculitis | 1 | (0.1) | 0 | (0.0) | 1 | (0.1) |

Every participant is counted a single time for each applicable row and column.
Grades are based on NCI CTCAE version 5
Non-serious adverse events up to 30 days of last treatment and serious adverse events up to 90 days of last treatment are included.
A system organ class or specific adverse event appears on this report only if its incidence in one or more of the columns meets the incidence criterion in the report title, after rounding.
MedDRA V26.1 preferred terms "Neoplasm progression", "Malignant neoplasm progression" and "Disease progression" not related to the drug are excluded.
06MAR2024

Source: [P010V01MK7684a: adam-adsl; adae]

Table 2-26
Summary of Concomitant Corticosteroid Use for AEOSI Episodes
(APaT Population)

| | MK-7684A Q3W | Pembrolizumab (MK-3475) Q3W |
|---|---|---|
| Total episodes | 325 | 230 |
| **High starting dose[a], n (%)** | **61 (18.8)** | **35 (15.2)** |
| Starting dose (mg/day) | | |
| Mean (SD) | 171.4 (281.5) | 138.2 (173.1) |
| Median (Range) | 75.0 (40 - 1250) | 87.5 (40 - 937.5) |
| Duration[b] (days) | | |
| Mean (SD) | 4.7 (4.8) | 4.4 (3.5) |
| Median (Range) | 4.0 (1 - 32) | 4.0 (1 - 16) |
| **Low starting dose[a], n (%)** | **46 (14.2)** | **12 (5.2)** |
| Starting dose (mg/day) | | |
| Mean (SD) | 13.8 (10.9) | 12.7 (10.1) |
| Median (Range) | 10.0 (1.25 - 37.5) | 10.0 (1.25 - 37.5) |
| Duration[b] (days) | | |
| Mean (SD) | 11.0 (15.0) | 17.0 (20.7) |
| Median (Range) | 4.5 (1 - 69) | 6.0 (2 - 62) |
| **Not treated with systemic corticosteroid, n (%)** | **218 (67.1)** | **183 (79.6)** |
| **Adrenal Insufficiency** | | |
| Total episodes | 24 | 7 |
| **High starting dose[a], n (%)** | **4 (16.7)** | **1 (14.3)** |
| Starting dose (mg/day) | | |
| Mean (SD) | 56.3 (12.5) | 100.0 (.) |
| Median (Range) | 50.0 (50 - 75) | 100.0 (100 - 100) |
| Duration[b] (days) | | |
| Mean (SD) | 2.5 (1.0) | 2.0 (.) |
| Median (Range) | 2.0 (2 - 4) | 2.0 (2 - 2) |
| **Low starting dose[a], n (%)** | **17 (70.8)** | **4 (57.1)** |
| Starting dose (mg/day) | | |
| Mean (SD) | 13.1 (10.2) | 7.5 (2.0) |
| Median (Range) | 10.0 (5 - 37.5) | 7.5 (5 - 10) |

Summary of Concomitant Corticosteroid Use for AEOSI Episodes
(APaT Population)

| | MK-7684A Q3W | Pembrolizumab (MK-3475) Q3W |
|---|---|---|
| Duration[b] (days) | | |
| Mean (SD) | 10.4 (12.8) | 24.7 (32.6) |
| Median (Range) | 5.0 (1 - 46) | 10.0 (2 - 62) |
| **Not treated with systemic corticosteroid, n (%)** | **3 (12.5)** | **2 (28.6)** |
| **Arthritis** | | |
| Total episodes | 2 | 1 |
| **High starting dose[a], n (%)** | | |
| **Low starting dose[a], n (%)** | **1 (50.0)** | **1 (100.0)** |
| Starting dose (mg/day) | | |
| Mean (SD) | 10.0 (.) | 10.0 (.) |
| Median (Range) | 10.0 (10 - 10) | 10.0 (10 - 10) |
| Duration[b] (days) | | |
| Mean (SD) | . (.) | 34.0 (.) |
| Median (Range) | . (. -.) | 34.0 (34 - 34) |
| **Not treated with systemic corticosteroid, n (%)** | **1 (50.0)** | **0 (0.0)** |
| **Colitis** | | |
| Total episodes | 11 | 9 |
| **High starting dose[a], n (%)** | **8 (72.7)** | **6 (66.7)** |
| Starting dose (mg/day) | | |
| Mean (SD) | 90.0 (22.2) | 88.5 (36.3) |
| Median (Range) | 90.0 (60 - 125) | 77.5 (60 - 156.25) |
| Duration[b] (days) | | |
| Mean (SD) | 4.0 (2.7) | 5.2 (3.3) |
| Median (Range) | 4.5 (1 - 7) | 5.0 (1 - 9) |
| **Low starting dose[a], n (%)** | **0 (0.0)** | **1 (11.1)** |
| Starting dose (mg/day) | | |

Summary of Concomitant Corticosteroid Use for AEOSI Episodes
(APaT Population)

| | MK-7684A Q3W | Pembrolizumab (MK-3475) Q3W |
|---|---|---|
| Mean (SD) | | 20.0 (.) |
| Median (Range) | | 20.0 (20 - 20) |
| Duration[b] (days) | | |
| Mean (SD) | | 5.0 (.) |
| Median (Range) | | 5.0 (5 - 5) |
| **Not treated with systemic corticosteroid, n (%)** | **3 (27.3)** | **2 (22.2)** |
| **Encephalitis** | | |
| Total episodes | 2 | 0 |
| **High starting dose[a], n (%)** | **1 (50.0)** | **0** |
| Starting dose (mg/day) | | |
| Mean (SD) | 1250 (.) | |
| Median (Range) | 1250 (1250 - 1250) | |
| Duration[b] (days) | | |
| Mean (SD) | 7.0 (.) | |
| Median (Range) | 7.0 (7 - 7) | |
| **Low starting dose[a], n (%)** | | |
| **Not treated with systemic corticosteroid, n (%)** | **1 (50.0)** | **0** |
| **Gastritis** | | |
| Total episodes | 3 | 10 |
| **High starting dose[a], n (%)** | **1 (33.3)** | **0** |
| Starting dose (mg/day) | | |
| Mean (SD) | 50.0 (.) | |
| Median (Range) | 50.0 (50 - 50) | |
| Duration[b] (days) | | |
| Mean (SD) | 15.0 (.) | |
| Median (Range) | 15.0 (15 - 15) | |

Summary of Concomitant Corticosteroid Use for AEOSI Episodes
(APaT Population)

| | MK-7684A Q3W | Pembrolizumab (MK-3475) Q3W |
|---|---|---|
| **Low starting dose[a], n (%)** | | |
| **Not treated with systemic corticosteroid, n (%)** | **2 (66.7)** | **10 (100.0)** |
| **Guillain-Barre Syndrome** | | |
| Total episodes | 1 | 0 |
| **High starting dose[a], n (%)** | | |
| **Low starting dose[a], n (%)** | **1 (100.0)** | **0** |
| Starting dose (mg/day) | | |
| Mean (SD) | 1.3 (.) | |
| Median (Range) | 1.3 (1.25 - 1.25) | |
| Duration[b] (days) | | |
| Mean (SD) | 5.0 (.) | |
| Median (Range) | 5.0 (5 - 5) | |
| **Not treated with systemic corticosteroid, n (%)** | | |
| **Haemolytic Anaemia** | | |
| Total episodes | 1 | 0 |
| **High starting dose[a], n (%)** | **1 (100.0)** | **0** |
| Starting dose (mg/day) | | |
| Mean (SD) | 125.0 (.) | |
| Median (Range) | 125.0 (125 - 125) | |
| Duration[b] (days) | | |
| Mean (SD) | 1.0 (.) | |
| Median (Range) | 1.0 (1 - 1) | |
| **Low starting dose[a], n (%)** | | |
| **Not treated with systemic corticosteroid, n (%)** | | |

Summary of Concomitant Corticosteroid Use for AEOSI Episodes
(APaT Population)

| | MK-7684A Q3W | Pembrolizumab (MK-3475) Q3W |
|---|---|---|
| **Hepatitis** | | |
| Total episodes | 18 | 13 |
| **High starting dose[a], n (%)** | **12 (66.7)** | **8 (61.5)** |
| Starting dose (mg/day) | | |
| Mean (SD) | 204.6 (338.6) | 94.4 (49.3) |
| Median (Range) | 83.8 (50 - 1250) | 77.5 (50 - 175) |
| Duration[b] (days) | | |
| Mean (SD) | 4.4 (3.2) | 5.6 (4.7) |
| Median (Range) | 3.5 (1 - 11) | 4.0 (2 - 16) |
| **Low starting dose[a], n (%)** | **2 (11.1)** | **3 (23.1)** |
| Starting dose (mg/day) | | |
| Mean (SD) | 31.3 (8.8) | 19.6 (18.1) |
| Median (Range) | 31.3 (25 - 37.5) | 20.0 (1.25 - 37.5) |
| Duration[b] (days) | | |
| Mean (SD) | 4.5 (2.1) | 4.7 (2.1) |
| Median (Range) | 4.5 (3 - 6) | 4.0 (3 - 7) |
| **Not treated with systemic corticosteroid, n (%)** | **4 (22.2)** | **2 (15.4)** |
| **Hyperthyroidism** | | |
| Total episodes | 97 | 83 |
| **High starting dose[a], n (%)** | **1 (1.0)** | **1 (1.2)** |
| Starting dose (mg/day) | | |
| Mean (SD) | 40.0 (.) | 50.0 (.) |
| Median (Range) | 40.0 (40 - 40) | 50.0 (50 - 50) |
| Duration[b] (days) | | |
| Mean (SD) | 6.0 (.) | 1.0 (.) |
| Median (Range) | 6.0 (6 - 6) | 1.0 (1 - 1) |
| **Low starting dose[a], n (%)** | **1 (1.0)** | **2 (2.4)** |
| Starting dose (mg/day) | | |

Summary of Concomitant Corticosteroid Use for AEOSI Episodes
(APaT Population)

| | MK-7684A Q3W | Pembrolizumab (MK-3475) Q3W |
|---|---|---|
| Mean (SD) | 10.0 (.) | 15.0 (7.1) |
| Median (Range) | 10.0 (10 - 10) | 15.0 (10 - 20) |
| Duration[b] (days) | | |
| Mean (SD) | 8.0 (.) | 21.5 (24.7) |
| Median (Range) | 8.0 (8 - 8) | 21.5 (4 - 39) |
| **Not treated with systemic corticosteroid, n (%)** | **95 (97.9)** | **80 (96.4)** |
| | | |
| **Hypophysitis** | | |
| Total episodes | 13 | 2 |
| **High starting dose[a], n (%)** | **3 (23.1)** | **0** |
| Starting dose (mg/day) | | |
| Mean (SD) | 74.3 (43.9) | |
| Median (Range) | 50.0 (48 - 125) | |
| Duration[b] (days) | | |
| Mean (SD) | 1.3 (0.6) | |
| Median (Range) | 1.0 (1 - 2) | |
| **Low starting dose[a], n (%)** | **9 (69.2)** | **1 (50.0)** |
| Starting dose (mg/day) | | |
| Mean (SD) | 14.6 (10.9) | 3.8 (.) |
| Median (Range) | 10.0 (3.75 - 35) | 3.8 (3.75 - 3.75) |
| Duration[b] (days) | | |
| Mean (SD) | 11.8 (23.3) | . (.) |
| Median (Range) | 2.5 (1 - 69) | . (. -.) |
| **Not treated with systemic corticosteroid, n (%)** | **1 (7.7)** | **1 (50.0)** |
| | | |
| **Hypothyroidism** | | |
| Total episodes | 70 | 66 |
| **High starting dose[a], n (%)** | | |

Summary of Concomitant Corticosteroid Use for AEOSI Episodes
(APaT Population)

| | MK-7684A Q3W | Pembrolizumab (MK-3475) Q3W |
|---|---|---|
| **Low starting dose[a], n (%)** | | |
| **Not treated with systemic corticosteroid, n (%)** | **70 (100.0)** | **66 (100.0)** |
| **Infusion Reactions** | | |
| Total episodes | 15 | 4 |
| **High starting dose[a], n (%)** | | |
| **Low starting dose[a], n (%)** | **2 (13.3)** | **0** |
| Starting dose (mg/day) | | |
| Mean (SD) | 19.8 (19.2) | |
| Median (Range) | 19.8 (6.25 - 33.35) | |
| Duration[b] (days) | | |
| Mean (SD) | 1.0 (0.0) | |
| Median (Range) | 1.0 (1 - 1) | |
| **Not treated with systemic corticosteroid, n (%)** | **13 (86.7)** | **4 (100.0)** |
| **Myasthenic Syndrome** | | |
| Total episodes | 1 | 0 |
| **High starting dose[a], n (%)** | **1 (100.0)** | **0** |
| Starting dose (mg/day) | | |
| Mean (SD) | 625.0 (.) | |
| Median (Range) | 625.0 (625 - 625) | |
| Duration[b] (days) | | |
| Mean (SD) | 1.0 (.) | |
| Median (Range) | 1.0 (1 - 1) | |
| **Low starting dose[a], n (%)** | | |
| **Not treated with systemic corticosteroid, n (%)** | | |

Summary of Concomitant Corticosteroid Use for AEOSI Episodes
(APaT Population)

| | MK-7684A Q3W | Pembrolizumab (MK-3475) Q3W |
|---|---|---|
| **Myelitis** | | |
| Total episodes | 1 | 0 |
| **High starting dose[a], n (%)** | **1 (100.0)** | **0** |
| Starting dose (mg/day) | | |
| Mean (SD) | 60.0 (.) | |
| Median (Range) | 60.0 (60 - 60) | |
| Duration[b] (days) | | |
| Mean (SD) | 17.0 (.) | |
| Median (Range) | 17.0 (17 - 17) | |
| **Low starting dose[a], n (%)** | | |
| **Not treated with systemic corticosteroid, n (%)** | | |
| **Myocarditis** | | |
| Total episodes | 6 | 4 |
| **High starting dose[a], n (%)** | **3 (50.0)** | **4 (100.0)** |
| Starting dose (mg/day) | | |
| Mean (SD) | 758.3 (440.4) | 251.9 (252.1) |
| Median (Range) | 625.0 (400 - 1250) | 156.3 (70 - 625) |
| Duration[b] (days) | | |
| Mean (SD) | 2.3 (1.2) | 5.0 (2.7) |
| Median (Range) | 3.0 (1 - 3) | 4.0 (3 - 9) |
| **Low starting dose[a], n (%)** | **1 (16.7)** | **0** |
| Starting dose (mg/day) | | |
| Mean (SD) | 1.3 (.) | |
| Median (Range) | 1.3 (1.25 - 1.25) | |
| Duration[b] (days) | | |
| Mean (SD) | 3.0 (.) | |
| Median (Range) | 3.0 (3 - 3) | |

Summary of Concomitant Corticosteroid Use for AEOSI Episodes
(APaT Population)

| | MK-7684A Q3W | Pembrolizumab (MK-3475) Q3W |
|---|---|---|
| **Not treated with systemic corticosteroid, n (%)** | **2 (33.3)** | **0** |
| **Myositis** | | |
| Total episodes | 4 | 5 |
| **High starting dose[a], n (%)** | **3 (75.0)** | **4 (80.0)** |
| Starting dose (mg/day) | | |
| Mean (SD) | 318.3 (278.9) | 137.5 (118.4) |
| Median (Range) | 250.0 (80 - 625) | 105.0 (40 - 300) |
| Duration[b] (days) | | |
| Mean (SD) | 3.7 (4.6) | 2.3 (1.5) |
| Median (Range) | 1.0 (1 - 9) | 2.0 (1 - 4) |
| **Low starting dose[a], n (%)** | | |
| **Not treated with systemic corticosteroid, n (%)** | **1 (25.0)** | **1 (20.0)** |
| **Nephritis** | | |
| Total episodes | 1 | 4 |
| **High starting dose[a], n (%)** | **1 (100.0)** | **3 (75.0)** |
| Starting dose (mg/day) | | |
| Mean (SD) | 40.0 (.) | 67.8 (27.9) |
| Median (Range) | 40.0 (40 - 40) | 53.4 (50 - 100) |
| Duration[b] (days) | | |
| Mean (SD) | 4.0 (.) | 4.7 (6.4) |
| Median (Range) | 4.0 (4 - 4) | 1.0 (1 - 12) |
| **Low starting dose[a], n (%)** | | |
| **Not treated with systemic corticosteroid, n (%)** | **0 (0.0)** | **1 (25.0)** |

Summary of Concomitant Corticosteroid Use for AEOSI Episodes
(APaT Population)

| | MK-7684A Q3W | Pembrolizumab (MK-3475) Q3W |
|---|---|---|
| **Pancreatitis** | | |
| Total episodes | 1 | 0 |
| **High starting dose[a], n (%)** | | |
| **Low starting dose[a], n (%)** | | |
| **Not treated with systemic corticosteroid, n (%)** | **1 (100.0)** | **0** |
| **Pneumonitis** | | |
| Total episodes | 7 | 8 |
| **High starting dose[a], n (%)** | **5 (71.4)** | **6 (75.0)** |
| Starting dose (mg/day) | | |
| Mean (SD) | 98.0 (72.7) | 102.3 (34.7) |
| Median (Range) | 75.0 (40 - 225) | 110.0 (50 - 143.75) |
| Duration[b] (days) | | |
| Mean (SD) | 4.4 (1.7) | 4.8 (2.6) |
| Median (Range) | 4.0 (3 - 7) | 5.0 (1 - 8) |
| **Low starting dose[a], n (%)** | **1 (14.3)** | **0** |
| Starting dose (mg/day) | | |
| Mean (SD) | 25.0 (.) | |
| Median (Range) | 25.0 (25 - 25) | |
| Duration[b] (days) | | |
| Mean (SD) | 3.0 (.) | |
| Median (Range) | 3.0 (3 - 3) | |
| **Not treated with systemic corticosteroid, n (%)** | **1 (14.3)** | **2 (25.0)** |
| **Sarcoidosis** | | |
| Total episodes | 1 | 0 |

Summary of Concomitant Corticosteroid Use for AEOSI Episodes
(APaT Population)

| | MK-7684A Q3W | Pembrolizumab (MK-3475) Q3W |
|---|---|---|
| **High starting dose[a], n (%)** | | |
| **Low starting dose[a], n (%)** | | |
| **Not treated with systemic corticosteroid, n (%)** | **1 (100.0)** | **0** |
| **Severe Skin Reactions** | | |
| Total episodes | 29 | 0 |
| **High starting dose[a], n (%)** | **14 (48.3)** | **0** |
| Starting dose (mg/day) | | |
| Mean (SD) | 57.4 (24.3) | |
| Median (Range) | 50.0 (40 - 125) | |
| Duration[b] (days) | | |
| Mean (SD) | 4.0 (1.8) | |
| Median (Range) | 4.0 (1 - 7) | |
| **Low starting dose[a], n (%)** | **9 (31.0)** | **0** |
| Starting dose (mg/day) | | |
| Mean (SD) | 13.8 (10.6) | |
| Median (Range) | 10.0 (2.5 - 30) | |
| Duration[b] (days) | | |
| Mean (SD) | 19.3 (15.0) | |
| Median (Range) | 17.5 (4 - 41) | |
| **Not treated with systemic corticosteroid, n (%)** | **6 (20.7)** | **0** |
| **Thyroiditis** | | |
| Total episodes | 6 | 6 |
| **High starting dose[a], n (%)** | | |
| **Low starting dose[a], n (%)** | **1 (16.7)** | **0** |

Summary of Concomitant Corticosteroid Use for AEOSI Episodes
(APaT Population)

| | MK-7684A Q3W | Pembrolizumab (MK-3475) Q3W |
|---|---|---|
| Starting dose (mg/day) | | |
| Mean (SD) | 3.8 (.) | |
| Median (Range) | 3.8 (3.75 - 3.75) | |
| Duration[b] (days) | | |
| Mean (SD) | . (.) | |
| Median (Range) | . (. -.) | |
| **Not treated with systemic corticosteroid, n (%)** | **5 (83.3)** | **6 (100.0)** |
| **Type 1 Diabetes Mellitus** | | |
| Total episodes | 6 | 6 |
| **High starting dose[a], n (%)** | **0 (0.0)** | **1 (16.7)** |
| Starting dose (mg/day) | | |
| Mean (SD) | | 87.5 (.) |
| Median (Range) | | 87.5 (87.5 - 87.5) |
| Duration[b] (days) | | |
| Mean (SD) | | 1.0 (.) |
| Median (Range) | | 1.0 (1 - 1) |
| **Low starting dose[a], n (%)** | | |
| **Not treated with systemic corticosteroid, n (%)** | **6 (100.0)** | **5 (83.3)** |
| **Uveitis** | | |
| Total episodes | 4 | 2 |
| **High starting dose[a], n (%)** | **1 (25.0)** | **1 (50.0)** |
| Starting dose (mg/day) | | |
| Mean (SD) | 40.0 (.) | 937.5 (.) |
| Median (Range) | 40.0 (40 - 40) | 937.5 (937.5 - 937.5 |
| Duration[b] (days) | | |
| Mean (SD) | 32.0 (.) | 5.0 (.) |
| Median (Range) | 32.0 (32 - 32) | 5.0 (5 - 5) |

Summary of Concomitant Corticosteroid Use for AEOSI Episodes
(APaT Population)

| | MK-7684A Q3W | Pembrolizumab (MK-3475) Q3W |
|---|---|---|
| **Low starting dose[a], n (%)** | **1 (25.0)** | **0** |
| Starting dose (mg/day) | | |
| Mean (SD) | 1.3 (.) | |
| Median (Range) | 1.3 (1.25 - 1.25) | |
| Duration[b] (days) | | |
| Mean (SD) | 4.0 (.) | |
| Median (Range) | 4.0 (4 - 4) | |
| **Not treated with systemic corticosteroid, n (%)** | **2 (50.0)** | **1 (50.0)** |
| **Vasculitis** | | |
| Total episodes | 1 | 0 |
| **High starting dose[a], n (%)** | **1 (100.0)** | **0** |
| Starting dose (mg/day) | | |
| Mean (SD) | 80.0 (.) | |
| Median (Range) | 80.0 (80 - 80) | |
| Duration[b] (days) | | |
| Mean (SD) | 6.0 (.) | |
| Median (Range) | 6.0 (6 - 6) | |
| **Low starting dose[a], n (%)** | | |
| **Not treated with systemic corticosteroid, n (%)** | | |

The number of total episodes in each category is used as the denominator for the percentage calculation.
[a] High starting dose corticosteroid treatment is defined as ≥ 40 mg/day prednisone or equivalent, Low starting dose corticosteroid treatment is defined as < 40 mg/day prednisone or equivalent.
[b] Ongoing corticosteroid treatment is censored at the cutoff date or date of death, whichever occurs first.
Database Cutoff Date: 06MAR2024.

Source: [P010V01MK7684a: adam-adsl; adae; adcm]

Table 2-27
Summary of Outcome for Participants With AEOSI
(Incidence >0% in One or More Treatment Groups)
APaT Population

| | Outcome | MK-7684A Q3W | Pembrolizumab (MK-3475) Q3W |
|---|---|---|---|
| | | n (%) | n (%) |
| Participants in population | | 698 | 700 |
| **With one or more AEOSI** | **Overall** | **212 (30.4)** | **168 (24.0)** |
| | Fatal | 2 (0.9) | 1 (0.6) |
| | Not Resolved | 106 (50.0) | 64 (38.1) |
| | Resolving | 38 (17.9) | 47 (28.0) |
| | Unknown | 4 (1.9) | 2 (1.2) |
| | Sequelae | 0 (0.0) | 1 (0.6) |
| | Resolved | 62 (29.2) | 53 (31.5) |
| **Adrenal Insufficiency** | **Overall** | **24 (3.4)** | **7 (1.0)** |
| | Fatal | 0 (0.0) | 0 (0.0) |
| | Not Resolved | 10 (41.7) | 4 (57.1) |
| | Resolving | 9 (37.5) | 2 (28.6) |
| | Unknown | 0 (0.0) | 0 (0.0) |
| | Sequelae | 0 (0.0) | 0 (0.0) |
| | Resolved | 5 (20.8) | 1 (14.3) |

Summary of Outcome for Participants With AEOSI
(Incidence >0% in One or More Treatment Groups)
APaT Population

| | | MK-7684A Q3W | Pembrolizumab (MK-3475) Q3W |
|---|---|---|---|
| | Outcome | n (%) | n (%) |
| **Arthritis** | **Overall** | **2 (0.3)** | **1 (0.1)** |
| | Fatal | 0 (0.0) | 0 (0.0) |
| | Not Resolved | 2 (100.0) | 1 (100.0) |
| | Resolving | 0 (0.0) | 0 (0.0) |
| | Unknown | 0 (0.0) | 0 (0.0) |
| | Sequelae | 0 (0.0) | 0 (0.0) |
| | Resolved | 0 (0.0) | 0 (0.0) |
| **Colitis** | **Overall** | **10 (1.4)** | **7 (1.0)** |
| | Fatal | 0 (0.0) | 0 (0.0) |
| | Not Resolved | 1 (10.0) | 0 (0.0) |
| | Resolving | 0 (0.0) | 3 (42.9) |
| | Unknown | 0 (0.0) | 0 (0.0) |
| | Sequelae | 0 (0.0) | 0 (0.0) |
| | Resolved | 9 (90.0) | 4 (57.1) |
| **Encephalitis** | **Overall** | **2 (0.3)** | **0 (0.0)** |

Summary of Outcome for Participants With AEOSI
(Incidence >0% in One or More Treatment Groups)
APaT Population

| | | MK-7684A Q3W | Pembrolizumab (MK-3475) Q3W |
|---|---|---|---|
| | Outcome | n (%) | n (%) |
| Encephalitis | Fatal | 0 (0.0) | |
| | Not Resolved | 1 (50.0) | |
| | Resolving | 1 (50.0) | |
| | Unknown | 0 (0.0) | |
| | Sequelae | 0 (0.0) | |
| | Resolved | 0 (0.0) | |
| **Gastritis** | **Overall** | **3 (0.4)** | **10 (1.4)** |
| | Fatal | 0 (0.0) | 0 (0.0) |
| | Not Resolved | 0 (0.0) | 1 (10.0) |
| | Resolving | 2 (66.7) | 1 (10.0) |
| | Unknown | 0 (0.0) | 0 (0.0) |
| | Sequelae | 0 (0.0) | 0 (0.0) |
| | Resolved | 1 (33.3) | 8 (80.0) |
| **Guillain-Barre Syndrome** | **Overall** | **1 (0.1)** | **0 (0.0)** |
| | Fatal | 0 (0.0) | |
| | Not Resolved | 1 (100.0) | |

Summary of Outcome for Participants With AEOSI
(Incidence >0% in One or More Treatment Groups)
APaT Population

| | | MK-7684A Q3W | Pembrolizumab (MK-3475) Q3W |
|---|---|---|---|
| | Outcome | n (%) | n (%) |
| Guillain-Barre Syndrome | Resolving | 0 (0.0) | |
| | Unknown | 0 (0.0) | |
| | Sequelae | 0 (0.0) | |
| | Resolved | 0 (0.0) | |
| **Haemolytic Anaemia** | **Overall** | **1 (0.1)** | **0 (0.0)** |
| | Fatal | 0 (0.0) | |
| | Not Resolved | 0 (0.0) | |
| | Resolving | 1 (100.0) | |
| | Unknown | 0 (0.0) | |
| | Sequelae | 0 (0.0) | |
| | Resolved | 0 (0.0) | |
| **Hepatitis** | **Overall** | **17 (2.4)** | **13 (1.9)** |
| | Fatal | 0 (0.0) | 0 (0.0) |
| | Not Resolved | 9 (52.9) | 5 (38.5) |
| | Resolving | 2 (11.8) | 1 (7.7) |
| | Unknown | 0 (0.0) | 0 (0.0) |

Summary of Outcome for Participants With AEOSI
(Incidence >0% in One or More Treatment Groups)
APaT Population

| | | MK-7684A Q3W | Pembrolizumab (MK-3475) Q3W |
|---|---|---|---|
| | Outcome | n (%) | n (%) |
| Hepatitis | Sequelae | 0 (0.0) | 1 (7.7) |
| | Resolved | 6 (35.3) | 6 (46.2) |
| **Hyperthyroidism** | **Overall** | **88 (12.6)** | **81 (11.6)** |
| | Fatal | 0 (0.0) | 0 (0.0) |
| | Not Resolved | 19 (21.6) | 18 (22.2) |
| | Resolving | 4 (4.5) | 7 (8.6) |
| | Unknown | 0 (0.0) | 0 (0.0) |
| | Sequelae | 1 (1.1) | 1 (1.2) |
| | Resolved | 64 (72.7) | 55 (67.9) |
| **Hypophysitis** | **Overall** | **13 (1.9)** | **2 (0.3)** |
| | Fatal | 0 (0.0) | 0 (0.0) |
| | Not Resolved | 6 (46.2) | 1 (50.0) |
| | Resolving | 4 (30.8) | 1 (50.0) |
| | Unknown | 0 (0.0) | 0 (0.0) |
| | Sequelae | 0 (0.0) | 0 (0.0) |
| | Resolved | 3 (23.1) | 0 (0.0) |

Summary of Outcome for Participants With AEOSI
(Incidence >0% in One or More Treatment Groups)
APaT Population

| | | MK-7684A Q3W | Pembrolizumab (MK-3475) Q3W |
|---|---|---|---|
| | Outcome | n (%) | n (%) |
| **Hypothyroidism** | **Overall** | **69 (9.9)** | **65 (9.3)** |
| | Fatal | 0 (0.0) | 0 (0.0) |
| | Not Resolved | 44 (63.8) | 26 (40.0) |
| | Resolving | 15 (21.7) | 30 (46.2) |
| | Unknown | 3 (4.3) | 2 (3.1) |
| | Sequelae | 1 (1.4) | 0 (0.0) |
| | Resolved | 6 (8.7) | 7 (10.8) |
| **Infusion Reactions** | **Overall** | **13 (1.9)** | **4 (0.6)** |
| | Fatal | 0 (0.0) | 0 (0.0) |
| | Not Resolved | 1 (7.7) | 1 (25.0) |
| | Resolving | 0 (0.0) | 0 (0.0) |
| | Unknown | 0 (0.0) | 0 (0.0) |
| | Sequelae | 0 (0.0) | 0 (0.0) |
| | Resolved | 12 (92.3) | 3 (75.0) |
| **Myasthenic Syndrome** | **Overall** | **1 (0.1)** | **0 (0.0)** |

Summary of Outcome for Participants With AEOSI
(Incidence >0% in One or More Treatment Groups)
APaT Population

| | | MK-7684A Q3W | Pembrolizumab (MK-3475) Q3W |
|---|---|---|---|
| | Outcome | n (%) | n (%) |
| Myasthenic Syndrome | Fatal | 1 (100.0) | |
| | Not Resolved | 0 (0.0) | |
| | Resolving | 0 (0.0) | |
| | Unknown | 0 (0.0) | |
| | Sequelae | 0 (0.0) | |
| | Resolved | 0 (0.0) | |
| **Myelitis** | **Overall** | **1 (0.1)** | **0 (0.0)** |
| | Fatal | 0 (0.0) | |
| | Not Resolved | 1 (100.0) | |
| | Resolving | 0 (0.0) | |
| | Unknown | 0 (0.0) | |
| | Sequelae | 0 (0.0) | |
| | Resolved | 0 (0.0) | |
| **Myocarditis** | **Overall** | **6 (0.9)** | **4 (0.6)** |
| | Fatal | 1 (16.7) | 0 (0.0) |
| | Not Resolved | 3 (50.0) | 0 (0.0) |

Summary of Outcome for Participants With AEOSI
(Incidence >0% in One or More Treatment Groups)
APaT Population

| | | MK-7684A Q3W | Pembrolizumab (MK-3475) Q3W |
|---|---|---|---|
| | Outcome | n (%) | n (%) |
| Myocarditis | Resolving | 0 (0.0) | 1 (25.0) |
| | Unknown | 0 (0.0) | 0 (0.0) |
| | Sequelae | 0 (0.0) | 0 (0.0) |
| | Resolved | 2 (33.3) | 3 (75.0) |
| **Myositis** | **Overall** | **4 (0.6)** | **5 (0.7)** |
| | Fatal | 0 (0.0) | 1 (20.0) |
| | Not Resolved | 2 (50.0) | 1 (20.0) |
| | Resolving | 0 (0.0) | 0 (0.0) |
| | Unknown | 0 (0.0) | 0 (0.0) |
| | Sequelae | 0 (0.0) | 0 (0.0) |
| | Resolved | 2 (50.0) | 3 (60.0) |
| **Nephritis** | **Overall** | **1 (0.1)** | **4 (0.6)** |
| | Fatal | 0 (0.0) | 0 (0.0) |
| | Not Resolved | 0 (0.0) | 2 (50.0) |
| | Resolving | 0 (0.0) | 1 (25.0) |
| | Unknown | 0 (0.0) | 0 (0.0) |

Summary of Outcome for Participants With AEOSI
(Incidence >0% in One or More Treatment Groups)
APaT Population

| | | MK-7684A Q3W | Pembrolizumab (MK-3475) Q3W |
|---|---|---|---|
| | Outcome | n (%) | n (%) |
| Nephritis | Sequelae | 0 (0.0) | 0 (0.0) |
| | Resolved | 1 (100.0) | 1 (25.0) |
| **Pancreatitis** | **Overall** | **1 (0.1)** | **0 (0.0)** |
| | Fatal | 0 (0.0) | |
| | Not Resolved | 0 (0.0) | |
| | Resolving | 0 (0.0) | |
| | Unknown | 0 (0.0) | |
| | Sequelae | 0 (0.0) | |
| | Resolved | 1 (100.0) | |
| **Pneumonitis** | **Overall** | **7 (1.0)** | **7 (1.0)** |
| | Fatal | 0 (0.0) | 0 (0.0) |
| | Not Resolved | 1 (14.3) | 3 (42.9) |
| | Resolving | 1 (14.3) | 1 (14.3) |
| | Unknown | 0 (0.0) | 0 (0.0) |
| | Sequelae | 0 (0.0) | 0 (0.0) |
| | Resolved | 5 (71.4) | 3 (42.9) |

Summary of Outcome for Participants With AEOSI
(Incidence >0% in One or More Treatment Groups)
APaT Population

| | | MK-7684A Q3W | Pembrolizumab (MK-3475) Q3W |
|---|---|---|---|
| | Outcome | n (%) | n (%) |
| **Sarcoidosis** | **Overall** | **1 (0.1)** | **0 (0.0)** |
| | Fatal | 0 (0.0) | |
| | Not Resolved | 1 (100.0) | |
| | Resolving | 0 (0.0) | |
| | Unknown | 0 (0.0) | |
| | Sequelae | 0 (0.0) | |
| | Resolved | 0 (0.0) | |
| **Severe Skin Reactions** | **Overall** | **26 (3.7)** | **0 (0.0)** |
| | Fatal | 0 (0.0) | |
| | Not Resolved | 16 (61.5) | |
| | Resolving | 2 (7.7) | |
| | Unknown | 0 (0.0) | |
| | Sequelae | 0 (0.0) | |
| | Resolved | 8 (30.8) | |
| **Thyroiditis** | **Overall** | **6 (0.9)** | **6 (0.9)** |

Summary of Outcome for Participants With AEOSI
(Incidence >0% in One or More Treatment Groups)
APaT Population

| | | MK-7684A Q3W | Pembrolizumab (MK-3475) Q3W |
|---|---|---|---|
| | Outcome | n (%) | n (%) |
| Thyroiditis | Fatal | 0 (0.0) | 0 (0.0) |
| | Not Resolved | 5 (83.3) | 3 (50.0) |
| | Resolving | 0 (0.0) | 0 (0.0) |
| | Unknown | 0 (0.0) | 0 (0.0) |
| | Sequelae | 0 (0.0) | 0 (0.0) |
| | Resolved | 1 (16.7) | 3 (50.0) |
| **Type 1 Diabetes Mellitus** | **Overall** | **6 (0.9)** | **4 (0.6)** |
| | Fatal | 0 (0.0) | 0 (0.0) |
| | Not Resolved | 1 (16.7) | 3 (75.0) |
| | Resolving | 2 (33.3) | 1 (25.0) |
| | Unknown | 1 (16.7) | 0 (0.0) |
| | Sequelae | 0 (0.0) | 0 (0.0) |
| | Resolved | 2 (33.3) | 0 (0.0) |
| **Uveitis** | **Overall** | **4 (0.6)** | **2 (0.3)** |
| | Fatal | 0 (0.0) | 0 (0.0) |
| | Not Resolved | 0 (0.0) | 0 (0.0) |

Summary of Outcome for Participants With AEOSI
(Incidence >0% in One or More Treatment Groups)
APaT Population

| | | MK-7684A Q3W | Pembrolizumab (MK-3475) Q3W |
|---|---|---|---|
| | Outcome | n (%) | n (%) |
| Uveitis | Resolving | 4 (100.0) | 1 (50.0) |
| | Unknown | 0 (0.0) | 0 (0.0) |
| | Sequelae | 0 (0.0) | 0 (0.0) |
| | Resolved | 0 (0.0) | 1 (50.0) |
| **Vasculitis** | **Overall** | **1 (0.1)** | **0 (0.0)** |
| | Fatal | 0 (0.0) | |
| | Not Resolved | 0 (0.0) | |
| | Resolving | 1 (100.0) | |
| | Unknown | 0 (0.0) | |
| | Sequelae | 0 (0.0) | |

Summary of Outcome for Participants With AEOSI
(Incidence >0% in One or More Treatment Groups)
APaT Population

| | | MK-7684A Q3W | Pembrolizumab (MK-3475) Q3W |
|---|---|---|---|
| | Outcome | n (%) | n (%) |
| Vasculitis | Resolved | 0 (0.0) | |

Every participant is counted once for each specific AEOSI according to the worst outcome; the ordering of the outcome is as follows: Fatal>Not Resolved>Resolving>Unknown>Sequelae>Resolved.

"Participants in population" is used for percentage calculation for the Overall row in each section. Within each section, the overall total is used for percentage calculation for each outcome.

**Outcome:** Resolved = RECOVERED/RESOLVED, Resolving = RECOVERING/RESOLVING, Sequelae = RECOVERED/RESOLVED WITH SEQUELAE, Not resolved = NOT RECOVERED/NOT RESOLVED.

Non-serious adverse events up to 30 days of last treatment and serious adverse events up to 90 days of last treatment are included.

Database Cutoff Date: 06MAR2024.

Source: [P010V01MK7684a: adam-adsl; adae]