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: B-000056613 (+) L-004811422 (MK-7684A)

PROTOCOL TITLE: A Phase 2, Multicenter, Randomized Study to Compare the Efficacy and Safety of MK-7684A or MK-7684A Plus Docetaxel Versus Docetaxel Monotherapy in the Treatment of Participants With Metastatic Non-small Cell Lung Cancer With Progressive Disease After Treatment With a Platinum Doublet Chemotherapy and Immunotherapy

The following terms may be used interchangeably in this report:

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

STUDY IDENTIFIERS:

IND: 147424	EudraCT: 2020-004034-38	WHO: Not applicable	NCT: 04725188
jRCT: Not applicable	UTN: Not applicable	EU CT: 2022-500420-30-00	

STUDY PHASE: Phase 2

INDICATION: Non-small cell lung cancer stage IV

STUDY CENTERS: This study was conducted at 95 centers in 20 countries.

STUDY STATUS:

This study is ongoing; this report is based on the FA.

First Participant First Visit	20-APR-2021
Data Cutoff	26-JAN-2023
Last Data Available	Not applicable
Database Lock Date	02-MAR-2023

METHODOLOGY:

MK-7684A-002 is a randomized, placebo- and active-controlled, parallel-group, multisite, partially blinded study (Arms 1 and 3 are double blinded, Arm 2 is open label), comparing MK-7684A + docetaxel (Arm 1) or MK-7684A alone (Arm 2) to normal saline placebo + docetaxel (Arm 3). MK-7684A is a coformulation of MK-7684 and pembrolizumab. MK-7684 is a humanized, antagonist mAb that binds to the immune-checkpoint receptor, TIGIT, and blocks the interaction between TIGIT and its ligands.

Participants with metastatic NSCLC, PD after platinum doublet chemotherapy and treatment with one prior anti-PD-1/PD-L1 mAb (either sequentially or in combination with chemotherapy), measurable disease based on RECIST 1.1 (as determined by the local site assessment), and those in whom *EGFR*-, *ALK*-, or *ROS1*-targeted therapy was not indicated were enrolled in the study. The approvals of several immune-checkpoint inhibitors for the treatment of first- and second-line metastatic NSCLC changed the treatment landscape for this patient population in recent years. However, long-term survival benefit is still poor for the majority of patients living with this condition. For most patients, resistance to immunotherapy will develop. There are currently no approved treatments available specifically for patients who have disease progression on or after anti-PD-1/PD-L1 therapy.

Anti-PD-1/PD-L1 treatment progression was defined in this study by meeting all of the following criteria:

- Treatment with at least 2 doses of an anti-PD-1/PD-L1 mAb.
- PD after an anti-PD-1/PD-L1 mAb as defined by RECIST 1.1, based on the following:
  - Imaging before anti-PD-1/PD-L1 treatment or imaging showing nadir during anti-PD-1/PD-L1 treatment; and
  - Imaging to determine that radiographic progression had occurred per RECIST 1.1 within 12 weeks (84 days) from the last dose of an anti-PD-1/PD-L1 mAb.

A total of 255 participants were randomized in a 1:1:1 ratio to receive MK-7684A + docetaxel, MK-7684A, or normal saline placebo + docetaxel. Participants were stratified by prior anti-PD-1/PD-L1 mAb (immediate prior therapy vs not immediate prior therapy), PD-L1 TPS (<50% vs ≥50%), and ECOG PS (0 vs 1).

Treatment with MK-7684A/normal saline placebo continued for up to 35 treatment cycles, or until a discontinuation criterion was met; treatment could be discontinued for participants with a confirmed CR. Treatment with docetaxel could be continued until a discontinuation criterion was met, or as per approved local label.

Participants were evaluated with radiographic imaging to assess response to study intervention every 6 weeks from randomization through 36 weeks, every 9 weeks through 54 weeks, and subsequently every 12 weeks until confirmed PD or initiation of a new anticancer regimen. All imaging obtained during the initial treatment phase of the study were submitted to the imaging contract research organization for BICR, which assessed the images using RECIST 1.1 for determination of PFS, OR, and DOR.

Participants were permitted to continue study intervention beyond PD (confirmed by BICR per RECIST 1.1) if the treating investigator considered that the participant could experience clinical benefit with continued treatment and the participant was clinically stable and tolerating study intervention; however, this decision was to be approved by the Sponsor.

AEs were monitored and graded in severity according to the guidelines outlined in the NCI CTCAE, version 5.0. External Data Monitoring Committee monitoring for safety was conducted every 6 months.

Arm Name	Intervention Name	Unit Dose Strength(s)	Dosage Level(s)	Route of Administration	Regimen/Treatment Period/Vaccination Regimen	Use
Arm 1	MK-7684A	MK-7684 200 mg + pembrolizumab 200 mg/20 mL vial	200 mg/200 mg	IV Infusion	Q3W up to 35 cycles	Test Product
Arm 1	Docetaxel	20 mg/mL	75 mg/m^2	IV Infusion	Q3W until a discontinuation criterion is met or as per approved local label.	Test Product
Arm 2	MK-7684A	MK-7684 200 mg + pembrolizumab 200 mg/20 mL vial	200 mg/200 mg	IV Infusion	Q3W up to 35 cycles	Test Product
Arm 3	Docetaxel	20 mg/mL	75 mg/m^2	IV Infusion	Q3W until a discontinuation criterion is met or as per approved local label.	Test Product
Arm 3	Normal saline placebo	0 mg	0 mg	IV Infusion	Q3W up to 35 cycles	Placebo

Abbreviations: IV = intravenous; Q3W = every 3 weeks.
Note: MK-7684A = coformulated as 200 mg MK-7684 and 200 mg pembrolizumab.

Part of this study was conducted during the COVID-19 pandemic. The Sponsor developed several COVID-19 Guidance Response Plans for sites to address basic study management questions during the pandemic. The Guidance Response Plans provided options for sites and participants to continue in the study with access to study intervention, procedures, and safety monitoring. There were no changes in the planned conduct of the study as a result of the COVID-19 pandemic.

The Sponsor continued to follow the COVID-19 Guidance Response Plans and its SOPs for study conduct, monitoring, and oversight during the COVID-19 pandemic. Exceptions and deviations from SOPs were documented.

A risk-based approach was used to assess and mitigate the impact of the pandemic on study conduct to (a) ensure the safety of study participants, study staff, and health care providers;

(b) maintain compliance with GCP principles; and (c) minimize risks to study data integrity. Contingency measures were implemented as per the Sponsor's SOP for exception and deviation management and as appropriate to the country, region, and individual study site. Due to the COVID-19 pandemic, instances of delayed imaging (3), missed imaging (1), missed visit (1), delayed SAE reporting (2), and study intervention out of window (2) were reported as deviations but did not impact efficacy or safety assessment of participants in the study.

ELIGIBILITY CRITERIA:

The study included male and female participants at least 18 years of age with a histologically or cytologically confirmed diagnosis of metastatic NSCLC Stage IV, PD after platinum doublet chemotherapy and treatment with 1 prior anti-PD-1/PD-L1 mAb (either concomitantly or sequentially), radiographically measurable disease based on RECIST 1.1, and an ECOG PS of 0 to 1 assessed within 7 days before randomization. Participants were not eligible if they had active or untreated central nervous system metastases and/or carcinomatous meningitis, current pneumonitis, a history of non-infectious pneumonitis that required steroids or a known history of interstitial lung disease (lymphangitic spread of the NSCLC was not exclusionary), an active infection requiring systemic therapy, or an active autoimmune disease that required systemic treatment in the past 2 years.

OBJECTIVES AND ENDPOINTS:

Primary Objective	Primary Endpoint
• Objective: To compare MK-7684A + docetaxel to normal saline placebo + docetaxel with respect to PFS per RECIST 1.1 by BICR. • Hypothesis (H1): MK-7684A + docetaxel is superior to normal saline placebo + docetaxel with respect to PFS per RECIST 1.1 by BICR. • Objective: To compare MK-7684A to normal saline placebo + docetaxel with respect to PFS per RECIST 1.1 as assessed by BICR. • Hypothesis (H2): MK-7684A is superior to normal saline placebo + docetaxel with respect to PFS per RECIST 1.1 by BICR.	• PFS: The time from randomization to the first documented disease progression or death due to any cause, whichever occurs first.

Secondary Objectives	Secondary Endpoints
• To evaluate ORR in participants treated with MK-7684A + docetaxel, MK-7684A, or normal saline placebo + docetaxel per RECIST 1.1 by BICR.	• Objective response: defined as a confirmed CR or PR.
• To evaluate OS in participants treated with MK-7684A + docetaxel, MK-7684A, or normal saline placebo + docetaxel.	• OS: defined as the time from randomization to the date of death due to any cause.
• To evaluate DOR per RECIST 1.1 as assessed by BICR in participants treated with MK-7684A + docetaxel, MK-7684A, or normal saline placebo + docetaxel.	• DOR: for participants who demonstrate confirmed CR or PR, DOR is defined as the time from first documented evidence of CR or PR until disease progression or death due to any cause, whichever occurs first.
• To evaluate the safety and tolerability in participants treated with MK-7684A + docetaxel, MK-7684A, or normal saline placebo + docetaxel.	• AEs. • Discontinuations of study intervention due to an AE.

NUMBER OF PARTICIPANTS (planned and analyzed):

The planned enrollment for this study was 240 participants. As of the data cutoff date for this report (26-JAN-2023):

- A total of 255 participants were randomized (87 in the MK-7684A + docetaxel group, 83 in the MK-7684A group, and 85 in the placebo + docetaxel group).
- A total of 251 participants were randomized and received at least 1 dose of study intervention (85 in the MK-7684A + docetaxel group, 83 in the MK-7684A group, and 83 in the placebo + docetaxel group).

STATISTICAL AND ANALYSIS METHODS:

The planned analyses, comparisons, statistical tests, and determination of sample size are described in the protocol or in the latest version of the sSAP.

The analyses of efficacy endpoints were based on the ITT population, which included all randomized participants. The APaT population was used for the analysis of safety data. The

APaT population consisted of all randomized participants who received at least 1 dose of study intervention.

The primary endpoint, PFS per RECIST 1.1 by BICR, was evaluated by a stratified log-rank test; the HR was estimated by stratified Cox model with Efron's tie handling method. The KM method was used to estimate the PFS and OS curves in each treatment group. The magnitude of the treatment difference in OS (secondary endpoint) was estimated by stratified Cox model with Efron's tie handling method. OR per RECIST 1.1 by BICR, was evaluated using the stratified Miettinen and Nurminen method, and DOR per RECIST 1.1 by BICR was estimated using the KM method. The stratification factors used for randomization (prior anti-PD-1/PD-L1 mAb [immediate prior therapy vs not the immediate prior therapy], PD-L1 TPS [<50% vs ≥50%], and ECOG PS [0 vs 1]) were applied to all stratified analyses, in particular, the stratified log-rank test, stratified Cox model, and stratified Miettinen and Nurminen method with small strata collapsed as pre-specified in the sSAP. Each of the 2 primary hypotheses (see objectives and endpoints table above) were tested at 0.05 (1-sided) alpha level. There were no hypotheses for the secondary endpoints (OS, OR, and DOR), and they were not formally tested.

The analysis of safety results followed a tiered approach, and safety parameters were analyzed using descriptive statistics.

The study had no interim analyses. This report provides a summary of efficacy and safety results generated through FA (data cutoff 26-JAN-2023).

No changes were made to the planned analysis of the study due to the COVID-19 pandemic.

RESULTS:

Participant Disposition:

At the data cutoff, 18 participants in the MK-7684A + docetaxel, 9 participants in the MK-7684A group, and 12 participants in the placebo + docetaxel group remained on treatment. In all treatment groups, the most common reason for treatment discontinuation was PD [Table 2-1].

Table 2-1
Disposition of Participants
(ITT Population)

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Participants in population	87		83		85	
Status for Trial						
Discontinued	46	(52.9)	48	(57.8)	50	(58.8)
Death	44	(50.6)	46	(55.4)	48	(56.5)
Associated with COVID-19	2	(2.3)	1	(1.2)	3	(3.5)
Lost To Follow-Up	0	(0.0)	0	(0.0)	1	(1.2)
Withdrawal By Subject	2	(2.3)	2	(2.4)	1	(1.2)
COVID-19 association unspecified, Subsequently died	0	(0.0)	1	(1.2)	0	(0.0)
Participants Ongoing	41	(47.1)	35	(42.2)	35	(41.2)
Status for Study Treatment in Trial						
Started	85		83		83	
Discontinued	67	(78.8)	74	(89.2)	71	(85.5)
Adverse Event	21	(24.7)	12	(14.5)	16	(19.3)
Associated with COVID-19	1	(1.2)	0	(0.0)	1	(1.2)
Clinical Progression	7	(8.2)	1	(1.2)	7	(8.4)
Associated with COVID-19	0	(0.0)	0	(0.0)	1	(1.2)
Lost To Follow-Up	0	(0.0)	0	(0.0)	1	(1.2)
Physician Decision	1	(1.2)	1	(1.2)	1	(1.2)
Progressive Disease	34	(40.0)	59	(71.1)	43	(51.8)
Withdrawal By Subject	4	(4.7)	1	(1.2)	3	(3.6)

Disposition of Participants
(ITT Population)

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Status for Study Treatment in Trial						
Participants Ongoing	18	(21.2)	9	(10.8)	12	(14.5)

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

Database Cutoff Date: 26Jan2023

Source: [P002V01MK7684A: adam-adsl]

Demographics and Baseline Characteristics:

The demographics and baseline characteristics were generally balanced across treatment groups. Most participants in all treatment groups had PD-L1 TPS <50%, had received 1 or 2 prior lines of therapy, had immediate prior anti-PD-1/PD-L1 therapy, and were treated with pembrolizumab as the only anti-PD-1/PD-L1 [Table 2-2].

Table 2-2
Participant Characteristics
(ITT Population)

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel		Total	
	n	(%)	n	(%)	n	(%)	n	(%)
Participants in population	87		83		85		255	
Sex								
Male	60	(69.0)	60	(72.3)	61	(71.8)	181	(71.0)
Female	27	(31.0)	23	(27.7)	24	(28.2)	74	(29.0)
Age (Years)								
< 65	40	(46.0)	33	(39.8)	33	(38.8)	106	(41.6)
>= 65	47	(54.0)	50	(60.2)	52	(61.2)	149	(58.4)
Mean	64.7		66.0		65.8		65.5	
SD	8.8		7.4		8.0		8.1	
Median	66.0		67.0		67.0		67.0	
Range	39 to 79		47 to 83		44 to 83		39 to 83	
Race								
Asian	11	(12.6)	14	(16.9)	10	(11.8)	35	(13.7)
Black Or African American	0	(0.0)	1	(1.2)	1	(1.2)	2	(0.8)
Native Hawaiian Or Other Pacific Islander	1	(1.1)	0	(0.0)	0	(0.0)	1	(0.4)
White	62	(71.3)	63	(75.9)	60	(70.6)	185	(72.5)
Missing	13	(14.9)	5	(6.0)	14	(16.5)	32	(12.5)

Participant Characteristics
(ITT Population)

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel		Total	
	n	(%)	n	(%)	n	(%)	n	(%)
Ethnicity								
Hispanic Or Latino	12	(13.8)	9	(10.8)	6	(7.1)	27	(10.6)
Not Hispanic Or Latino	62	(71.3)	68	(81.9)	65	(76.5)	195	(76.5)
Not Reported	13	(14.9)	5	(6.0)	13	(15.3)	31	(12.2)
Unknown	0	(0.0)	1	(1.2)	1	(1.2)	2	(0.8)
Geographic Region								
East Asia	11	(12.6)	14	(16.9)	10	(11.8)	35	(13.7)
Non-East Asia	76	(87.4)	69	(83.1)	75	(88.2)	220	(86.3)
Smoking Status								
Never Smoker	9	(10.3)	10	(12.0)	8	(9.4)	27	(10.6)
Former Smoker	60	(69.0)	56	(67.5)	63	(74.1)	179	(70.2)
Current Smoker	18	(20.7)	17	(20.5)	14	(16.5)	49	(19.2)
ECOG								
0	33	(37.9)	30	(36.1)	31	(36.5)	94	(36.9)
1	54	(62.1)	53	(63.9)	54	(63.5)	161	(63.1)
PD-L1 Status								
TPS >=50%	15	(17.2)	14	(16.9)	13	(15.3)	42	(16.5)

Participant Characteristics
(ITT Population)

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel		Total	
	n	(%)	n	(%)	n	(%)	n	(%)
TPS 1-49%	34	(39.1)	19	(22.9)	35	(41.2)	88	(34.5)
TPS <1%	37	(42.5)	45	(54.2)	34	(40.0)	116	(45.5)
Unknown[a]	1	(1.1)	5	(6.0)	3	(3.5)	9	(3.5)
Predominant Tumor Histology								
Squamous	26	(29.9)	20	(24.1)	34	(40.0)	80	(31.4)
Non-squamous	61	(70.1)	63	(75.9)	51	(60.0)	175	(68.6)
Overall Tumor Stage								
IVA	35	(40.2)	32	(38.6)	43	(50.6)	110	(43.1)
IVB	52	(59.8)	51	(61.4)	42	(49.4)	145	(56.9)
Baseline Tumor Size								
Participants with data	85		82		84		251	
Mean	86.6		103.5		107.1		99.0	
SD	48.6		62.1		64.5		59.2	
Median	80.0		84.5		90.5		86.0	
Range	14.0 to 228.0		12.0 to 276.0		16.0 to 356.0		12.0 to 356.0	
Current Brain Metastasis at Baseline								
Yes	10	(11.5)	17	(20.5)	18	(21.2)	45	(17.6)
No	77	(88.5)	66	(79.5)	67	(78.8)	210	(82.4)

Participant Characteristics
(ITT Population)

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel		Total	
	n	(%)	n	(%)	n	(%)	n	(%)
History Brain Metastasis								
Yes	10	(11.5)	13	(15.7)	17	(20.0)	40	(15.7)
No	77	(88.5)	70	(84.3)	68	(80.0)	215	(84.3)
Liver Metastasis at Baseline								
Yes	20	(23.0)	25	(30.1)	19	(22.4)	64	(25.1)
No	67	(77.0)	58	(69.9)	66	(77.6)	191	(74.9)
Prior Radiation								
Yes	36	(41.4)	41	(49.4)	38	(44.7)	115	(45.1)
No	51	(58.6)	42	(50.6)	47	(55.3)	140	(54.9)
Prior Lines of Therapy								
1	58	(66.7)	49	(59.0)	52	(61.2)	159	(62.4)
2	25	(28.7)	28	(33.7)	26	(30.6)	79	(31.0)
3	1	(1.1)	4	(4.8)	7	(8.2)	12	(4.7)
4	1	(1.1)	2	(2.4)	0	(0.0)	3	(1.2)
>/=5	2	(2.3)	0	(0.0)	0	(0.0)	2	(0.8)
Prior Adjuvant and Neo-adjuvant therapy								
Yes	9	(10.3)	19	(22.9)	23	(27.1)	51	(20.0)

Participant Characteristics
(ITT Population)

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel		Total	
	n	(%)	n	(%)	n	(%)	n	(%)
No	78	(89.7)	64	(77.1)	62	(72.9)	204	(80.0)
Sequence of Prior Anti-PD-1/PD-L1								
Immediate Prior Therapy	72	(82.8)	70	(84.3)	72	(84.7)	214	(83.9)
Not the Immediate Prior Therapy	15	(17.2)	13	(15.7)	13	(15.3)	41	(16.1)
Sequence of Prior Anti-PD-/PDL1 with Chemotherapy								
Concomitantly	61	(70.1)	54	(65.1)	59	(69.4)	174	(68.2)
Sequentially	26	(29.9)	29	(34.9)	26	(30.6)	81	(31.8)
Prior Anti-PD-1/PD-L1								
Pembrolizumab as the only Anti-PD-1/PD-L1	62	(71.3)	62	(74.7)	61	(71.8)	185	(72.5)
Other drug as the only Anti-PD-1/PD-L1[b]	24	(27.6)	21	(25.3)	23	(27.1)	68	(26.7)

Participant Characteristics
(ITT Population)

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel		Total	
	n	(%)	n	(%)	n	(%)	n	(%)
More than 1 Anti-PD-1/PD-L1	1	(1.1)	0	(0.0)	1	(1.2)	2	(0.8)

SD=Standard deviation.

[a] Not evaluable due to <100 viable tumor cells.

[b] One subject received either pembrolizumab or dostarlimab in a blinded study; the treatment arm was not unblinded.

In Race missing category, 31 subjects in France missing race and ethnicity data due to local privacy laws, 1 subject in USA unknown race; 1 subject in Brazil and 1 subject in Israel Unknown ethnicity.

Database cutoff date: 26Jan2023

Source: [P002V01MK7684A: adam-adsl]

Efficacy:

Primary Efficacy Endpoint – PFS

- The point estimate of PFS HR favored MK-7684A + docetaxel when compared with placebo + docetaxel, with an HR of 0.77 (95% CI: 0.53, 1.13; 1-sided *p*=0.0910), but the improvement did not achieve statistical significance. The median PFS was 5.6 months for MK-7684A + docetaxel and 3.2 months for placebo + docetaxel. The PFS rates for MK-7684A + docetaxel at 6, 9, and 12 months were 44.4%, 27.8%, and 23.2%, respectively, versus 36.3%, 23.4%, and 12.5%, respectively, for placebo + docetaxel [Table 2-4] [Figure 2-1].
- MK-7684A alone did not improve PFS when compared with placebo + docetaxel (HR=1.40 [95% CI: 0.96, 2.02; 1-sided *p*=0.9622]). The median PFS was 2.7 months for MK-7684A alone. The PFS rates for MK-7684A alone at 6, 9, and 12 months were 18.2%, 13.3%, and 8.0%, respectively [Table 2-4] [Figure 2-1].

Secondary Efficacy Endpoint – OS

- The point estimate of OS HR favored MK-7684A + docetaxel when compared with placebo + docetaxel, with an HR of 0.76 (95% CI: 0.50, 1.15; 1-sided nominal *p*=0.0943). The OS HR for MK-7684A alone when compared with placebo + docetaxel was 1.05 [95% CI: 0.70, 1.58; 1-sided nominal *p*=0.5974]). Median OS was 10.2 months in the MK-7684A + docetaxel group, 7.5 months in the MK-7684A group, and 8.8 months in the placebo + docetaxel group [Table 2-5] [Figure 2-2].

Secondary Efficacy Endpoint – ORR

- The observed ORR was 29.9% (95% CI: 20.5, 40.6) in the MK-7684A + docetaxel group, 6.0% (95% CI: 2.0, 13.5) in the MK-7684A group, and 15.3% (95% CI: 8.4, 24.7) in the placebo + docetaxel group [Table 2-6] [Table 2-7].

Secondary Efficacy Endpoint – DOR

- Median DOR per RECIST 1.1 by BICR was 6.5 months in the MK-7684A + docetaxel group and was not reached neither in the MK-7684A group nor in the placebo + docetaxel group. Responses to MK-7684A + docetaxel were durable, with responses lasting 6 months or longer by KM estimation in 54.7% of participants. Median time to response was 1.8 months in the MK-7684A + docetaxel group, 4.1 months in the MK-7684A group, and 1.6 months in the placebo + docetaxel group [Table 2-8] [Figure 2-3].

Safety:

A total of 251 participants were included in the APaT population for safety analyses: 85 received MK-7684A + docetaxel, 83 received MK-7684A, and 83 received placebo + docetaxel [Table 2-9].

The median duration of exposure was 120, 64, and 77 days for the MK-7684A + docetaxel, MK-7684A, and placebo + docetaxel groups, respectively [Table 2-10].

MK-7684A had a tolerable safety profile that is generally consistent with the established safety profile of pembrolizumab. No new safety concerns were identified.

- The most frequently reported AEs (>20% of participants) were:
  - in the MK-7684A + docetaxel group: diarrhea, pruritus, anemia, asthenia, alopecia, fatigue, nausea, constipation, rash, dyspnea, and decreased appetite.
  - in the MK-7684A group: pruritus.
  - in the placebo + docetaxel group: anemia, asthenia, fatigue, diarrhea, nausea, alopecia, and decreased appetite [Table 2-11] [Table 2-12].
- The percentage of participants with drug-related AEs was similar in the MK-7684A + docetaxel group compared with the placebo + docetaxel group (96.5% vs 89.2%). The percentage of participants with drug-related AEs was lower in the MK-7684A group compared with the placebo + docetaxel group (60.2% vs 89.2%) [Table 2-13].
- The percentage of participants with Grade 3 to 5 AEs was similar in the MK-7684A + docetaxel group compared with the placebo + docetaxel group (65.9% vs 53.0%) and in the MK-7684A group compared with the placebo + docetaxel group (48.2% vs 53.0%) [Table 2-14].
- The percentage of participants with drug-related Grade 3 to 5 AEs was higher in the MK-7684A + docetaxel group compared with the placebo + docetaxel group (49.4% vs 32.5%); the percentage of participants with drug-related Grade 3 to 5 AEs was lower in the MK-7684A group compared with the placebo + docetaxel group (13.3% vs 32.5%). The most frequently reported drug-related Grade 3 to 5 AE was decreased neutrophil count in the MK-7684A + docetaxel and in the placebo + docetaxel groups (16.5% and 14.5%, respectively), and diarrhea, asthenia, and increased lipase (2.4% each) in the MK-7684A group [Table 2-15].
- The percentage of participants with SAEs was similar in the MK-7684A +docetaxel group compared with the placebo + docetaxel group (51.8% vs 43.4%) and in the MK-7684A group compared with the placebo + docetaxel group (30.1% vs 43.4%) [Table 2-3]. The most frequently reported SAE (incidence ≥5%) in all groups was pneumonia (7.1% in the MK-7684A + docetaxel group, 3.6% in the MK-7684A group, and 10.8% in the placebo + docetaxel group) [Table 2-16].

- The number of participants with AEs leading to death was similar across all treatment groups (11 [12.9%], 7 [8.4%], and 11 [13.3%] participants in the MK-7684A + docetaxel, MK-7684A, and the placebo + docetaxel groups, respectively) [Table 2-17]. Of these deaths, 4 in the MK-7684A + docetaxel group, 1 in the MK-7684A group, and 1 in the placebo + docetaxel group were considered by the investigator as related to study intervention [Table 2-3].
- The percentage of participants who discontinued study intervention due to AEs was higher in the MK-7684A + docetaxel group compared with the placebo + docetaxel group (43.5% vs 27.7%); the percentage of participants who discontinued study intervention due to AEs was 13.3% in the MK-7684A group [Table 2-3] [Table 2-18].
  - The percentage of participants with drug-related events requiring treatment discontinuation was higher in the MK-7684A + docetaxel group compared with the placebo + docetaxel group (36.5% vs 16.9%); the percentage of participants with drug-related events requiring treatment discontinuation was 6.0% in the MK-7684A group [Table 2-3].
  - The most frequently reported AEs leading to treatment discontinuation were decreased neutrophil count (3.5%) in the MK-7684A + docetaxel group, diarrhea (2.4%) in the MK-7684A group, and pneumonia and asthenia (3.6% each) in the placebo + docetaxel group [Table 2-18].
- As expected with immune therapy, the percentage of participants with AEOSIs was higher in both the MK-7684A + docetaxel group (29.4%) and the MK-7684A group (20.5%) compared with the placebo + docetaxel group (12.0%) [Table 2-19].
  - The most frequently reported AEOSIs (in at least 3% of participants) were severe skin reactions, pneumonitis, hypothyroidism, hyperthyroidism, and infusion reactions in the MK-7684A +docetaxel group; and pneumonitis, hypothyroidism, and hyperthyroidism in the MK-7684A group [Table 2-20].
  - All the reported severe skin reactions were Grade 1 to 3. In the MK-7684A + docetaxel group, Grade 3 severe skin reactions included pruritus (n=3), rash (n=2), pemphigoid (n=1), and maculopapular rash (n=1). In the MK-7684A group, there was 1 Grade 3 severe skin reaction (rash) [Table 2-21].
  - The percentage of participants with pneumonitis was similar across the 3 groups (7.1% in the MK-7684A + docetaxel group, 7.2% in the MK-7684A group, and 6.0% in the placebo + docetaxel group) [Table 2-20]. Grade 3 pneumonitis occurred in 2 participants in the MK-7684A + docetaxel group, and Grade 4 pneumonitis occurred in 1 participant in the placebo + docetaxel group. Grade 5 pneumonitis occurred in 2 participants in the MK-7684A + docetaxel group [Table 2-21].
  - The percentage of participants with Grade 3 to 5 AEOSIs was 15.3% in the MK-7684A + docetaxel group and 2.4% each in the MK-7684A group and in the placebo + docetaxel group [Table 2-19].
  - Two participants experienced fatal AEOSIs, both were under pneumonitis category (with preferred terms of pneumonitis and interstitial lung disease) and occurred in the MK-7684A + docetaxel group [Table 2-19] [Table 2-21].

Table 2-3
Adverse Event Summary
(APaT Population)

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Participants in population	85		83		83	
with one or more adverse events	85	(100.0)	75	(90.4)	82	(98.8)
with no adverse event	0	(0.0)	8	(9.6)	1	(1.2)
with drug-related[a] adverse events	82	(96.5)	50	(60.2)	74	(89.2)
with toxicity grade 3-5 adverse events	56	(65.9)	40	(48.2)	44	(53.0)
with toxicity grade 3-5 drug-related adverse events	42	(49.4)	11	(13.3)	27	(32.5)
with serious adverse events	44	(51.8)	25	(30.1)	36	(43.4)
with serious drug-related adverse events	30	(35.3)	3	(3.6)	17	(20.5)
who died	11	(12.9)	7	(8.4)	11	(13.3)
who died due to a drug-related adverse event	4	(4.7)	1	(1.2)	1	(1.2)
discontinued any drug due to an adverse event	37	(43.5)	11	(13.3)	23	(27.7)
discontinued MK-7684A/PLACEBO	26	(30.6)	0	(0.0)	16	(19.3)
discontinued DOCETAXEL	31	(36.5)	0	(0.0)	22	(26.5)
discontinued MK-7684A	0	(0.0)	11	(13.3)	0	(0.0)
discontinued any drug due to a drug-related adverse event	31	(36.5)	5	(6.0)	14	(16.9)
discontinued MK-7684A/PLACEBO	20	(23.5)	0	(0.0)	7	(8.4)
discontinued DOCETAXEL	25	(29.4)	0	(0.0)	13	(15.7)
discontinued MK-7684A	0	(0.0)	5	(6.0)	0	(0.0)
discontinued any drug due to a serious adverse event	23	(27.1)	7	(8.4)	14	(16.9)
discontinued MK-7684A/PLACEBO	18	(21.2)	0	(0.0)	12	(14.5)
discontinued DOCETAXEL	18	(21.2)	0	(0.0)	14	(16.9)
discontinued MK-7684A	0	(0.0)	7	(8.4)	0	(0.0)

Adverse Event Summary
(APaT Population)

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
discontinued any drug due to a serious drug-related adverse event	17	(20.0)	1	(1.2)	6	(7.2)
discontinued MK-7684A/PLACEBO	14	(16.5)	0	(0.0)	4	(4.8)
discontinued DOCETAXEL	13	(15.3)	0	(0.0)	6	(7.2)
discontinued MK-7684A	0	(0.0)	1	(1.2)	0	(0.0)

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

Non-serious adverse events occurring within 30 days after the last dose of study intervention and serious adverse events occurring within 90 days after the last dose of study intervention, or 30 days after the last dose of study intervention if a new anticancer therapy is initiated, whichever is earlier are included.

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

Grades are based on NCI CTCAE version 5.0.

Adverse event terms are based on MedDRA version 25.1.

Database cutoff date: 26Jan2023

Source: [P002V01MK7684A: adam-adsl; adae]

CONCLUSIONS:

Efficacy

Based on the results from this study, the following efficacy conclusions can be made:

- The point estimate of PFS HR favors MK-7684A + docetaxel over placebo + docetaxel, but the improvement in PFS is not statistically significant.
- MK-7684A alone does not improve PFS over placebo + docetaxel.

Safety

Based on the results from this study, the following safety conclusions can be made:

- The frequency, type, and severity of AEOSIs in the MK-7684A and MK-7684A + docetaxel groups were, in general, similar to those previously reported for pembrolizumab.
- The safety profile of MK-7684A is generally consistent with the established safety profile of pembrolizumab monotherapy.
- The overall AE profile for participants who received MK-7684A + docetaxel was generally consistent with the previously observed safety profile for pembrolizumab in combination with chemotherapy.
- There were no new safety concerns identified for MK-7684A or MK-7684A + docetaxel.

LIST OF ABBREVIATIONS:

Abbreviation/Term	Definition
AE	adverse event
AEOSI	adverse event of special interest
ALK	anaplastic lymphoma kinase
APaT	all participants as treated
BICR	blinded independent central review
CI	confidence interval
COVID-19	coronavirus disease caused by severe acute respiratory syndrome coronavirus 2
CR	complete response
CSR	Clinical Study Report
CTCAE	Common Terminology Criteria for Adverse Events
DOR	duration of response
ECOG	Eastern Cooperative Oncology Group
EGFR	epidermal growth factor receptor
TFA	final analysis
GCP	Good Clinical Practice
HR	hazard ratio
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
IEC	Independent Ethics Committee
ITT	intention-to-treat
KM	Kaplan Meier
mAb	monoclonal antibody
MedDRA	Medical Dictionary for Regulatory Activities
NCI	National Cancer Institute
NSCLC	non-small cell lung cancer
OR	objective response
ORR	objective response rate
OS	overall survival
PD	progressive disease

Abbreviation/Term	Definition
PD-1	programmed cell death 1
PD-L1	programmed cell death ligand 1
PFS	progression-free survival
PR	partial response
PS	performance status
RECIST 1.1	Response Evaluation Criteria in Solid Tumors 1.1
ROS	reactive oxygen species
SAE	serious adverse event
SD	standard deviation
SOP	standard operating procedure
sSAP	supplemental Statistical Analysis Plan
TIGIT	T-cell immunoreceptor
TPS	tumor proportion score
USA	United States of America

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

REPORT DATE: 13-JUL-2023

REVISED REPORT DATE: Not applicable

ADDITIONAL TABLES:

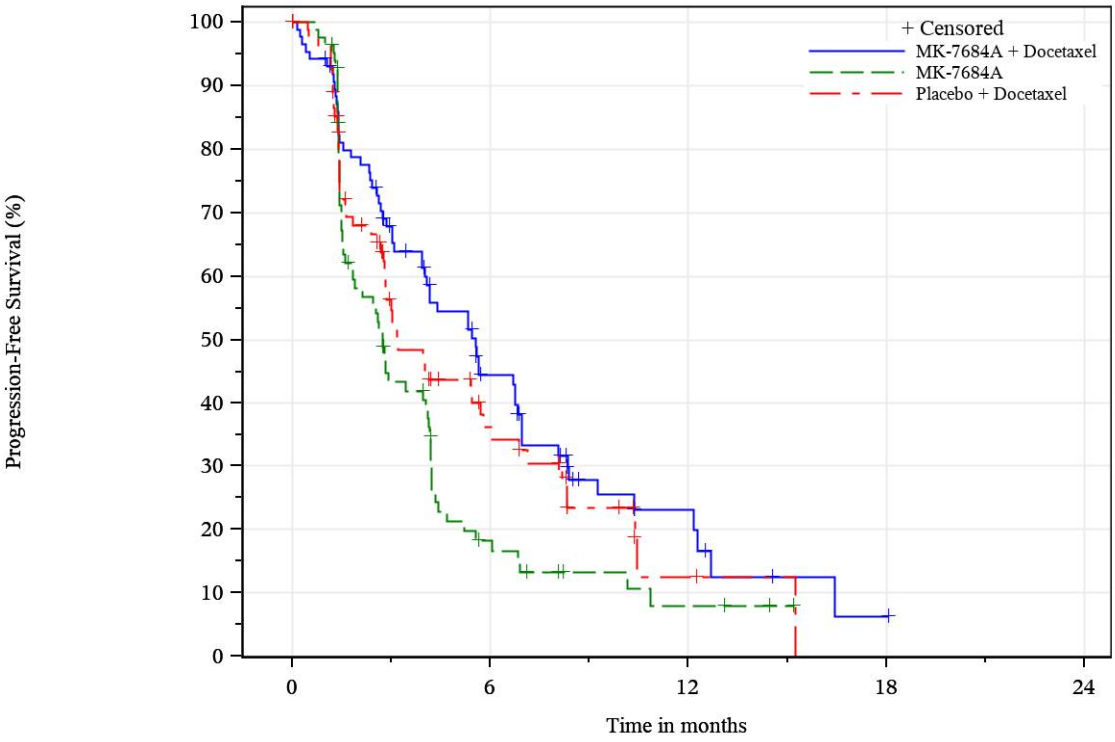
Table 2-4
Analysis of Progression-Free Survival (Primary Censoring Rule)
Based on BICR per RECIST 1.1
(ITT Population)

	MK-7684A + Docetaxel (N=87)	MK-7684A (N=83)	Placebo + Docetaxel (N=85)
Number of Events (%)	60 (69.0)	66 (79.5)	54 (63.5)
Death	14 (16.1)	14 (16.9)	10 (11.8)
Documented progression	46 (52.9)	52 (62.7)	44 (51.8)
Kaplan-Meier Estimates (months)[a]			
Median (95% CI)	5.6 (3.9, 6.8)	2.7 (1.8, 4.0)	3.2 (2.8, 5.7)
[Q1, Q3]	[2.4, 10.3]	[1.4, 4.3]	[1.4, 8.3]
Person-months	440.9	283.9	323.6
Event Rate / 100 Person-months	13.6	23.3	16.7
vs Placebo + Docetaxel			
Hazard Ratio (95% CI)[b]	0.77 (0.53, 1.13)	1.40 (0.96, 2.02)	
p-value[c]	0.0910	0.9622	
PFS Rate at month 6 (%) (95% CI)	44.4 (33.1, 55.1)	18.2 (10.2, 28.1)	36.3 (24.8, 47.9)
PFS Rate at month 9 (%) (95% CI)	27.8 (17.6, 38.9)	13.3 (6.5, 22.6)	23.4 (13.2, 35.3)
PFS Rate at month 12 (%) (95% CI)	23.2 (13.4, 34.5)	8.0 (2.5, 17.5)	12.5 (3.3, 28.2)

[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 ECOG (0 vs 1), PD-L1 TPS (<50% VS >=50%) and Prior anti-PD-1/PD-L1 mAb (immediate prior treatment vs not immediate prior treatment) with small strata collapsed as pre-specified in the sSAP .
[c] One-sided p-value based on log-rank test stratified by ECOG (0 vs 1), PD-L1 TPS (<50% VS >=50%) and Prior anti-PD-1/PD-L1 mAb (immediate prior treatment vs not immediate prior treatment) with small strata collapsed as pre-specified in the sSAP .
Database Cutoff Date: 26Jan2023

Source: [P002V01MK7684A: adam-adsl; adtte]

Figure 2-1
Kaplan-Meier Plot of Progression-Free Survival (Primary Censoring Rule)
Based on BICR per RECIST 1.1
(ITT Population)



Number of participants at risk

MK-7684A + Docetaxel	87	29	7	1	0
MK-7684A	83	11	3	0	0
Placebo + Docetaxel	85	19	2	0	0

Database cutoff date: 26Jan2023
Source: [P002V01MK7684A: adam-adsl; adtte]

Table 2-5
Analysis of Overall Survival
(ITT Population)

	MK-7684A + Docetaxel (N=87)	MK-7684A (N=83)	Placebo + Docetaxel (N=85)
Number of Events (%)	44 (50.6)	47 (56.6)	48 (56.5)
Kaplan-Meier Estimates (months)[a]			
Median (95% CI)	10.2 (8.6, 14.9)	7.5 (5.2, 13.4)	8.8 (6.4, 11.1)
[Q1, Q3]	[6.7, NR]	[3.9, NR]	[4.7, NR]
Person-months	732.6	584.7	640.2
Event Rate / 100 Person-months	6.0	8.0	7.5
vs Placebo + Docetaxel			
Hazard Ratio (95% CI)[b]	0.76 (0.50, 1.15)	1.05 (0.70, 1.58)	
p-value[c]	0.0943	0.5974	
OS Rate at month 6 (%) (95% CI)	76.4 (65.8, 84.1)	55.4 (43.9, 65.5)	65.2 (54.0, 74.4)
OS Rate at month 12 (%) (95% CI)	47.6 (35.6, 58.6)	41.0 (29.8, 51.8)	37.5 (25.5, 49.4)
OS Rate at month 18 (%) (95% CI)	33.7 (19.4, 48.6)	NR (NR, NR)	32.5 (20.7, 44.9)

[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 ECOG (0 vs 1), PD-L1 TPS (<50% VS >=50%) and Prior anti-PD-1/PD-L1 mAb (immediate prior treatment vs not immediate prior treatment) with small strata collapsed as pre-specified in the sSAP .

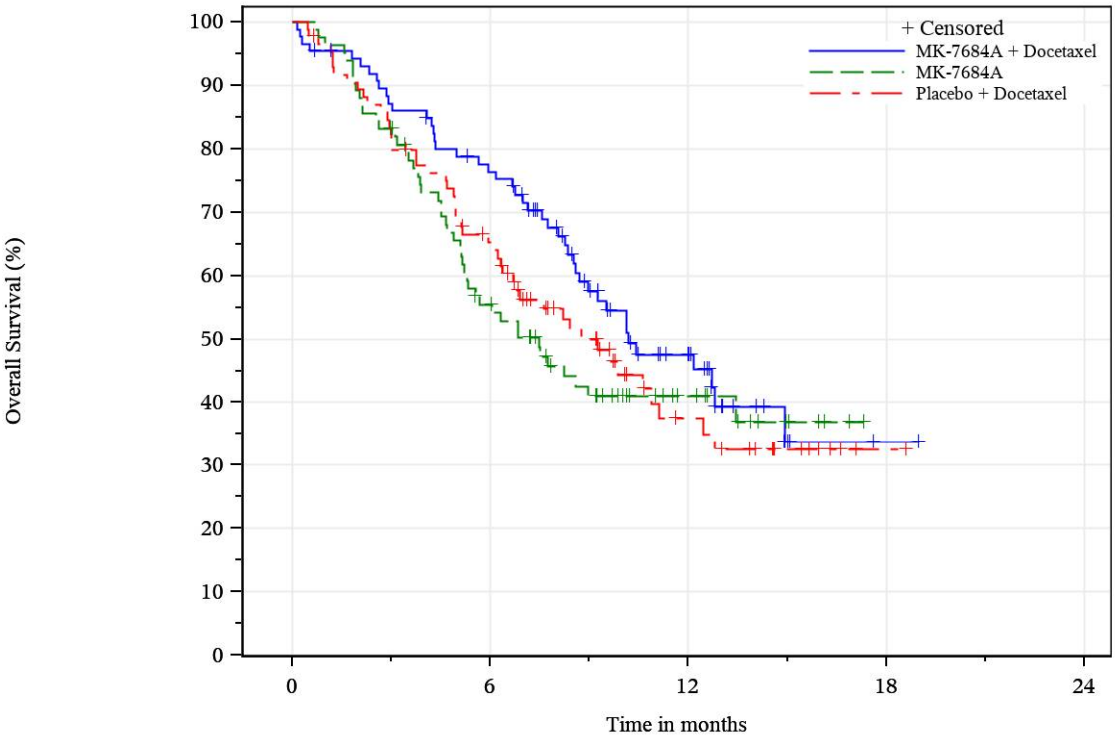
[c] One-sided p-value based on log-rank test stratified by ECOG (0 vs 1), PD-L1 TPS (<50% VS >=50%) and Prior anti-PD-1/PD-L1 mAb (immediate prior treatment vs not immediate prior treatment) with small strata collapsed as pre-specified in the sSAP .

NR = Not reached.

Database Cutoff Date: 26Jan2023

Source: [P002V01MK7684A: adam-adsl; adtte]

Figure 2-2
Kaplan-Meier Plot of Overall Survival
(ITT Population)



Number of participants at risk

MK-7684A + Docetaxel	87	63	22	1	0
MK-7684A	83	43	13	0	0
Placebo + Docetaxel	85	52	15	1	0

Database cutoff date: 26Jan2023
Source: [P002V01MK7684A: adam-adsl; adtte]

Table 2-6
Analysis of Objective Response (Confirmed) Based on BICR per RECIST 1.1
(ITT Population)

Treatment	N	Number of Responses	Objective Response Rate (%) (95% CI)	Difference in % vs. Placebo + Docetaxel	
				Estimate % (95% CI)[a]	p-Value[b]
MK-7684A + Docetaxel	87	26	29.9 (20.5, 40.6)	14.7 (2.1, 26.9)	0.0113
MK-7684A	83	5	6.0 (2.0, 13.5)	-9.4 (-19.6, 0.0)	0.9750
Placebo + Docetaxel	85	13	15.3 (8.4, 24.7)		

[a] Based on Miettinen & Nurminen method stratified by ECOG (0 vs 1), PD-L1 TPS (<50% vs >=50%) and Prior anti-PD-1/PD-L1 mAb (immediate prior treatment vs not immediate prior treatment) with small strata collapsed as pre-specified in the sSAP.

[b] One-sided p-value for testing. H0: difference in % = 0 versus H1: difference in % > 0.

Responses are based on BICR assessment per RECIST 1.1.

Database Cutoff Date: 26Jan2023.

Source: [P002V01MK7684A: adam-adsl; adrs]

Table 2-7
Summary of Best Objective Response (Confirmed) Based on BICR per RECIST 1.1
(ITT Population)

Response Evaluation	MK-7684A + Docetaxel			MK-7684A			Placebo + Docetaxel		
	n	%	95% CI[a]	n	%	95% CI[a]	n	%	95% CI[a]
Participants in population	**87**			**83**			**85**		
Complete Response (CR)	3	3.4	(0.7, 9.7)	1	1.2	(0.0, 6.5)	0	0.0	(0.0, 4.2)
Partial Response (PR)	23	26.4	(17.6, 37.0)	4	4.8	(1.3, 11.9)	13	15.3	(8.4, 24.7)
Overall Objective Response (CR+PR)	**26**	**29.9**	**(20.5, 40.6)**	**5**	**6.0**	**(2.0, 13.5)**	**13**	**15.3**	**(8.4, 24.7)**
Stable Disease (SD)	34	39.1	(28.8, 50.1)	38	45.8	(34.8, 57.1)	39	45.9	(35.0, 57.0)
Disease Control (SD+CR+PR)	**60**	**69.0**	**(58.1, 78.5)**	**43**	**51.8**	**(40.6, 62.9)**	**52**	**61.2**	**(50.0, 71.6)**
Progressive Disease (PD)	18	20.7	(12.7, 30.7)	31	37.3	(27.0, 48.7)	20	23.5	(15.0, 34.0)
Non-evaluable (NE)[b]	4	4.6	(1.3, 11.4)	4	4.8	(1.3, 11.9)	3	3.5	(0.7, 10.0)
No Assessment[c]	5	5.7	(1.9, 12.9)	5	6.0	(2.0, 13.5)	10	11.8	(5.8, 20.6)

[a]Based on the Exact method for binomial data.
[b]Not-evaluable (NE) includes subjects with insufficient data for assessment of response per RECIST 1.1.
[c]No Assessment includes subjects without post-baseline assessment on the data cutoff date.
Database cutoff date: 26Jan2023

Source: [P002V01MK7684A: adam-adsl; adrs]

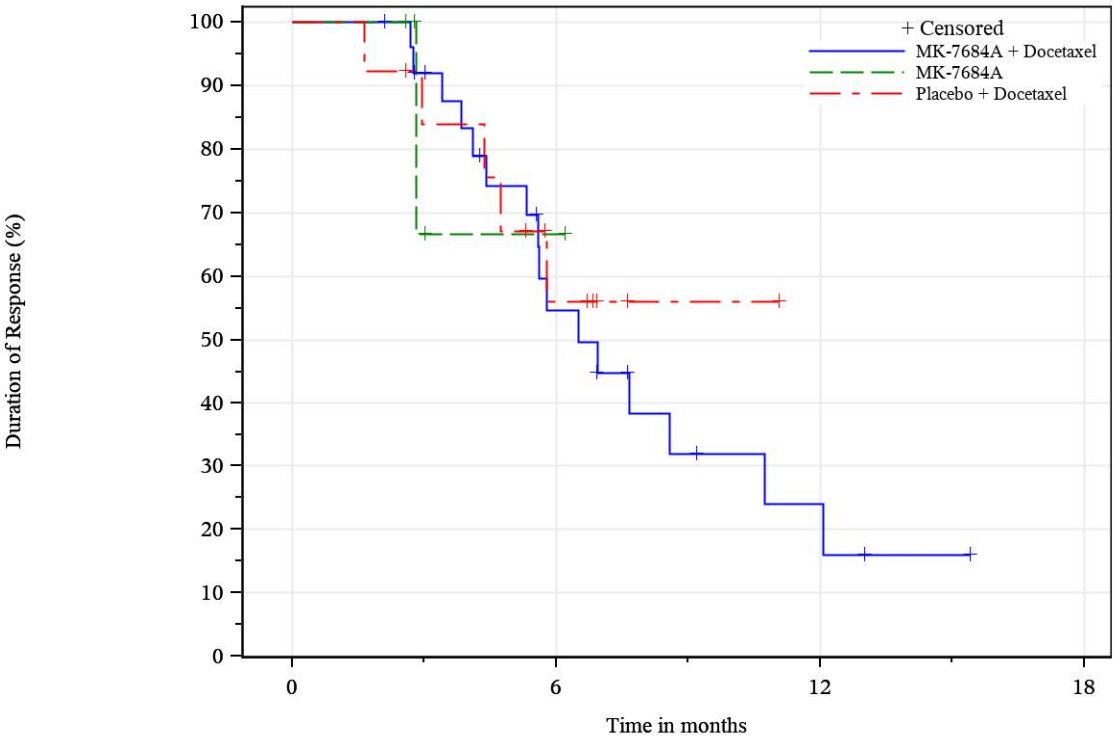
Table 2-8
Summary of Time to Response and Duration of Response
Based on BICR per RECIST 1.1 in Participants with a Confirmed Response
(ITT Population)

	MK-7684A + Docetaxel (N=87)	MK-7684A (N=83)	Placebo + Docetaxel (N=85)
Number of participants with response[a]	26	5	13
Time to Response (months)			
Mean (SD)	2.4 (1.5)	5.3 (4.6)	2.2 (1.3)
Median (Range)	1.8 (1.2-8.2)	4.1 (1.4-12.5)	1.6 (1.2-5.7)
Response Duration[b] (months)			
Median (Range)	6.5 (2.1+ - 15.4+)	NR (2.6+ - 6.2+)	NR (1.6 - 11.1+)
Number (%[b]) of Participants with Extended Response Duration:			
≥6 months	11 (54.7)	1 (66.7)	5 (55.9)
≥9 months	5 (31.9)	0 (NR)	1 (55.9)
≥12 months	3 (24.0)	0 (NR)	0 (NR)

[a] Includes participants with confirmed complete response or partial response
[b] From product-limit (Kaplan-Meier) method for censored data.
"+" indicates there is no progressive disease by the time of last disease assessment.
NR = Not Reached.
Database Cutoff Date: 26Jan2023

Source: [P002V01MK7684A: adam-adsl; adtte]

Figure 2-3
Kaplan-Meier Plot of Duration of Response
Based on BICR per RECIST 1.1
(In Participants with a Confirmed Response)



Number of participants at risk

MK-7684A + Docetaxel	26	11	3	0
MK-7684A	5	1	0	0
Placebo + Docetaxel	13	5	0	0

Database cutoff date: 26Jan2023
Source: [P002V01MK7684A: adam-adsl; adtte]

Table 2-9
Study Population

	MK-7684A + Docetaxel (N=87)		MK-7684A (N=83)		Placebo + Docetaxel (N=85)		Total (N=255)	
	n	(%)	n	(%)	n	(%)	n	(%)
Number of Participants Randomized (ITT)	87	(100.0)	83	(100.0)	85	(100.0)	255	(100.0)
Number of Participants Received Treatment (Actual Treatment) (APaT[a])	85	(97.7)	83	(100.0)	83	(97.6)	251	(98.4)
Number of Participants Randomized and Did not Receive Treatment	2	(2.3)	0	(0.0)	2	(2.4)	4	(1.6)
Number of Participants Discontinued Study Medication (Actual Treatment)	67	(77.0)	74	(89.2)	71	(83.5)	212	(83.1)
Number of Deaths (ITT)	44	(50.6)	47	(56.6)	48	(56.5)	139	(54.5)

[a]Consists of all participants randomized and received at least one dose of study treatment.
N is the number of all randomized participants, and used as the denominator for percentage calculation.
Database Cutoff Date: 26Jan2023

Source: [P002V01MK7684A: adam-adsl]

Table 2-10
Summary of Drug Exposure
(APaT Population)

	MK-7684A + Docetaxel (N=85)	MK-7684A (N=83)	Placebo + Docetaxel (N=83)
Study Days on Therapy (days)			
n	85	83	83
Mean (SD)	158.5 (122.8)	101.6 (109.4)	118.8 (113.4)
Median	120.0	64.0	77.0
Range	1.0 to 547.0	1.0 to 482.0	1.0 to 505.0
Number of Cycles			
n	85	83	83
Mean (SD)	7.7 (5.3)	5.4 (4.8)	6.3 (5.3)
Median	6.0	4.0	4.0
Range	1.0 to 25.0	1.0 to 23.0	1.0 to 25.0
Database Cutoff Date: 26Jan2023			

Source: [P002V01MK7684A: adam-adsl; adexsum]

Table 2-11
Participants With Adverse Events by Decreasing Incidence
(Incidence ≥10% in One or More Treatment Groups)
(APaT Population)

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Participants in population	85		83		83	
with one or more adverse events	85	(100.0)	75	(90.4)	82	(98.8)
with no adverse events	0	(0.0)	8	(9.6)	1	(1.2)
Diarrhoea	30	(35.3)	10	(12.0)	23	(27.7)
Pruritus	29	(34.1)	17	(20.5)	4	(4.8)
Anaemia	28	(32.9)	11	(13.3)	27	(32.5)
Asthenia	25	(29.4)	13	(15.7)	24	(28.9)
Alopecia	24	(28.2)	2	(2.4)	20	(24.1)
Fatigue	23	(27.1)	10	(12.0)	24	(28.9)
Nausea	23	(27.1)	11	(13.3)	22	(26.5)
Constipation	20	(23.5)	7	(8.4)	8	(9.6)
Rash	20	(23.5)	15	(18.1)	7	(8.4)
Dyspnoea	19	(22.4)	15	(18.1)	12	(14.5)
Decreased appetite	18	(21.2)	11	(13.3)	19	(22.9)
Neutrophil count decreased	16	(18.8)	0	(0.0)	16	(19.3)
COVID-19	15	(17.6)	7	(8.4)	8	(9.6)
Oedema peripheral	15	(17.6)	2	(2.4)	8	(9.6)
Stomatitis	14	(16.5)	1	(1.2)	4	(4.8)
Cough	13	(15.3)	5	(6.0)	11	(13.3)
Neuropathy peripheral	13	(15.3)	0	(0.0)	7	(8.4)

Participants With Adverse Events by Decreasing Incidence (Incidence ≥10% in One or More Treatment Groups) (APaT Population)

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Arthralgia	12	(14.1)	3	(3.6)	8	(9.6)
Dysgeusia	12	(14.1)	0	(0.0)	7	(8.4)
Vomiting	12	(14.1)	4	(4.8)	10	(12.0)
Weight decreased	11	(12.9)	4	(4.8)	9	(10.8)
Pneumonia	10	(11.8)	6	(7.2)	14	(16.9)
Pyrexia	8	(9.4)	5	(6.0)	11	(13.3)

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.

Non-serious adverse events occurring within 30 days after the last dose of study intervention and serious adverse events occurring within 90 days after the last dose of study intervention, or 30 days after the last dose of study intervention if a new anticancer therapy is initiated, whichever is earlier are included.

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

Adverse event terms are based on MedDRA version 25.1.

Database cutoff date: 26Jan2023

Source: [P002V01MK7684A: adam-adsl; adae]

Table 2-12
Participants With Adverse Events by System Organ Class and Preferred Term
(Incidence >0% in One or More Treatment Groups)
(APaT Population)

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Participants in population	85		83		83	
with one or more adverse events	85	(100.0)	75	(90.4)	82	(98.8)
with no adverse events	0	(0.0)	8	(9.6)	1	(1.2)
Blood and lymphatic system disorders	**32**	**(37.6)**	**11**	**(13.3)**	**31**	**(37.3)**
Anaemia	28	(32.9)	11	(13.3)	27	(32.5)
Eosinophilia	0	(0.0)	1	(1.2)	0	(0.0)
Febrile bone marrow aplasia	1	(1.2)	0	(0.0)	0	(0.0)
Febrile neutropenia	3	(3.5)	0	(0.0)	4	(4.8)
Haemorrhagic diathesis	0	(0.0)	0	(0.0)	1	(1.2)
Hyperleukocytosis	1	(1.2)	0	(0.0)	0	(0.0)
Leukocytosis	3	(3.5)	0	(0.0)	1	(1.2)
Lymphadenopathy	1	(1.2)	0	(0.0)	1	(1.2)
Cardiac disorders	**6**	**(7.1)**	**5**	**(6.0)**	**4**	**(4.8)**
Atrial fibrillation	1	(1.2)	1	(1.2)	2	(2.4)
Cardiac arrest	0	(0.0)	0	(0.0)	1	(1.2)
Cardiac failure	2	(2.4)	1	(1.2)	0	(0.0)
Myocardial infarction	0	(0.0)	1	(1.2)	0	(0.0)
Palpitations	1	(1.2)	0	(0.0)	1	(1.2)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Cardiac disorders	**6**	**(7.1)**	**5**	**(6.0)**	**4**	**(4.8)**
Pericardial effusion	1	(1.2)	2	(2.4)	0	(0.0)
Sinus tachycardia	1	(1.2)	0	(0.0)	0	(0.0)
Congenital, familial and genetic disorders	**1**	**(1.2)**	**0**	**(0.0)**	**0**	**(0.0)**
Phimosis	1	(1.2)	0	(0.0)	0	(0.0)
Ear and labyrinth disorders	**4**	**(4.7)**	**2**	**(2.4)**	**1**	**(1.2)**
Deafness	1	(1.2)	0	(0.0)	0	(0.0)
Ear pruritus	1	(1.2)	0	(0.0)	0	(0.0)
Ear swelling	1	(1.2)	0	(0.0)	0	(0.0)
External ear pain	1	(1.2)	0	(0.0)	0	(0.0)
Vertigo	0	(0.0)	2	(2.4)	1	(1.2)
Endocrine disorders	**12**	**(14.1)**	**6**	**(7.2)**	**3**	**(3.6)**
Adrenal insufficiency	2	(2.4)	0	(0.0)	0	(0.0)
Basedow's disease	0	(0.0)	1	(1.2)	0	(0.0)
Central hypothyroidism	1	(1.2)	0	(0.0)	0	(0.0)
Hyperthyroidism	4	(4.7)	2	(2.4)	2	(2.4)
Hypophysitis	1	(1.2)	0	(0.0)	0	(0.0)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Endocrine disorders	**12**	**(14.1)**	**6**	**(7.2)**	**3**	**(3.6)**
Hypothyroidism	5	(5.9)	4	(4.8)	1	(1.2)
Eye disorders	**16**	**(18.8)**	**1**	**(1.2)**	**8**	**(9.6)**
Blepharospasm	1	(1.2)	0	(0.0)	0	(0.0)
Cataract	1	(1.2)	0	(0.0)	0	(0.0)
Dry eye	2	(2.4)	0	(0.0)	2	(2.4)
Eye inflammation	1	(1.2)	0	(0.0)	0	(0.0)
Eye irritation	1	(1.2)	0	(0.0)	0	(0.0)
Eyelid disorder	1	(1.2)	0	(0.0)	0	(0.0)
Lacrimation increased	6	(7.1)	0	(0.0)	5	(6.0)
Ocular toxicity	1	(1.2)	0	(0.0)	0	(0.0)
Retinal detachment	1	(1.2)	0	(0.0)	0	(0.0)
Vision blurred	1	(1.2)	0	(0.0)	2	(2.4)
Visual acuity reduced	0	(0.0)	0	(0.0)	1	(1.2)
Visual impairment	1	(1.2)	1	(1.2)	0	(0.0)
Xerophthalmia	1	(1.2)	0	(0.0)	0	(0.0)
Gastrointestinal disorders	**57**	**(67.1)**	**29**	**(34.9)**	**45**	**(54.2)**
Abdominal discomfort	1	(1.2)	0	(0.0)	0	(0.0)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Gastrointestinal disorders	**57**	**(67.1)**	**29**	**(34.9)**	**45**	**(54.2)**
Abdominal pain	4	(4.7)	2	(2.4)	5	(6.0)
Abdominal pain upper	1	(1.2)	0	(0.0)	4	(4.8)
Anal fistula	1	(1.2)	0	(0.0)	0	(0.0)
Anal inflammation	1	(1.2)	0	(0.0)	0	(0.0)
Anal pruritus	1	(1.2)	0	(0.0)	0	(0.0)
Angular cheilitis	0	(0.0)	0	(0.0)	1	(1.2)
Aphthous ulcer	2	(2.4)	0	(0.0)	0	(0.0)
Ascites	1	(1.2)	0	(0.0)	1	(1.2)
Bowel movement irregularity	0	(0.0)	0	(0.0)	2	(2.4)
Colitis	1	(1.2)	1	(1.2)	1	(1.2)
Constipation	20	(23.5)	7	(8.4)	8	(9.6)
Dental caries	1	(1.2)	0	(0.0)	0	(0.0)
Diarrhoea	30	(35.3)	10	(12.0)	23	(27.7)
Diverticulum	0	(0.0)	1	(1.2)	0	(0.0)
Dry mouth	3	(3.5)	0	(0.0)	1	(1.2)
Dyspepsia	3	(3.5)	0	(0.0)	2	(2.4)
Dysphagia	1	(1.2)	1	(1.2)	0	(0.0)
Flatulence	0	(0.0)	0	(0.0)	1	(1.2)
Gastric ulcer	1	(1.2)	0	(0.0)	0	(0.0)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Gastrointestinal disorders	**57**	**(67.1)**	**29**	**(34.9)**	**45**	**(54.2)**
Gastritis	2	(2.4)	0	(0.0)	1	(1.2)
Gastrointestinal disorder	1	(1.2)	0	(0.0)	0	(0.0)
Gastrointestinal pain	1	(1.2)	0	(0.0)	0	(0.0)
Gastrointestinal toxicity	0	(0.0)	0	(0.0)	1	(1.2)
Gastrooesophageal reflux disease	0	(0.0)	1	(1.2)	3	(3.6)
Glossodynia	1	(1.2)	0	(0.0)	0	(0.0)
Haemorrhoidal haemorrhage	0	(0.0)	0	(0.0)	1	(1.2)
Haemorrhoids	3	(3.5)	1	(1.2)	2	(2.4)
Immune-mediated enterocolitis	1	(1.2)	0	(0.0)	0	(0.0)
Incarcerated inguinal hernia	0	(0.0)	1	(1.2)	0	(0.0)
Inguinal hernia	0	(0.0)	1	(1.2)	0	(0.0)
Intestinal haemorrhage	1	(1.2)	0	(0.0)	0	(0.0)
Intestinal perforation	0	(0.0)	1	(1.2)	0	(0.0)
Mouth ulceration	1	(1.2)	0	(0.0)	1	(1.2)
Nausea	23	(27.1)	11	(13.3)	22	(26.5)
Odynophagia	1	(1.2)	1	(1.2)	1	(1.2)
Oesophageal compression	0	(0.0)	1	(1.2)	0	(0.0)
Oral discomfort	0	(0.0)	0	(0.0)	1	(1.2)
Oral mucosal blistering	1	(1.2)	0	(0.0)	0	(0.0)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Gastrointestinal disorders	**57**	**(67.1)**	**29**	**(34.9)**	**45**	**(54.2)**
Oral pain	1	(1.2)	0	(0.0)	0	(0.0)
Periodontal disease	0	(0.0)	0	(0.0)	1	(1.2)
Rectal haemorrhage	1	(1.2)	0	(0.0)	0	(0.0)
Segmental diverticular colitis	0	(0.0)	1	(1.2)	0	(0.0)
Stomatitis	14	(16.5)	1	(1.2)	4	(4.8)
Upper gastrointestinal haemorrhage	1	(1.2)	0	(0.0)	0	(0.0)
Vomiting	12	(14.1)	4	(4.8)	10	(12.0)
General disorders and administration site conditions	**61**	**(71.8)**	**33**	**(39.8)**	**54**	**(65.1)**
Administration site extravasation	0	(0.0)	0	(0.0)	1	(1.2)
Asthenia	25	(29.4)	13	(15.7)	24	(28.9)
Capsular contracture associated with breast implant	0	(0.0)	1	(1.2)	0	(0.0)
Chest discomfort	0	(0.0)	0	(0.0)	1	(1.2)
Chest pain	1	(1.2)	3	(3.6)	5	(6.0)
Chills	1	(1.2)	0	(0.0)	2	(2.4)
Death	1	(1.2)	1	(1.2)	2	(2.4)
Fatigue	23	(27.1)	10	(12.0)	24	(28.9)
Feeling abnormal	1	(1.2)	0	(0.0)	0	(0.0)
Gait disturbance	0	(0.0)	1	(1.2)	0	(0.0)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
General disorders and administration site conditions	**61**	**(71.8)**	**33**	**(39.8)**	**54**	**(65.1)**
General physical health deterioration	3	(3.5)	1	(1.2)	1	(1.2)
Implant site extravasation	0	(0.0)	1	(1.2)	0	(0.0)
Inflammation	1	(1.2)	0	(0.0)	0	(0.0)
Infusion site extravasation	0	(0.0)	0	(0.0)	1	(1.2)
Infusion site pain	1	(1.2)	0	(0.0)	0	(0.0)
Localised oedema	1	(1.2)	0	(0.0)	0	(0.0)
Malaise	4	(4.7)	0	(0.0)	0	(0.0)
Mucosal dryness	1	(1.2)	0	(0.0)	0	(0.0)
Mucosal inflammation	6	(7.1)	1	(1.2)	3	(3.6)
Non-cardiac chest pain	0	(0.0)	0	(0.0)	1	(1.2)
Oedema	1	(1.2)	0	(0.0)	1	(1.2)
Oedema peripheral	15	(17.6)	2	(2.4)	8	(9.6)
Pain	1	(1.2)	2	(2.4)	2	(2.4)
Performance status decreased	1	(1.2)	0	(0.0)	0	(0.0)
Peripheral swelling	1	(1.2)	0	(0.0)	1	(1.2)
Pyrexia	8	(9.4)	5	(6.0)	11	(13.3)
Swelling	1	(1.2)	1	(1.2)	0	(0.0)
Swelling face	1	(1.2)	1	(1.2)	0	(0.0)
Xerosis	1	(1.2)	0	(0.0)	0	(0.0)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Hepatobiliary disorders	**1**	**(1.2)**	**0**	**(0.0)**	**1**	**(1.2)**
Cholestasis	1	(1.2)	0	(0.0)	0	(0.0)
Hypertransaminasaemia	0	(0.0)	0	(0.0)	1	(1.2)
Immune system disorders	**4**	**(4.7)**	**2**	**(2.4)**	**1**	**(1.2)**
Contrast media reaction	1	(1.2)	1	(1.2)	0	(0.0)
Drug hypersensitivity	0	(0.0)	0	(0.0)	1	(1.2)
Hypersensitivity	2	(2.4)	1	(1.2)	0	(0.0)
Infusion related hypersensitivity reaction	1	(1.2)	0	(0.0)	0	(0.0)
Infections and infestations	**48**	**(56.5)**	**25**	**(30.1)**	**37**	**(44.6)**
Abdominal sepsis	1	(1.2)	0	(0.0)	0	(0.0)
Abscess limb	1	(1.2)	0	(0.0)	0	(0.0)
Abscess neck	1	(1.2)	0	(0.0)	0	(0.0)
Bacteraemia	0	(0.0)	0	(0.0)	1	(1.2)
Bronchitis	2	(2.4)	2	(2.4)	3	(3.6)
Burkholderia pseudomallei infection	0	(0.0)	0	(0.0)	1	(1.2)
COVID-19	15	(17.6)	7	(8.4)	8	(9.6)
COVID-19 pneumonia	0	(0.0)	2	(2.4)	1	(1.2)
Cellulitis	2	(2.4)	0	(0.0)	0	(0.0)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Infections and infestations	**48**	**(56.5)**	**25**	**(30.1)**	**37**	**(44.6)**
Clostridium difficile colitis	0	(0.0)	0	(0.0)	1	(1.2)
Cystitis	3	(3.5)	0	(0.0)	1	(1.2)
Device related bacteraemia	1	(1.2)	0	(0.0)	0	(0.0)
Diverticulitis intestinal perforated	0	(0.0)	0	(0.0)	1	(1.2)
Enterococcal infection	1	(1.2)	0	(0.0)	0	(0.0)
Fungal infection	1	(1.2)	0	(0.0)	0	(0.0)
Gangrene	1	(1.2)	0	(0.0)	0	(0.0)
Gastroenteritis	1	(1.2)	0	(0.0)	0	(0.0)
Genital candidiasis	1	(1.2)	0	(0.0)	0	(0.0)
Genital infection fungal	1	(1.2)	0	(0.0)	0	(0.0)
Herpes virus infection	0	(0.0)	0	(0.0)	1	(1.2)
Herpes zoster	1	(1.2)	2	(2.4)	3	(3.6)
Hordeolum	0	(0.0)	1	(1.2)	0	(0.0)
Impetigo	1	(1.2)	0	(0.0)	0	(0.0)
Infection	2	(2.4)	0	(0.0)	0	(0.0)
Infectious pleural effusion	0	(0.0)	0	(0.0)	1	(1.2)
Influenza	1	(1.2)	2	(2.4)	1	(1.2)
Large intestine infection	1	(1.2)	0	(0.0)	0	(0.0)
Laryngitis	1	(1.2)	0	(0.0)	0	(0.0)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Infections and infestations	**48**	**(56.5)**	**25**	**(30.1)**	**37**	**(44.6)**
Lower respiratory tract infection	0	(0.0)	0	(0.0)	4	(4.8)
Nasopharyngitis	3	(3.5)	1	(1.2)	1	(1.2)
Neutropenic sepsis	1	(1.2)	0	(0.0)	1	(1.2)
Onychomycosis	1	(1.2)	0	(0.0)	0	(0.0)
Ophthalmic herpes zoster	1	(1.2)	0	(0.0)	0	(0.0)
Oral candidiasis	5	(5.9)	1	(1.2)	1	(1.2)
Oral fungal infection	1	(1.2)	0	(0.0)	0	(0.0)
Oral herpes	0	(0.0)	0	(0.0)	1	(1.2)
Oropharyngeal candidiasis	1	(1.2)	0	(0.0)	0	(0.0)
Paronychia	2	(2.4)	1	(1.2)	1	(1.2)
Pharyngitis	2	(2.4)	0	(0.0)	0	(0.0)
Pneumonia	10	(11.8)	6	(7.2)	14	(16.9)
Pneumonia aspiration	0	(0.0)	0	(0.0)	1	(1.2)
Pneumonia haemophilus	0	(0.0)	0	(0.0)	1	(1.2)
Post-acute COVID-19 syndrome	0	(0.0)	0	(0.0)	1	(1.2)
Postoperative wound infection	1	(1.2)	0	(0.0)	0	(0.0)
Rash pustular	1	(1.2)	0	(0.0)	0	(0.0)
Respiratory syncytial virus infection	0	(0.0)	0	(0.0)	1	(1.2)
Respiratory tract infection	1	(1.2)	1	(1.2)	2	(2.4)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Infections and infestations	**48**	**(56.5)**	**25**	**(30.1)**	**37**	**(44.6)**
Respiratory tract infection viral	1	(1.2)	0	(0.0)	0	(0.0)
Rhinitis	4	(4.7)	0	(0.0)	1	(1.2)
Sepsis	0	(0.0)	1	(1.2)	0	(0.0)
Septic shock	3	(3.5)	0	(0.0)	0	(0.0)
Sinusitis	0	(0.0)	1	(1.2)	0	(0.0)
Skin candida	1	(1.2)	0	(0.0)	0	(0.0)
Soft tissue infection	0	(0.0)	0	(0.0)	1	(1.2)
Stoma site infection	1	(1.2)	0	(0.0)	0	(0.0)
Sweating fever	1	(1.2)	0	(0.0)	0	(0.0)
Tooth abscess	1	(1.2)	0	(0.0)	0	(0.0)
Tooth infection	1	(1.2)	0	(0.0)	0	(0.0)
Upper respiratory tract infection	3	(3.5)	1	(1.2)	1	(1.2)
Urinary tract infection	4	(4.7)	2	(2.4)	3	(3.6)
Injury, poisoning and procedural complications	**10**	**(11.8)**	**6**	**(7.2)**	**6**	**(7.2)**
Burn oral cavity	0	(0.0)	0	(0.0)	1	(1.2)
Chemical burns of eye	0	(0.0)	0	(0.0)	1	(1.2)
Contusion	1	(1.2)	0	(0.0)	0	(0.0)
Fall	4	(4.7)	0	(0.0)	2	(2.4)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Injury, poisoning and procedural complications	**10**	**(11.8)**	**6**	**(7.2)**	**6**	**(7.2)**
Femur fracture	0	(0.0)	1	(1.2)	0	(0.0)
Head injury	0	(0.0)	1	(1.2)	0	(0.0)
Hip fracture	2	(2.4)	0	(0.0)	0	(0.0)
Humerus fracture	1	(1.2)	0	(0.0)	0	(0.0)
Infusion related reaction	1	(1.2)	1	(1.2)	1	(1.2)
Lumbar vertebral fracture	0	(0.0)	0	(0.0)	1	(1.2)
Nail injury	0	(0.0)	1	(1.2)	0	(0.0)
Post-traumatic pain	0	(0.0)	1	(1.2)	0	(0.0)
Procedural complication	0	(0.0)	1	(1.2)	0	(0.0)
Skin injury	0	(0.0)	1	(1.2)	0	(0.0)
Subdural haematoma	0	(0.0)	0	(0.0)	1	(1.2)
Sunburn	1	(1.2)	0	(0.0)	0	(0.0)
Thoracic vertebral fracture	0	(0.0)	1	(1.2)	0	(0.0)
Investigations	**40**	**(47.1)**	**14**	**(16.9)**	**34**	**(41.0)**
Alanine aminotransferase increased	2	(2.4)	1	(1.2)	1	(1.2)
Amylase increased	2	(2.4)	5	(6.0)	1	(1.2)
Anti-thyroid antibody increased	1	(1.2)	0	(0.0)	0	(0.0)
Aspartate aminotransferase increased	3	(3.5)	2	(2.4)	0	(0.0)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Investigations	**40**	**(47.1)**	**14**	**(16.9)**	**34**	**(41.0)**
Blood alkaline phosphatase increased	3	(3.5)	2	(2.4)	0	(0.0)
Blood creatine phosphokinase increased	0	(0.0)	0	(0.0)	1	(1.2)
Blood creatinine increased	5	(5.9)	0	(0.0)	2	(2.4)
Blood glucose increased	3	(3.5)	0	(0.0)	0	(0.0)
Blood lactate dehydrogenase increased	1	(1.2)	1	(1.2)	2	(2.4)
Blood potassium decreased	1	(1.2)	0	(0.0)	0	(0.0)
Blood sodium decreased	1	(1.2)	1	(1.2)	0	(0.0)
Blood thyroid stimulating hormone decreased	1	(1.2)	0	(0.0)	1	(1.2)
Blood thyroid stimulating hormone increased	4	(4.7)	0	(0.0)	0	(0.0)
Blood urea increased	0	(0.0)	1	(1.2)	0	(0.0)
C-reactive protein increased	1	(1.2)	1	(1.2)	1	(1.2)
Cortisol decreased	1	(1.2)	0	(0.0)	0	(0.0)
Gamma-glutamyltransferase increased	4	(4.7)	1	(1.2)	0	(0.0)
Glycosylated haemoglobin increased	1	(1.2)	0	(0.0)	0	(0.0)
Haemoglobin decreased	0	(0.0)	1	(1.2)	2	(2.4)
Lipase increased	1	(1.2)	5	(6.0)	1	(1.2)
Lymphocyte count decreased	2	(2.4)	0	(0.0)	2	(2.4)
Neutrophil count decreased	16	(18.8)	0	(0.0)	16	(19.3)
Neutrophil count increased	1	(1.2)	0	(0.0)	0	(0.0)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Investigations	**40**	**(47.1)**	**14**	**(16.9)**	**34**	**(41.0)**
Pancreatic enzymes increased	0	(0.0)	0	(0.0)	1	(1.2)
Platelet count decreased	2	(2.4)	0	(0.0)	3	(3.6)
Protein urine present	0	(0.0)	1	(1.2)	0	(0.0)
SARS-CoV-2 test positive	1	(1.2)	0	(0.0)	0	(0.0)
Thyroxine free decreased	1	(1.2)	0	(0.0)	0	(0.0)
Thyroxine free increased	1	(1.2)	0	(0.0)	0	(0.0)
Urine analysis abnormal	1	(1.2)	0	(0.0)	0	(0.0)
Weight decreased	11	(12.9)	4	(4.8)	9	(10.8)
Weight increased	1	(1.2)	0	(0.0)	2	(2.4)
White blood cell count decreased	4	(4.7)	0	(0.0)	2	(2.4)
White blood cell count increased	1	(1.2)	1	(1.2)	1	(1.2)
Metabolism and nutrition disorders	**34**	**(40.0)**	**20**	**(24.1)**	**31**	**(37.3)**
Decreased appetite	18	(21.2)	11	(13.3)	19	(22.9)
Dehydration	2	(2.4)	0	(0.0)	1	(1.2)
Diabetes mellitus	0	(0.0)	0	(0.0)	1	(1.2)
Electrolyte imbalance	0	(0.0)	0	(0.0)	1	(1.2)
Fluid retention	0	(0.0)	0	(0.0)	1	(1.2)
Gout	0	(0.0)	0	(0.0)	1	(1.2)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Metabolism and nutrition disorders	**34**	**(40.0)**	**20**	**(24.1)**	**31**	**(37.3)**
Hypercalcaemia	1	(1.2)	4	(4.8)	2	(2.4)
Hyperglycaemia	6	(7.1)	2	(2.4)	3	(3.6)
Hyperkalaemia	0	(0.0)	1	(1.2)	0	(0.0)
Hyperphosphataemia	1	(1.2)	0	(0.0)	0	(0.0)
Hypoalbuminaemia	2	(2.4)	1	(1.2)	1	(1.2)
Hypocalcaemia	2	(2.4)	1	(1.2)	2	(2.4)
Hypoglycaemia	0	(0.0)	1	(1.2)	0	(0.0)
Hypokalaemia	6	(7.1)	3	(3.6)	3	(3.6)
Hypomagnesaemia	5	(5.9)	2	(2.4)	2	(2.4)
Hyponatraemia	2	(2.4)	1	(1.2)	1	(1.2)
Hypophagia	1	(1.2)	0	(0.0)	0	(0.0)
Hypophosphataemia	1	(1.2)	1	(1.2)	1	(1.2)
Iron deficiency	0	(0.0)	0	(0.0)	1	(1.2)
Malnutrition	0	(0.0)	1	(1.2)	0	(0.0)
Vitamin B12 deficiency	0	(0.0)	0	(0.0)	1	(1.2)
Musculoskeletal and connective tissue disorders	**30**	**(35.3)**	**18**	**(21.7)**	**23**	**(27.7)**
Arthralgia	12	(14.1)	3	(3.6)	8	(9.6)
Back pain	3	(3.5)	3	(3.6)	2	(2.4)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Musculoskeletal and connective tissue disorders	**30**	**(35.3)**	**18**	**(21.7)**	**23**	**(27.7)**
Bone pain	2	(2.4)	4	(4.8)	0	(0.0)
Flank pain	2	(2.4)	0	(0.0)	0	(0.0)
Groin pain	0	(0.0)	1	(1.2)	0	(0.0)
Hypercreatinaemia	0	(0.0)	0	(0.0)	1	(1.2)
Limb discomfort	1	(1.2)	0	(0.0)	0	(0.0)
Muscle contracture	0	(0.0)	0	(0.0)	2	(2.4)
Muscle oedema	1	(1.2)	0	(0.0)	0	(0.0)
Muscle spasms	0	(0.0)	0	(0.0)	1	(1.2)
Muscular weakness	2	(2.4)	0	(0.0)	2	(2.4)
Musculoskeletal chest pain	2	(2.4)	1	(1.2)	0	(0.0)
Musculoskeletal pain	1	(1.2)	2	(2.4)	3	(3.6)
Myalgia	7	(8.2)	1	(1.2)	6	(7.2)
Neck mass	0	(0.0)	0	(0.0)	1	(1.2)
Neck pain	1	(1.2)	2	(2.4)	1	(1.2)
Osteolysis	0	(0.0)	1	(1.2)	0	(0.0)
Osteonecrosis of jaw	1	(1.2)	0	(0.0)	0	(0.0)
Osteoporosis	1	(1.2)	0	(0.0)	0	(0.0)
Osteoporotic fracture	1	(1.2)	0	(0.0)	0	(0.0)
Pain in extremity	5	(5.9)	3	(3.6)	4	(4.8)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Musculoskeletal and connective tissue disorders	**30**	**(35.3)**	**18**	**(21.7)**	**23**	**(27.7)**
Pathological fracture	1	(1.2)	0	(0.0)	0	(0.0)
Sacral pain	0	(0.0)	1	(1.2)	0	(0.0)
Tendon pain	0	(0.0)	1	(1.2)	0	(0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**2**	**(2.4)**	**3**	**(3.6)**	**4**	**(4.8)**
Basal cell carcinoma	1	(1.2)	0	(0.0)	0	(0.0)
Cancer fatigue	0	(0.0)	0	(0.0)	1	(1.2)
Cancer pain	1	(1.2)	0	(0.0)	1	(1.2)
Malignant pleural effusion	0	(0.0)	1	(1.2)	1	(1.2)
Tumour compression	0	(0.0)	1	(1.2)	0	(0.0)
Tumour haemorrhage	0	(0.0)	1	(1.2)	0	(0.0)
Tumour pain	0	(0.0)	0	(0.0)	1	(1.2)
Nervous system disorders	**41**	**(48.2)**	**12**	**(14.5)**	**27**	**(32.5)**
Ageusia	2	(2.4)	0	(0.0)	2	(2.4)
Anosmia	1	(1.2)	0	(0.0)	0	(0.0)
Brain stem stroke	0	(0.0)	1	(1.2)	0	(0.0)
Cerebrovascular accident	1	(1.2)	1	(1.2)	0	(0.0)

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(APaT Population)

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Nervous system disorders	**41**	**(48.2)**	**12**	**(14.5)**	**27**	**(32.5)**
Cognitive disorder	1	(1.2)	0	(0.0)	0	(0.0)
Dizziness	2	(2.4)	3	(3.6)	2	(2.4)
Dysgeusia	12	(14.1)	0	(0.0)	7	(8.4)
Epilepsy	1	(1.2)	0	(0.0)	0	(0.0)
Headache	3	(3.5)	3	(3.6)	2	(2.4)
Hyperaesthesia	1	(1.2)	0	(0.0)	0	(0.0)
Hypoaesthesia	1	(1.2)	0	(0.0)	1	(1.2)
Lethargy	1	(1.2)	0	(0.0)	0	(0.0)
Memory impairment	1	(1.2)	0	(0.0)	0	(0.0)
Migraine	1	(1.2)	0	(0.0)	0	(0.0)
Neuralgia	0	(0.0)	1	(1.2)	0	(0.0)
Neuropathy peripheral	13	(15.3)	0	(0.0)	7	(8.4)
Neurotoxicity	0	(0.0)	0	(0.0)	2	(2.4)
Occipital neuralgia	0	(0.0)	1	(1.2)	0	(0.0)
Paraesthesia	4	(4.7)	1	(1.2)	6	(7.2)
Peripheral sensorimotor neuropathy	1	(1.2)	0	(0.0)	0	(0.0)
Peripheral sensory neuropathy	3	(3.5)	0	(0.0)	3	(3.6)
Polyneuropathy	3	(3.5)	0	(0.0)	0	(0.0)
Sciatic nerve neuropathy	0	(0.0)	1	(1.2)	0	(0.0)

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(APaT Population)

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Nervous system disorders	**41**	**(48.2)**	**12**	**(14.5)**	**27**	**(32.5)**
Sciatica	0	(0.0)	1	(1.2)	0	(0.0)
Seizure	0	(0.0)	0	(0.0)	1	(1.2)
Syncope	0	(0.0)	0	(0.0)	2	(2.4)
Taste disorder	2	(2.4)	0	(0.0)	1	(1.2)
Tremor	1	(1.2)	0	(0.0)	0	(0.0)
Vocal cord paralysis	0	(0.0)	0	(0.0)	1	(1.2)
Product issues	**0**	**(0.0)**	**1**	**(1.2)**	**0**	**(0.0)**
Thrombosis in device	0	(0.0)	1	(1.2)	0	(0.0)
Psychiatric disorders	**12**	**(14.1)**	**4**	**(4.8)**	**4**	**(4.8)**
Anxiety	1	(1.2)	0	(0.0)	0	(0.0)
Delirium	0	(0.0)	1	(1.2)	0	(0.0)
Depression	2	(2.4)	0	(0.0)	0	(0.0)
Insomnia	8	(9.4)	3	(3.6)	3	(3.6)
Irritability	1	(1.2)	0	(0.0)	0	(0.0)
Mood swings	0	(0.0)	1	(1.2)	0	(0.0)
Nervousness	0	(0.0)	0	(0.0)	1	(1.2)
Sleep disorder	1	(1.2)	0	(0.0)	0	(0.0)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Renal and urinary disorders	**6**	**(7.1)**	**7**	**(8.4)**	**0**	**(0.0)**
Acute kidney injury	1	(1.2)	0	(0.0)	0	(0.0)
Dysuria	1	(1.2)	0	(0.0)	0	(0.0)
Haematuria	0	(0.0)	1	(1.2)	0	(0.0)
Nocturia	0	(0.0)	1	(1.2)	0	(0.0)
Polyuria	1	(1.2)	0	(0.0)	0	(0.0)
Proteinuria	0	(0.0)	1	(1.2)	0	(0.0)
Renal failure	1	(1.2)	1	(1.2)	0	(0.0)
Renal impairment	1	(1.2)	0	(0.0)	0	(0.0)
Ureterolithiasis	0	(0.0)	1	(1.2)	0	(0.0)
Urinary incontinence	1	(1.2)	0	(0.0)	0	(0.0)
Urinary retention	0	(0.0)	2	(2.4)	0	(0.0)
Reproductive system and breast disorders	**4**	**(4.7)**	**2**	**(2.4)**	**0**	**(0.0)**
Balanoposthitis	1	(1.2)	0	(0.0)	0	(0.0)
Pruritus genital	1	(1.2)	0	(0.0)	0	(0.0)
Scrotal ulcer	1	(1.2)	0	(0.0)	0	(0.0)
Testicular hypertrophy	0	(0.0)	1	(1.2)	0	(0.0)
Vulvovaginal dryness	0	(0.0)	1	(1.2)	0	(0.0)
Vulvovaginal pruritus	1	(1.2)	0	(0.0)	0	(0.0)

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(APaT Population)

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Respiratory, thoracic and mediastinal disorders	**39**	**(45.9)**	**31**	**(37.3)**	**40**	**(48.2)**
Acute pulmonary oedema	1	(1.2)	0	(0.0)	0	(0.0)
Acute respiratory distress syndrome	1	(1.2)	0	(0.0)	0	(0.0)
Acute respiratory failure	1	(1.2)	0	(0.0)	0	(0.0)
Aphonia	1	(1.2)	0	(0.0)	0	(0.0)
Asthma	0	(0.0)	0	(0.0)	1	(1.2)
Bronchial obstruction	0	(0.0)	0	(0.0)	2	(2.4)
Bronchospasm	0	(0.0)	2	(2.4)	0	(0.0)
Chronic obstructive pulmonary disease	1	(1.2)	2	(2.4)	3	(3.6)
Cough	13	(15.3)	5	(6.0)	11	(13.3)
Dysphonia	0	(0.0)	0	(0.0)	3	(3.6)
Dyspnoea	19	(22.4)	15	(18.1)	12	(14.5)
Dyspnoea exertional	0	(0.0)	1	(1.2)	2	(2.4)
Epistaxis	1	(1.2)	0	(0.0)	4	(4.8)
Haemoptysis	3	(3.5)	2	(2.4)	6	(7.2)
Hiccups	0	(0.0)	0	(0.0)	2	(2.4)
Hypoxia	0	(0.0)	0	(0.0)	1	(1.2)
Immune-mediated lung disease	1	(1.2)	1	(1.2)	0	(0.0)
Interstitial lung disease	2	(2.4)	0	(0.0)	0	(0.0)
Lung disorder	1	(1.2)	0	(0.0)	0	(0.0)

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	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Respiratory, thoracic and mediastinal disorders	**39**	**(45.9)**	**31**	**(37.3)**	**40**	**(48.2)**
Nasal dryness	2	(2.4)	0	(0.0)	1	(1.2)
Nasal inflammation	0	(0.0)	0	(0.0)	1	(1.2)
Oropharyngeal pain	2	(2.4)	1	(1.2)	0	(0.0)
Pleural effusion	0	(0.0)	2	(2.4)	3	(3.6)
Pleurisy	0	(0.0)	1	(1.2)	0	(0.0)
Pneumonitis	3	(3.5)	5	(6.0)	5	(6.0)
Productive cough	2	(2.4)	0	(0.0)	1	(1.2)
Pulmonary embolism	0	(0.0)	2	(2.4)	2	(2.4)
Pulmonary toxicity	0	(0.0)	1	(1.2)	0	(0.0)
Respiratory failure	1	(1.2)	0	(0.0)	1	(1.2)
Rhinitis allergic	1	(1.2)	0	(0.0)	0	(0.0)
Rhinorrhoea	4	(4.7)	1	(1.2)	3	(3.6)
Sneezing	0	(0.0)	0	(0.0)	1	(1.2)
Tachypnoea	0	(0.0)	0	(0.0)	1	(1.2)
Skin and subcutaneous tissue disorders	**56**	**(65.9)**	**32**	**(38.6)**	**41**	**(49.4)**
Alopecia	24	(28.2)	2	(2.4)	20	(24.1)
Blood blister	0	(0.0)	0	(0.0)	1	(1.2)
Dermal cyst	1	(1.2)	0	(0.0)	0	(0.0)

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(APaT Population)

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Skin and subcutaneous tissue disorders	**56**	**(65.9)**	**32**	**(38.6)**	**41**	**(49.4)**
Dermatitis	1	(1.2)	2	(2.4)	0	(0.0)
Dermatitis acneiform	0	(0.0)	0	(0.0)	1	(1.2)
Dermatitis exfoliative generalised	1	(1.2)	0	(0.0)	0	(0.0)
Drug eruption	2	(2.4)	1	(1.2)	0	(0.0)
Dry skin	6	(7.1)	2	(2.4)	3	(3.6)
Eczema	7	(8.2)	0	(0.0)	2	(2.4)
Erythema	2	(2.4)	1	(1.2)	1	(1.2)
Hyperhidrosis	0	(0.0)	1	(1.2)	4	(4.8)
Lichenification	1	(1.2)	0	(0.0)	0	(0.0)
Nail discolouration	1	(1.2)	0	(0.0)	1	(1.2)
Nail disorder	7	(8.2)	0	(0.0)	4	(4.8)
Nail dystrophy	0	(0.0)	0	(0.0)	1	(1.2)
Nail toxicity	1	(1.2)	0	(0.0)	5	(6.0)
Night sweats	1	(1.2)	0	(0.0)	0	(0.0)
Onychalgia	1	(1.2)	0	(0.0)	0	(0.0)
Onychoclasis	1	(1.2)	0	(0.0)	0	(0.0)
Onycholysis	4	(4.7)	0	(0.0)	0	(0.0)
Onychomadesis	0	(0.0)	0	(0.0)	2	(2.4)
Pain of skin	1	(1.2)	0	(0.0)	0	(0.0)

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(APaT Population)

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Skin and subcutaneous tissue disorders	**56**	**(65.9)**	**32**	**(38.6)**	**41**	**(49.4)**
Palmar erythema	1	(1.2)	0	(0.0)	0	(0.0)
Palmar-plantar erythrodysaesthesia syndrome	4	(4.7)	1	(1.2)	5	(6.0)
Papule	0	(0.0)	0	(0.0)	1	(1.2)
Pemphigoid	1	(1.2)	0	(0.0)	0	(0.0)
Photosensitivity reaction	1	(1.2)	0	(0.0)	0	(0.0)
Pruritus	29	(34.1)	17	(20.5)	4	(4.8)
Pseudofolliculitis	0	(0.0)	0	(0.0)	1	(1.2)
Psoriasis	1	(1.2)	0	(0.0)	0	(0.0)
Rash	20	(23.5)	15	(18.1)	7	(8.4)
Rash erythematous	0	(0.0)	1	(1.2)	0	(0.0)
Rash macular	0	(0.0)	2	(2.4)	0	(0.0)
Rash maculo-papular	2	(2.4)	1	(1.2)	1	(1.2)
Rash morbilliform	1	(1.2)	0	(0.0)	0	(0.0)
Rash pruritic	2	(2.4)	2	(2.4)	0	(0.0)
Skin exfoliation	2	(2.4)	0	(0.0)	0	(0.0)
Skin fissures	1	(1.2)	0	(0.0)	0	(0.0)
Skin hyperpigmentation	0	(0.0)	0	(0.0)	1	(1.2)
Skin lesion	2	(2.4)	0	(0.0)	1	(1.2)
Skin mass	1	(1.2)	0	(0.0)	0	(0.0)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Skin and subcutaneous tissue disorders	**56**	**(65.9)**	**32**	**(38.6)**	**41**	**(49.4)**
Skin reaction	1	(1.2)	0	(0.0)	0	(0.0)
Skin toxicity	2	(2.4)	0	(0.0)	1	(1.2)
Skin ulcer	1	(1.2)	0	(0.0)	0	(0.0)
Toxic skin eruption	1	(1.2)	1	(1.2)	0	(0.0)
Urticaria	0	(0.0)	1	(1.2)	0	(0.0)
Surgical and medical procedures	**1**	**(1.2)**	**0**	**(0.0)**	**1**	**(1.2)**
Euthanasia	1	(1.2)	0	(0.0)	1	(1.2)
Vascular disorders	**15**	**(17.6)**	**10**	**(12.0)**	**9**	**(10.8)**
Blood pressure fluctuation	0	(0.0)	1	(1.2)	0	(0.0)
Deep vein thrombosis	0	(0.0)	1	(1.2)	3	(3.6)
Embolism	0	(0.0)	0	(0.0)	1	(1.2)
Flushing	1	(1.2)	1	(1.2)	0	(0.0)
Haematoma	1	(1.2)	0	(0.0)	0	(0.0)
Hot flush	1	(1.2)	0	(0.0)	1	(1.2)
Hypertension	5	(5.9)	3	(3.6)	1	(1.2)
Hypotension	2	(2.4)	3	(3.6)	0	(0.0)
Hypovolaemic shock	1	(1.2)	0	(0.0)	0	(0.0)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Vascular disorders	**15**	**(17.6)**	**10**	**(12.0)**	**9**	**(10.8)**
Lymphoedema	0	(0.0)	1	(1.2)	0	(0.0)
Orthostatic hypotension	0	(0.0)	1	(1.2)	0	(0.0)
Phlebitis	0	(0.0)	0	(0.0)	1	(1.2)
Superficial vein thrombosis	0	(0.0)	0	(0.0)	1	(1.2)
Superior vena cava occlusion	1	(1.2)	0	(0.0)	0	(0.0)
Superior vena cava syndrome	0	(0.0)	0	(0.0)	2	(2.4)
Thrombophlebitis	2	(2.4)	0	(0.0)	0	(0.0)
Vasculitis	0	(0.0)	1	(1.2)	0	(0.0)
Vein disorder	1	(1.2)	0	(0.0)	0	(0.0)

Every participant is counted a single time for each applicable row and column.

Non-serious adverse events occurring within 30 days after the last dose of study intervention and serious adverse events occurring within 90 days after the last dose of study intervention, or 30 days after the last dose of study intervention if a new anticancer therapy is initiated, whichever is earlier are included.

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

Adverse event terms are based on MedDRA version 25.1.

Database cutoff date: 26Jan2023

Source: [P002V01MK7684A: 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 + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Participants in population	85		83		83	
with one or more drug-related adverse events	82	(96.5)	50	(60.2)	74	(89.2)
with no drug-related adverse events	3	(3.5)	33	(39.8)	9	(10.8)
Pruritus	25	(29.4)	11	(13.3)	3	(3.6)
Alopecia	24	(28.2)	2	(2.4)	19	(22.9)
Anaemia	24	(28.2)	1	(1.2)	23	(27.7)
Diarrhoea	23	(27.1)	7	(8.4)	19	(22.9)
Fatigue	22	(25.9)	4	(4.8)	21	(25.3)
Nausea	20	(23.5)	6	(7.2)	19	(22.9)
Rash	20	(23.5)	13	(15.7)	5	(6.0)
Asthenia	19	(22.4)	8	(9.6)	16	(19.3)
Neutrophil count decreased	16	(18.8)	0	(0.0)	16	(19.3)
Decreased appetite	15	(17.6)	6	(7.2)	14	(16.9)
Stomatitis	14	(16.5)	1	(1.2)	4	(4.8)
Neuropathy peripheral	13	(15.3)	0	(0.0)	5	(6.0)
Dysgeusia	11	(12.9)	0	(0.0)	5	(6.0)
Constipation	9	(10.6)	0	(0.0)	6	(7.2)
Vomiting	9	(10.6)	1	(1.2)	9	(10.8)
Arthralgia	7	(8.2)	0	(0.0)	4	(4.8)
Eczema	7	(8.2)	0	(0.0)	2	(2.4)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Dry skin	6	(7.1)	1	(1.2)	3	(3.6)
Lacrimation increased	6	(7.1)	0	(0.0)	4	(4.8)
Nail disorder	6	(7.1)	0	(0.0)	4	(4.8)
Oedema peripheral	6	(7.1)	0	(0.0)	6	(7.2)
Weight decreased	6	(7.1)	1	(1.2)	5	(6.0)
Dyspnoea	5	(5.9)	0	(0.0)	2	(2.4)
Mucosal inflammation	5	(5.9)	0	(0.0)	3	(3.6)
Pyrexia	5	(5.9)	0	(0.0)	4	(4.8)
Hypomagnesaemia	4	(4.7)	0	(0.0)	1	(1.2)
Hypothyroidism	4	(4.7)	3	(3.6)	0	(0.0)
Malaise	4	(4.7)	0	(0.0)	0	(0.0)
Myalgia	4	(4.7)	1	(1.2)	5	(6.0)
Palmar-plantar erythrodysaesthesia syndrome	4	(4.7)	0	(0.0)	5	(6.0)
Pneumonia	4	(4.7)	0	(0.0)	6	(7.2)
Blood thyroid stimulating hormone increased	3	(3.5)	0	(0.0)	0	(0.0)
Dyspepsia	3	(3.5)	0	(0.0)	0	(0.0)
Febrile neutropenia	3	(3.5)	0	(0.0)	3	(3.6)
Onycholysis	3	(3.5)	0	(0.0)	0	(0.0)
Paraesthesia	3	(3.5)	0	(0.0)	5	(6.0)
Peripheral sensory neuropathy	3	(3.5)	0	(0.0)	3	(3.6)
Pneumonitis	3	(3.5)	5	(6.0)	5	(6.0)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Polyneuropathy	3	(3.5)	0	(0.0)	0	(0.0)
White blood cell count decreased	3	(3.5)	0	(0.0)	2	(2.4)
Adrenal insufficiency	2	(2.4)	0	(0.0)	0	(0.0)
Ageusia	2	(2.4)	0	(0.0)	2	(2.4)
Aphthous ulcer	2	(2.4)	0	(0.0)	0	(0.0)
Aspartate aminotransferase increased	2	(2.4)	1	(1.2)	0	(0.0)
Blood creatinine increased	2	(2.4)	0	(0.0)	2	(2.4)
Drug eruption	2	(2.4)	1	(1.2)	0	(0.0)
Dry mouth	2	(2.4)	0	(0.0)	0	(0.0)
Erythema	2	(2.4)	0	(0.0)	1	(1.2)
Gamma-glutamyltransferase increased	2	(2.4)	0	(0.0)	0	(0.0)
Hypersensitivity	2	(2.4)	1	(1.2)	0	(0.0)
Hyperthyroidism	2	(2.4)	1	(1.2)	2	(2.4)
Infection	2	(2.4)	0	(0.0)	0	(0.0)
Interstitial lung disease	2	(2.4)	0	(0.0)	0	(0.0)
Lymphocyte count decreased	2	(2.4)	0	(0.0)	2	(2.4)
Muscular weakness	2	(2.4)	0	(0.0)	1	(1.2)
Nasal dryness	2	(2.4)	0	(0.0)	1	(1.2)
Oral candidiasis	2	(2.4)	1	(1.2)	1	(1.2)
Rash maculo-papular	2	(2.4)	1	(1.2)	1	(1.2)
Rash pruritic	2	(2.4)	2	(2.4)	0	(0.0)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Skin toxicity	2	(2.4)	0	(0.0)	1	(1.2)
Taste disorder	2	(2.4)	0	(0.0)	1	(1.2)
Abdominal discomfort	1	(1.2)	0	(0.0)	0	(0.0)
Abdominal pain	1	(1.2)	0	(0.0)	1	(1.2)
Abdominal sepsis	1	(1.2)	0	(0.0)	0	(0.0)
Acute pulmonary oedema	1	(1.2)	0	(0.0)	0	(0.0)
Acute respiratory distress syndrome	1	(1.2)	0	(0.0)	0	(0.0)
Alanine aminotransferase increased	1	(1.2)	0	(0.0)	1	(1.2)
Amylase increased	1	(1.2)	4	(4.8)	1	(1.2)
Anal inflammation	1	(1.2)	0	(0.0)	0	(0.0)
Anal pruritus	1	(1.2)	0	(0.0)	0	(0.0)
Anosmia	1	(1.2)	0	(0.0)	0	(0.0)
Blood alkaline phosphatase increased	1	(1.2)	1	(1.2)	0	(0.0)
Blood thyroid stimulating hormone decreased	1	(1.2)	0	(0.0)	1	(1.2)
Bone pain	1	(1.2)	1	(1.2)	0	(0.0)
C-reactive protein increased	1	(1.2)	0	(0.0)	0	(0.0)
Cardiac failure	1	(1.2)	0	(0.0)	0	(0.0)
Central hypothyroidism	1	(1.2)	0	(0.0)	0	(0.0)
Chills	1	(1.2)	0	(0.0)	1	(1.2)
Cholestasis	1	(1.2)	0	(0.0)	0	(0.0)
Chronic obstructive pulmonary disease	1	(1.2)	0	(0.0)	0	(0.0)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Cognitive disorder	1	(1.2)	0	(0.0)	0	(0.0)
Colitis	1	(1.2)	1	(1.2)	1	(1.2)
Cortisol decreased	1	(1.2)	0	(0.0)	0	(0.0)
Cystitis	1	(1.2)	0	(0.0)	0	(0.0)
Dermatitis	1	(1.2)	2	(2.4)	0	(0.0)
Dermatitis exfoliative generalised	1	(1.2)	0	(0.0)	0	(0.0)
Dry eye	1	(1.2)	0	(0.0)	2	(2.4)
Ear pruritus	1	(1.2)	0	(0.0)	0	(0.0)
Enterococcal infection	1	(1.2)	0	(0.0)	0	(0.0)
Epistaxis	1	(1.2)	0	(0.0)	3	(3.6)
External ear pain	1	(1.2)	0	(0.0)	0	(0.0)
Eye inflammation	1	(1.2)	0	(0.0)	0	(0.0)
Eye irritation	1	(1.2)	0	(0.0)	0	(0.0)
Febrile bone marrow aplasia	1	(1.2)	0	(0.0)	0	(0.0)
Flushing	1	(1.2)	0	(0.0)	0	(0.0)
Fungal infection	1	(1.2)	0	(0.0)	0	(0.0)
Gastritis	1	(1.2)	0	(0.0)	0	(0.0)
Gastroenteritis	1	(1.2)	0	(0.0)	0	(0.0)
General physical health deterioration	1	(1.2)	1	(1.2)	1	(1.2)
Genital infection fungal	1	(1.2)	0	(0.0)	0	(0.0)
Glossodynia	1	(1.2)	0	(0.0)	0	(0.0)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Haemoptysis	1	(1.2)	0	(0.0)	0	(0.0)
Haemorrhoids	1	(1.2)	0	(0.0)	1	(1.2)
Headache	1	(1.2)	1	(1.2)	1	(1.2)
Hypercalcaemia	1	(1.2)	0	(0.0)	0	(0.0)
Hyperglycaemia	1	(1.2)	0	(0.0)	1	(1.2)
Hypoaesthesia	1	(1.2)	0	(0.0)	1	(1.2)
Hyponatraemia	1	(1.2)	0	(0.0)	0	(0.0)
Hypophagia	1	(1.2)	0	(0.0)	0	(0.0)
Hypophosphataemia	1	(1.2)	0	(0.0)	1	(1.2)
Hypophysitis	1	(1.2)	0	(0.0)	0	(0.0)
Hypotension	1	(1.2)	0	(0.0)	0	(0.0)
Hypovolaemic shock	1	(1.2)	0	(0.0)	0	(0.0)
Immune-mediated enterocolitis	1	(1.2)	0	(0.0)	0	(0.0)
Immune-mediated lung disease	1	(1.2)	1	(1.2)	0	(0.0)
Inflammation	1	(1.2)	0	(0.0)	0	(0.0)
Infusion related reaction	1	(1.2)	1	(1.2)	1	(1.2)
Insomnia	1	(1.2)	0	(0.0)	0	(0.0)
Lethargy	1	(1.2)	0	(0.0)	0	(0.0)
Lichenification	1	(1.2)	0	(0.0)	0	(0.0)
Lipase increased	1	(1.2)	5	(6.0)	1	(1.2)
Localised oedema	1	(1.2)	0	(0.0)	0	(0.0)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Mouth ulceration	1	(1.2)	0	(0.0)	1	(1.2)
Mucosal dryness	1	(1.2)	0	(0.0)	0	(0.0)
Muscle oedema	1	(1.2)	0	(0.0)	0	(0.0)
Musculoskeletal pain	1	(1.2)	0	(0.0)	0	(0.0)
Nail discolouration	1	(1.2)	0	(0.0)	1	(1.2)
Nail toxicity	1	(1.2)	0	(0.0)	5	(6.0)
Nasopharyngitis	1	(1.2)	0	(0.0)	0	(0.0)
Neutropenic sepsis	1	(1.2)	0	(0.0)	1	(1.2)
Odynophagia	1	(1.2)	0	(0.0)	0	(0.0)
Oedema	1	(1.2)	0	(0.0)	1	(1.2)
Onychalgia	1	(1.2)	0	(0.0)	0	(0.0)
Onychoclasis	1	(1.2)	0	(0.0)	0	(0.0)
Oral fungal infection	1	(1.2)	0	(0.0)	0	(0.0)
Oral mucosal blistering	1	(1.2)	0	(0.0)	0	(0.0)
Oral pain	1	(1.2)	0	(0.0)	0	(0.0)
Pain in extremity	1	(1.2)	0	(0.0)	1	(1.2)
Pain of skin	1	(1.2)	0	(0.0)	0	(0.0)
Palmar erythema	1	(1.2)	0	(0.0)	0	(0.0)
Paronychia	1	(1.2)	0	(0.0)	0	(0.0)
Performance status decreased	1	(1.2)	0	(0.0)	0	(0.0)
Pericardial effusion	1	(1.2)	0	(0.0)	0	(0.0)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Peripheral sensorimotor neuropathy	1	(1.2)	0	(0.0)	0	(0.0)
Peripheral swelling	1	(1.2)	0	(0.0)	1	(1.2)
Pharyngitis	1	(1.2)	0	(0.0)	0	(0.0)
Phimosis	1	(1.2)	0	(0.0)	0	(0.0)
Photosensitivity reaction	1	(1.2)	0	(0.0)	0	(0.0)
Platelet count decreased	1	(1.2)	0	(0.0)	3	(3.6)
Pruritus genital	1	(1.2)	0	(0.0)	0	(0.0)
Psoriasis	1	(1.2)	0	(0.0)	0	(0.0)
Rash morbilliform	1	(1.2)	0	(0.0)	0	(0.0)
Rash pustular	1	(1.2)	0	(0.0)	0	(0.0)
Renal failure	1	(1.2)	0	(0.0)	0	(0.0)
Rhinitis allergic	1	(1.2)	0	(0.0)	0	(0.0)
Scrotal ulcer	1	(1.2)	0	(0.0)	0	(0.0)
Septic shock	1	(1.2)	0	(0.0)	0	(0.0)
Skin exfoliation	1	(1.2)	0	(0.0)	0	(0.0)
Skin fissures	1	(1.2)	0	(0.0)	0	(0.0)
Skin lesion	1	(1.2)	0	(0.0)	0	(0.0)
Skin reaction	1	(1.2)	0	(0.0)	0	(0.0)
Skin ulcer	1	(1.2)	0	(0.0)	0	(0.0)
Sleep disorder	1	(1.2)	0	(0.0)	0	(0.0)
Thyroxine free increased	1	(1.2)	0	(0.0)	0	(0.0)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Toxic skin eruption	1	(1.2)	1	(1.2)	0	(0.0)
Vein disorder	1	(1.2)	0	(0.0)	0	(0.0)
Visual impairment	1	(1.2)	0	(0.0)	0	(0.0)
Vulvovaginal pruritus	1	(1.2)	0	(0.0)	0	(0.0)
Xerophthalmia	1	(1.2)	0	(0.0)	0	(0.0)
Abdominal pain upper	0	(0.0)	0	(0.0)	3	(3.6)
Bowel movement irregularity	0	(0.0)	0	(0.0)	2	(2.4)
Bronchitis	0	(0.0)	0	(0.0)	1	(1.2)
Burn oral cavity	0	(0.0)	0	(0.0)	1	(1.2)
Cancer fatigue	0	(0.0)	0	(0.0)	1	(1.2)
Chemical burns of eye	0	(0.0)	0	(0.0)	1	(1.2)
Chest discomfort	0	(0.0)	0	(0.0)	1	(1.2)
Chest pain	0	(0.0)	1	(1.2)	0	(0.0)
Clostridium difficile colitis	0	(0.0)	0	(0.0)	1	(1.2)
Death	0	(0.0)	1	(1.2)	0	(0.0)
Dermatitis acneiform	0	(0.0)	0	(0.0)	1	(1.2)
Dizziness	0	(0.0)	0	(0.0)	1	(1.2)
Drug hypersensitivity	0	(0.0)	0	(0.0)	1	(1.2)
Fluid retention	0	(0.0)	0	(0.0)	1	(1.2)
Gastrointestinal toxicity	0	(0.0)	0	(0.0)	1	(1.2)
Gastrooesophageal reflux disease	0	(0.0)	0	(0.0)	1	(1.2)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Haemoglobin decreased	0	(0.0)	0	(0.0)	2	(2.4)
Herpes zoster	0	(0.0)	0	(0.0)	1	(1.2)
Hypercreatinaemia	0	(0.0)	0	(0.0)	1	(1.2)
Hyperhidrosis	0	(0.0)	1	(1.2)	2	(2.4)
Hypocalcaemia	0	(0.0)	0	(0.0)	2	(2.4)
Hypokalaemia	0	(0.0)	0	(0.0)	1	(1.2)
Infusion site extravasation	0	(0.0)	0	(0.0)	1	(1.2)
Lower respiratory tract infection	0	(0.0)	0	(0.0)	1	(1.2)
Lymphadenopathy	0	(0.0)	0	(0.0)	1	(1.2)
Muscle spasms	0	(0.0)	0	(0.0)	1	(1.2)
Nail dystrophy	0	(0.0)	0	(0.0)	1	(1.2)
Nasal inflammation	0	(0.0)	0	(0.0)	1	(1.2)
Neurotoxicity	0	(0.0)	0	(0.0)	2	(2.4)
Onychomadesis	0	(0.0)	0	(0.0)	2	(2.4)
Oral discomfort	0	(0.0)	0	(0.0)	1	(1.2)
Oral herpes	0	(0.0)	0	(0.0)	1	(1.2)
Pain	0	(0.0)	0	(0.0)	1	(1.2)
Pancreatic enzymes increased	0	(0.0)	0	(0.0)	1	(1.2)
Periodontal disease	0	(0.0)	0	(0.0)	1	(1.2)
Protein urine present	0	(0.0)	1	(1.2)	0	(0.0)
Pulmonary toxicity	0	(0.0)	1	(1.2)	0	(0.0)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Rash erythematous	0	(0.0)	1	(1.2)	0	(0.0)
Rash macular	0	(0.0)	2	(2.4)	0	(0.0)
Rhinorrhoea	0	(0.0)	0	(0.0)	2	(2.4)
Skin hyperpigmentation	0	(0.0)	0	(0.0)	1	(1.2)
Skin injury	0	(0.0)	1	(1.2)	0	(0.0)
Soft tissue infection	0	(0.0)	0	(0.0)	1	(1.2)
Subdural haematoma	0	(0.0)	0	(0.0)	1	(1.2)
Syncope	0	(0.0)	0	(0.0)	1	(1.2)
Tendon pain	0	(0.0)	1	(1.2)	0	(0.0)
Upper respiratory tract infection	0	(0.0)	0	(0.0)	1	(1.2)
Urinary tract infection	0	(0.0)	0	(0.0)	1	(1.2)
Urticaria	0	(0.0)	1	(1.2)	0	(0.0)
Vulvovaginal dryness	0	(0.0)	1	(1.2)	0	(0.0)

Every participant is counted a single time for each applicable row and column.
Non-serious adverse events occurring within 30 days after the last dose of study intervention and serious adverse events occurring within 90 days after the last dose of study intervention, or 30 days after the last dose of study intervention if a new anticancer therapy is initiated, whichever is earlier are included.
Adverse event terms are based on MedDRA version 25.1.
Database cutoff date: 26Jan2023

Source: [P002V01MK7684A: adam-adsl; adae]

Table 2-14
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 + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Participants in population	85		83		83	
with one or more grade 3-5 adverse events	56	(65.9)	40	(48.2)	44	(53.0)
with no grade 3-5 adverse events	29	(34.1)	43	(51.8)	39	(47.0)
Blood and lymphatic system disorders	**9**	**(10.6)**	**2**	**(2.4)**	**8**	**(9.6)**
Anaemia	8	(9.4)	2	(2.4)	5	(6.0)
Febrile neutropenia	3	(3.5)	0	(0.0)	4	(4.8)
Cardiac disorders	**3**	**(3.5)**	**3**	**(3.6)**	**1**	**(1.2)**
Atrial fibrillation	1	(1.2)	1	(1.2)	0	(0.0)
Cardiac arrest	0	(0.0)	0	(0.0)	1	(1.2)
Cardiac failure	2	(2.4)	0	(0.0)	0	(0.0)
Myocardial infarction	0	(0.0)	1	(1.2)	0	(0.0)
Pericardial effusion	0	(0.0)	1	(1.2)	0	(0.0)
Congenital, familial and genetic disorders	**1**	**(1.2)**	**0**	**(0.0)**	**0**	**(0.0)**
Phimosis	1	(1.2)	0	(0.0)	0	(0.0)
Endocrine disorders	**1**	**(1.2)**	**1**	**(1.2)**	**0**	**(0.0)**
Hypophysitis	1	(1.2)	0	(0.0)	0	(0.0)

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 + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Endocrine disorders	**1**	**(1.2)**	**1**	**(1.2)**	**0**	**(0.0)**
Hypothyroidism	0	(0.0)	1	(1.2)	0	(0.0)
Eye disorders	**1**	**(1.2)**	**0**	**(0.0)**	**0**	**(0.0)**
Retinal detachment	1	(1.2)	0	(0.0)	0	(0.0)
Gastrointestinal disorders	**12**	**(14.1)**	**6**	**(7.2)**	**2**	**(2.4)**
Abdominal pain	0	(0.0)	1	(1.2)	0	(0.0)
Ascites	1	(1.2)	0	(0.0)	0	(0.0)
Colitis	1	(1.2)	0	(0.0)	0	(0.0)
Dental caries	1	(1.2)	0	(0.0)	0	(0.0)
Diarrhoea	3	(3.5)	3	(3.6)	2	(2.4)
Dysphagia	0	(0.0)	1	(1.2)	0	(0.0)
Gastric ulcer	1	(1.2)	0	(0.0)	0	(0.0)
Gastritis	2	(2.4)	0	(0.0)	0	(0.0)
Gastrointestinal disorder	1	(1.2)	0	(0.0)	0	(0.0)
Gastrointestinal toxicity	0	(0.0)	0	(0.0)	1	(1.2)
Immune-mediated enterocolitis	1	(1.2)	0	(0.0)	0	(0.0)
Intestinal haemorrhage	1	(1.2)	0	(0.0)	0	(0.0)
Intestinal perforation	0	(0.0)	1	(1.2)	0	(0.0)

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 + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Gastrointestinal disorders	**12**	**(14.1)**	**6**	**(7.2)**	**2**	**(2.4)**
Segmental diverticular colitis	0	(0.0)	1	(1.2)	0	(0.0)
Stomatitis	1	(1.2)	0	(0.0)	0	(0.0)
Vomiting	0	(0.0)	0	(0.0)	1	(1.2)
General disorders and administration site conditions	**12**	**(14.1)**	**5**	**(6.0)**	**9**	**(10.8)**
Asthenia	5	(5.9)	2	(2.4)	2	(2.4)
Chest pain	0	(0.0)	0	(0.0)	1	(1.2)
Death	1	(1.2)	1	(1.2)	2	(2.4)
Fatigue	2	(2.4)	1	(1.2)	3	(3.6)
Gait disturbance	0	(0.0)	1	(1.2)	0	(0.0)
General physical health deterioration	1	(1.2)	1	(1.2)	0	(0.0)
Oedema peripheral	1	(1.2)	0	(0.0)	0	(0.0)
Pain	0	(0.0)	0	(0.0)	1	(1.2)
Performance status decreased	1	(1.2)	0	(0.0)	0	(0.0)
Pyrexia	1	(1.2)	0	(0.0)	0	(0.0)
Hepatobiliary disorders	**1**	**(1.2)**	**0**	**(0.0)**	**0**	**(0.0)**
Cholestasis	1	(1.2)	0	(0.0)	0	(0.0)

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 + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Immune system disorders	**1**	**(1.2)**	**0**	**(0.0)**	**1**	**(1.2)**
Drug hypersensitivity	0	(0.0)	0	(0.0)	1	(1.2)
Hypersensitivity	1	(1.2)	0	(0.0)	0	(0.0)
Infections and infestations	**18**	**(21.2)**	**7**	**(8.4)**	**16**	**(19.3)**
Abdominal sepsis	1	(1.2)	0	(0.0)	0	(0.0)
Bacteraemia	0	(0.0)	0	(0.0)	1	(1.2)
Bronchitis	0	(0.0)	0	(0.0)	1	(1.2)
Burkholderia pseudomallei infection	0	(0.0)	0	(0.0)	1	(1.2)
COVID-19	3	(3.5)	1	(1.2)	1	(1.2)
COVID-19 pneumonia	0	(0.0)	2	(2.4)	1	(1.2)
Cellulitis	1	(1.2)	0	(0.0)	0	(0.0)
Cystitis	1	(1.2)	0	(0.0)	0	(0.0)
Device related bacteraemia	1	(1.2)	0	(0.0)	0	(0.0)
Enterococcal infection	1	(1.2)	0	(0.0)	0	(0.0)
Herpes zoster	1	(1.2)	0	(0.0)	0	(0.0)
Infectious pleural effusion	0	(0.0)	0	(0.0)	1	(1.2)
Large intestine infection	1	(1.2)	0	(0.0)	0	(0.0)
Lower respiratory tract infection	0	(0.0)	0	(0.0)	1	(1.2)
Neutropenic sepsis	1	(1.2)	0	(0.0)	1	(1.2)

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 + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Infections and infestations	**18**	**(21.2)**	**7**	**(8.4)**	**16**	**(19.3)**
Oral candidiasis	2	(2.4)	0	(0.0)	0	(0.0)
Oral fungal infection	1	(1.2)	0	(0.0)	0	(0.0)
Pneumonia	7	(8.2)	3	(3.6)	10	(12.0)
Pneumonia aspiration	0	(0.0)	0	(0.0)	1	(1.2)
Respiratory syncytial virus infection	0	(0.0)	0	(0.0)	1	(1.2)
Respiratory tract infection	0	(0.0)	0	(0.0)	1	(1.2)
Sepsis	0	(0.0)	1	(1.2)	0	(0.0)
Septic shock	3	(3.5)	0	(0.0)	0	(0.0)
Urinary tract infection	0	(0.0)	1	(1.2)	0	(0.0)
Injury, poisoning and procedural complications	**3**	**(3.5)**	**3**	**(3.6)**	**1**	**(1.2)**
Femur fracture	0	(0.0)	1	(1.2)	0	(0.0)
Hip fracture	2	(2.4)	0	(0.0)	0	(0.0)
Humerus fracture	1	(1.2)	0	(0.0)	0	(0.0)
Lumbar vertebral fracture	0	(0.0)	0	(0.0)	1	(1.2)
Procedural complication	0	(0.0)	1	(1.2)	0	(0.0)
Thoracic vertebral fracture	0	(0.0)	1	(1.2)	0	(0.0)
Investigations	**18**	**(21.2)**	**3**	**(3.6)**	**17**	**(20.5)**

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 + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Investigations	**18**	**(21.2)**	**3**	**(3.6)**	**17**	**(20.5)**
Alanine aminotransferase increased	0	(0.0)	1	(1.2)	0	(0.0)
Aspartate aminotransferase increased	0	(0.0)	1	(1.2)	0	(0.0)
Blood alkaline phosphatase increased	0	(0.0)	1	(1.2)	0	(0.0)
Blood creatinine increased	0	(0.0)	0	(0.0)	1	(1.2)
Blood glucose increased	2	(2.4)	0	(0.0)	0	(0.0)
Gamma-glutamyltransferase increased	1	(1.2)	1	(1.2)	0	(0.0)
Glycosylated haemoglobin increased	1	(1.2)	0	(0.0)	0	(0.0)
Haemoglobin decreased	0	(0.0)	0	(0.0)	1	(1.2)
Lipase increased	0	(0.0)	2	(2.4)	1	(1.2)
Lymphocyte count decreased	1	(1.2)	0	(0.0)	1	(1.2)
Neutrophil count decreased	14	(16.5)	0	(0.0)	12	(14.5)
Platelet count decreased	1	(1.2)	0	(0.0)	0	(0.0)
Weight decreased	0	(0.0)	0	(0.0)	1	(1.2)
White blood cell count decreased	2	(2.4)	0	(0.0)	2	(2.4)
White blood cell count increased	0	(0.0)	0	(0.0)	1	(1.2)
Metabolism and nutrition disorders	**6**	**(7.1)**	**3**	**(3.6)**	**5**	**(6.0)**
Decreased appetite	2	(2.4)	0	(0.0)	2	(2.4)
Dehydration	2	(2.4)	0	(0.0)	0	(0.0)

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 + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Metabolism and nutrition disorders	**6**	**(7.1)**	**3**	**(3.6)**	**5**	**(6.0)**
Hypercalcaemia	0	(0.0)	1	(1.2)	1	(1.2)
Hyperglycaemia	0	(0.0)	1	(1.2)	0	(0.0)
Hypocalcaemia	0	(0.0)	0	(0.0)	1	(1.2)
Hypokalaemia	3	(3.5)	1	(1.2)	1	(1.2)
Hypomagnesaemia	0	(0.0)	0	(0.0)	1	(1.2)
Musculoskeletal and connective tissue disorders	**2**	**(2.4)**	**3**	**(3.6)**	**1**	**(1.2)**
Arthralgia	0	(0.0)	1	(1.2)	0	(0.0)
Hypercreatinaemia	0	(0.0)	0	(0.0)	1	(1.2)
Musculoskeletal chest pain	1	(1.2)	0	(0.0)	0	(0.0)
Osteolysis	0	(0.0)	1	(1.2)	0	(0.0)
Osteonecrosis of jaw	1	(1.2)	0	(0.0)	0	(0.0)
Pain in extremity	0	(0.0)	1	(1.2)	0	(0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**0**	**(0.0)**	**2**	**(2.4)**	**2**	**(2.4)**
Cancer fatigue	0	(0.0)	0	(0.0)	1	(1.2)
Malignant pleural effusion	0	(0.0)	0	(0.0)	1	(1.2)
Tumour compression	0	(0.0)	1	(1.2)	0	(0.0)

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 + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**0**	**(0.0)**	**2**	**(2.4)**	**2**	**(2.4)**
Tumour haemorrhage	0	(0.0)	1	(1.2)	0	(0.0)
Nervous system disorders	**6**	**(7.1)**	**3**	**(3.6)**	**2**	**(2.4)**
Brain stem stroke	0	(0.0)	1	(1.2)	0	(0.0)
Cerebrovascular accident	1	(1.2)	1	(1.2)	0	(0.0)
Dizziness	0	(0.0)	1	(1.2)	0	(0.0)
Epilepsy	1	(1.2)	0	(0.0)	0	(0.0)
Hyperaesthesia	1	(1.2)	0	(0.0)	0	(0.0)
Neuropathy peripheral	1	(1.2)	0	(0.0)	0	(0.0)
Paraesthesia	0	(0.0)	0	(0.0)	1	(1.2)
Peripheral sensorimotor neuropathy	1	(1.2)	0	(0.0)	0	(0.0)
Polyneuropathy	1	(1.2)	0	(0.0)	0	(0.0)
Syncope	0	(0.0)	0	(0.0)	1	(1.2)
Psychiatric disorders	**1**	**(1.2)**	**0**	**(0.0)**	**0**	**(0.0)**
Insomnia	1	(1.2)	0	(0.0)	0	(0.0)
Renal and urinary disorders	**1**	**(1.2)**	**2**	**(2.4)**	**0**	**(0.0)**

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 + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Renal and urinary disorders	**1**	**(1.2)**	**2**	**(2.4)**	**0**	**(0.0)**
Renal failure	1	(1.2)	1	(1.2)	0	(0.0)
Ureterolithiasis	0	(0.0)	1	(1.2)	0	(0.0)
Respiratory, thoracic and mediastinal disorders	**9**	**(10.6)**	**9**	**(10.8)**	**10**	**(12.0)**
Acute pulmonary oedema	1	(1.2)	0	(0.0)	0	(0.0)
Acute respiratory distress syndrome	1	(1.2)	0	(0.0)	0	(0.0)
Acute respiratory failure	1	(1.2)	0	(0.0)	0	(0.0)
Aphonia	1	(1.2)	0	(0.0)	0	(0.0)
Chronic obstructive pulmonary disease	1	(1.2)	1	(1.2)	2	(2.4)
Dyspnoea	1	(1.2)	3	(3.6)	3	(3.6)
Haemoptysis	0	(0.0)	0	(0.0)	2	(2.4)
Immune-mediated lung disease	1	(1.2)	0	(0.0)	0	(0.0)
Interstitial lung disease	2	(2.4)	0	(0.0)	0	(0.0)
Pleural effusion	0	(0.0)	1	(1.2)	1	(1.2)
Pleurisy	0	(0.0)	1	(1.2)	0	(0.0)
Pneumonitis	1	(1.2)	0	(0.0)	1	(1.2)
Pulmonary embolism	0	(0.0)	2	(2.4)	2	(2.4)
Pulmonary toxicity	0	(0.0)	1	(1.2)	0	(0.0)
Respiratory failure	1	(1.2)	0	(0.0)	1	(1.2)

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 + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Skin and subcutaneous tissue disorders	**13**	**(15.3)**	**1**	**(1.2)**	**0**	**(0.0)**
Dermatitis	1	(1.2)	0	(0.0)	0	(0.0)
Drug eruption	2	(2.4)	0	(0.0)	0	(0.0)
Eczema	1	(1.2)	0	(0.0)	0	(0.0)
Lichenification	1	(1.2)	0	(0.0)	0	(0.0)
Nail toxicity	1	(1.2)	0	(0.0)	0	(0.0)
Pemphigoid	1	(1.2)	0	(0.0)	0	(0.0)
Pruritus	3	(3.5)	0	(0.0)	0	(0.0)
Rash	2	(2.4)	1	(1.2)	0	(0.0)
Rash maculo-papular	1	(1.2)	0	(0.0)	0	(0.0)
Rash morbilliform	1	(1.2)	0	(0.0)	0	(0.0)
Skin toxicity	1	(1.2)	0	(0.0)	0	(0.0)
Surgical and medical procedures	**1**	**(1.2)**	**0**	**(0.0)**	**1**	**(1.2)**
Euthanasia	1	(1.2)	0	(0.0)	1	(1.2)
Vascular disorders	**4**	**(4.7)**	**2**	**(2.4)**	**3**	**(3.6)**
Hypertension	1	(1.2)	1	(1.2)	1	(1.2)
Hypotension	1	(1.2)	0	(0.0)	0	(0.0)
Hypovolaemic shock	1	(1.2)	0	(0.0)	0	(0.0)

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 + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Vascular disorders	**4**	**(4.7)**	**2**	**(2.4)**	**3**	**(3.6)**
Orthostatic hypotension	0	(0.0)	1	(1.2)	0	(0.0)
Superior vena cava occlusion	1	(1.2)	0	(0.0)	0	(0.0)
Superior vena cava syndrome	0	(0.0)	0	(0.0)	2	(2.4)

Every participant is counted a single time for each applicable row and column.

Non-serious adverse events occurring within 30 days after the last dose of study intervention and serious adverse events occurring within 90 days after the last dose of study intervention, or 30 days after the last dose of study intervention if a new anticancer therapy is initiated, whichever is earlier are included.

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

Grades are based on NCI CTCAE version 5.0.

Adverse event terms are based on MedDRA version 25.1.

Database cutoff date: 26Jan2023

Source: [P002V01MK7684A: adam-adsl; adae]

Table 2-15
Participants With Drug-Related Grade 3-5 Adverse Events by System Organ Class and Preferred Term
(Incidence >0% in One or More Treatment Groups)
(APaT Population)

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Participants in population	85		83		83	
with one or more drug-related grade 3-5 adverse events	42	(49.4)	11	(13.3)	27	(32.5)
with no drug-related grade 3-5 adverse events	43	(50.6)	72	(86.7)	56	(67.5)
Blood and lymphatic system disorders	**8**	**(9.4)**	**0**	**(0.0)**	**8**	**(9.6)**
Anaemia	6	(7.1)	0	(0.0)	5	(6.0)
Febrile neutropenia	3	(3.5)	0	(0.0)	3	(3.6)
Cardiac disorders	**1**	**(1.2)**	**0**	**(0.0)**	**0**	**(0.0)**
Cardiac failure	1	(1.2)	0	(0.0)	0	(0.0)
Congenital, familial and genetic disorders	**1**	**(1.2)**	**0**	**(0.0)**	**0**	**(0.0)**
Phimosis	1	(1.2)	0	(0.0)	0	(0.0)
Endocrine disorders	**1**	**(1.2)**	**1**	**(1.2)**	**0**	**(0.0)**
Hypophysitis	1	(1.2)	0	(0.0)	0	(0.0)
Hypothyroidism	0	(0.0)	1	(1.2)	0	(0.0)
Gastrointestinal disorders	**7**	**(8.2)**	**2**	**(2.4)**	**2**	**(2.4)**
Colitis	1	(1.2)	0	(0.0)	0	(0.0)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Gastrointestinal disorders	**7**	**(8.2)**	**2**	**(2.4)**	**2**	**(2.4)**
Diarrhoea	3	(3.5)	2	(2.4)	2	(2.4)
Gastritis	1	(1.2)	0	(0.0)	0	(0.0)
Gastrointestinal toxicity	0	(0.0)	0	(0.0)	1	(1.2)
Immune-mediated enterocolitis	1	(1.2)	0	(0.0)	0	(0.0)
Stomatitis	1	(1.2)	0	(0.0)	0	(0.0)
Vomiting	0	(0.0)	0	(0.0)	1	(1.2)
General disorders and administration site conditions	**7**	**(8.2)**	**4**	**(4.8)**	**5**	**(6.0)**
Asthenia	4	(4.7)	2	(2.4)	2	(2.4)
Death	0	(0.0)	1	(1.2)	0	(0.0)
Fatigue	1	(1.2)	1	(1.2)	2	(2.4)
General physical health deterioration	0	(0.0)	1	(1.2)	0	(0.0)
Oedema peripheral	1	(1.2)	0	(0.0)	0	(0.0)
Pain	0	(0.0)	0	(0.0)	1	(1.2)
Performance status decreased	1	(1.2)	0	(0.0)	0	(0.0)
Hepatobiliary disorders	**1**	**(1.2)**	**0**	**(0.0)**	**0**	**(0.0)**
Cholestasis	1	(1.2)	0	(0.0)	0	(0.0)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Immune system disorders	**1**	**(1.2)**	**0**	**(0.0)**	**1**	**(1.2)**
Drug hypersensitivity	0	(0.0)	0	(0.0)	1	(1.2)
Hypersensitivity	1	(1.2)	0	(0.0)	0	(0.0)
Infections and infestations	**9**	**(10.6)**	**0**	**(0.0)**	**7**	**(8.4)**
Abdominal sepsis	1	(1.2)	0	(0.0)	0	(0.0)
Enterococcal infection	1	(1.2)	0	(0.0)	0	(0.0)
Neutropenic sepsis	1	(1.2)	0	(0.0)	1	(1.2)
Oral candidiasis	1	(1.2)	0	(0.0)	0	(0.0)
Oral fungal infection	1	(1.2)	0	(0.0)	0	(0.0)
Pneumonia	4	(4.7)	0	(0.0)	6	(7.2)
Septic shock	1	(1.2)	0	(0.0)	0	(0.0)
Investigations	**16**	**(18.8)**	**2**	**(2.4)**	**16**	**(19.3)**
Blood creatinine increased	0	(0.0)	0	(0.0)	1	(1.2)
Gamma-glutamyltransferase increased	1	(1.2)	0	(0.0)	0	(0.0)
Haemoglobin decreased	0	(0.0)	0	(0.0)	1	(1.2)
Lipase increased	0	(0.0)	2	(2.4)	1	(1.2)
Lymphocyte count decreased	1	(1.2)	0	(0.0)	1	(1.2)
Neutrophil count decreased	14	(16.5)	0	(0.0)	12	(14.5)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Investigations	**16**	**(18.8)**	**2**	**(2.4)**	**16**	**(19.3)**
Platelet count decreased	1	(1.2)	0	(0.0)	0	(0.0)
White blood cell count decreased	2	(2.4)	0	(0.0)	2	(2.4)
Metabolism and nutrition disorders	**0**	**(0.0)**	**0**	**(0.0)**	**4**	**(4.8)**
Decreased appetite	0	(0.0)	0	(0.0)	2	(2.4)
Hypocalcaemia	0	(0.0)	0	(0.0)	1	(1.2)
Hypokalaemia	0	(0.0)	0	(0.0)	1	(1.2)
Hypomagnesaemia	0	(0.0)	0	(0.0)	1	(1.2)
Musculoskeletal and connective tissue disorders	**0**	**(0.0)**	**0**	**(0.0)**	**1**	**(1.2)**
Hypercreatinaemia	0	(0.0)	0	(0.0)	1	(1.2)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**0**	**(0.0)**	**0**	**(0.0)**	**1**	**(1.2)**
Cancer fatigue	0	(0.0)	0	(0.0)	1	(1.2)
Nervous system disorders	**3**	**(3.5)**	**0**	**(0.0)**	**1**	**(1.2)**
Neuropathy peripheral	1	(1.2)	0	(0.0)	0	(0.0)
Paraesthesia	0	(0.0)	0	(0.0)	1	(1.2)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Nervous system disorders	**3**	**(3.5)**	**0**	**(0.0)**	**1**	**(1.2)**
Peripheral sensorimotor neuropathy	1	(1.2)	0	(0.0)	0	(0.0)
Polyneuropathy	1	(1.2)	0	(0.0)	0	(0.0)
Renal and urinary disorders	**1**	**(1.2)**	**0**	**(0.0)**	**0**	**(0.0)**
Renal failure	1	(1.2)	0	(0.0)	0	(0.0)
Respiratory, thoracic and mediastinal disorders	**7**	**(8.2)**	**1**	**(1.2)**	**1**	**(1.2)**
Acute pulmonary oedema	1	(1.2)	0	(0.0)	0	(0.0)
Acute respiratory distress syndrome	1	(1.2)	0	(0.0)	0	(0.0)
Chronic obstructive pulmonary disease	1	(1.2)	0	(0.0)	0	(0.0)
Immune-mediated lung disease	1	(1.2)	0	(0.0)	0	(0.0)
Interstitial lung disease	2	(2.4)	0	(0.0)	0	(0.0)
Pneumonitis	1	(1.2)	0	(0.0)	1	(1.2)
Pulmonary toxicity	0	(0.0)	1	(1.2)	0	(0.0)
Skin and subcutaneous tissue disorders	**12**	**(14.1)**	**1**	**(1.2)**	**0**	**(0.0)**
Dermatitis	1	(1.2)	0	(0.0)	0	(0.0)
Drug eruption	2	(2.4)	0	(0.0)	0	(0.0)
Eczema	1	(1.2)	0	(0.0)	0	(0.0)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Skin and subcutaneous tissue disorders	**12**	**(14.1)**	**1**	**(1.2)**	**0**	**(0.0)**
Lichenification	1	(1.2)	0	(0.0)	0	(0.0)
Nail toxicity	1	(1.2)	0	(0.0)	0	(0.0)
Pruritus	3	(3.5)	0	(0.0)	0	(0.0)
Rash	2	(2.4)	1	(1.2)	0	(0.0)
Rash maculo-papular	1	(1.2)	0	(0.0)	0	(0.0)
Rash morbilliform	1	(1.2)	0	(0.0)	0	(0.0)
Skin toxicity	1	(1.2)	0	(0.0)	0	(0.0)
Vascular disorders	**2**	**(2.4)**	**0**	**(0.0)**	**0**	**(0.0)**
Hypotension	1	(1.2)	0	(0.0)	0	(0.0)
Hypovolaemic shock	1	(1.2)	0	(0.0)	0	(0.0)

Every participant is counted a single time for each applicable row and column.
Non-serious adverse events occurring within 30 days after the last dose of study intervention and serious adverse events occurring within 90 days after the last dose of study intervention, or 30 days after the last dose of study intervention if a new anticancer therapy is initiated, whichever is earlier are included.
Grades are based on NCI CTCAE version 5.0.
Adverse event terms are based on MedDRA version 25.1.
Database cutoff date: 26Jan2023

Source: [P002V01MK7684A: adam-adsl; adae]

Table 2-16
Participants With Serious Adverse Events by Decreasing Incidence
(Incidence ≥5% in One or More Treatment Groups)
(APaT Population)

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Participants in population	85		83		83	
with one or more serious adverse events	44	(51.8)	25	(30.1)	36	(43.4)
with no serious adverse events	41	(48.2)	58	(69.9)	47	(56.6)
Pneumonia	6	(7.1)	3	(3.6)	9	(10.8)

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.
Serious adverse events occurring within 90 days after the last dose of study intervention, or 30 days after the last dose of study intervention if a new anticancer therapy is initiated, whichever is earlier are included.
MedDRA preferred terms "Neoplasm progression", "Malignant neoplasm progression" and "Disease progression" not related to the drug are excluded.
Adverse event terms are based on MedDRA version 25.1.
Database cutoff date: 26Jan2023

Source: [P002V01MK7684A: adam-adsl; adae]

Table 2-17
Participants With Adverse Events Resulting in Death by Decreasing Incidence
(Incidence >0% in One or More Treatment Groups)
(APaT Population)

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Participants in population	85		83		83	
with one or more adverse events resulting in death	11	(12.9)	7	(8.4)	11	(13.3)
with no adverse events resulting in death	74	(87.1)	76	(91.6)	72	(86.7)
Septic shock	3	(3.5)	0	(0.0)	0	(0.0)
COVID-19	2	(2.4)	0	(0.0)	1	(1.2)
Acute pulmonary oedema	1	(1.2)	0	(0.0)	0	(0.0)
Death	1	(1.2)	1	(1.2)	2	(2.4)
Euthanasia	1	(1.2)	0	(0.0)	1	(1.2)
Hip fracture	1	(1.2)	0	(0.0)	0	(0.0)
Interstitial lung disease	1	(1.2)	0	(0.0)	0	(0.0)
Pneumonitis	1	(1.2)	0	(0.0)	0	(0.0)
Bacteraemia	0	(0.0)	0	(0.0)	1	(1.2)
COVID-19 pneumonia	0	(0.0)	1	(1.2)	0	(0.0)
Cardiac arrest	0	(0.0)	0	(0.0)	1	(1.2)
Cerebrovascular accident	0	(0.0)	1	(1.2)	0	(0.0)
Chronic obstructive pulmonary disease	0	(0.0)	1	(1.2)	0	(0.0)
Dyspnoea	0	(0.0)	0	(0.0)	1	(1.2)
Haemoptysis	0	(0.0)	0	(0.0)	1	(1.2)
Intestinal perforation	0	(0.0)	1	(1.2)	0	(0.0)
Myocardial infarction	0	(0.0)	1	(1.2)	0	(0.0)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Pneumonia	0	(0.0)	0	(0.0)	1	(1.2)
Procedural complication	0	(0.0)	1	(1.2)	0	(0.0)
Respiratory failure	0	(0.0)	0	(0.0)	1	(1.2)
Respiratory tract infection	0	(0.0)	0	(0.0)	1	(1.2)

Every participant is counted a single time for each applicable row and column.

Serious adverse events occurring within 90 days after the last dose of study intervention, or 30 days after the last dose of study intervention if a new anticancer therapy is initiated, whichever is earlier are included.

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

Adverse event terms are based on MedDRA version 25.1.

Database cutoff date: 26Jan2023

Source: [P002V01MK7684A: adam-adsl; adae]

Table 2-18
Participants With Adverse Events Resulting in Any Treatment Discontinuation by Decreasing Incidence
(Incidence >0% in One or More Treatment Groups)
(APaT Population)

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Participants in population	85		83		83	
with one or more adverse events resulting in any treatment discontinuation	37	(43.5)	11	(13.3)	23	(27.7)
with no adverse events resulting in any treatment discontinuation	48	(56.5)	72	(86.7)	60	(72.3)
Neutrophil count decreased	3	(3.5)	0	(0.0)	0	(0.0)
Drug eruption	2	(2.4)	0	(0.0)	0	(0.0)
Eczema	2	(2.4)	0	(0.0)	0	(0.0)
Febrile neutropenia	2	(2.4)	0	(0.0)	0	(0.0)
Interstitial lung disease	2	(2.4)	0	(0.0)	0	(0.0)
Pneumonia	2	(2.4)	1	(1.2)	3	(3.6)
Pneumonitis	2	(2.4)	1	(1.2)	2	(2.4)
Septic shock	2	(2.4)	0	(0.0)	0	(0.0)
Acute pulmonary oedema	1	(1.2)	0	(0.0)	0	(0.0)
Anaemia	1	(1.2)	0	(0.0)	0	(0.0)
COVID-19	1	(1.2)	0	(0.0)	1	(1.2)
Death	1	(1.2)	1	(1.2)	1	(1.2)
Diarrhoea	1	(1.2)	2	(2.4)	2	(2.4)
Dyspepsia	1	(1.2)	0	(0.0)	0	(0.0)
Epilepsy	1	(1.2)	0	(0.0)	0	(0.0)
Gastritis	1	(1.2)	0	(0.0)	0	(0.0)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
General physical health deterioration	1	(1.2)	0	(0.0)	0	(0.0)
Hip fracture	1	(1.2)	0	(0.0)	0	(0.0)
Hypersensitivity	1	(1.2)	0	(0.0)	0	(0.0)
Immune-mediated enterocolitis	1	(1.2)	0	(0.0)	0	(0.0)
Immune-mediated lung disease	1	(1.2)	0	(0.0)	0	(0.0)
Lichenification	1	(1.2)	0	(0.0)	0	(0.0)
Mucosal inflammation	1	(1.2)	0	(0.0)	0	(0.0)
Neuropathy peripheral	1	(1.2)	0	(0.0)	1	(1.2)
Neutropenic sepsis	1	(1.2)	0	(0.0)	1	(1.2)
Oral candidiasis	1	(1.2)	0	(0.0)	0	(0.0)
Palmar-plantar erythrodysaesthesia syndrome	1	(1.2)	0	(0.0)	0	(0.0)
Pemphigoid	1	(1.2)	0	(0.0)	0	(0.0)
Peripheral sensorimotor neuropathy	1	(1.2)	0	(0.0)	0	(0.0)
Pruritus	1	(1.2)	0	(0.0)	0	(0.0)
Rash	1	(1.2)	0	(0.0)	0	(0.0)
Rash maculo-papular	1	(1.2)	0	(0.0)	0	(0.0)
Rash morbilliform	1	(1.2)	0	(0.0)	0	(0.0)
Stomatitis	1	(1.2)	0	(0.0)	1	(1.2)
Toxic skin eruption	1	(1.2)	0	(0.0)	0	(0.0)
Asthenia	0	(0.0)	0	(0.0)	3	(3.6)
Cardiac arrest	0	(0.0)	0	(0.0)	1	(1.2)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Cerebrovascular accident	0	(0.0)	1	(1.2)	0	(0.0)
Decreased appetite	0	(0.0)	0	(0.0)	1	(1.2)
Diverticulitis intestinal perforated	0	(0.0)	0	(0.0)	1	(1.2)
Drug hypersensitivity	0	(0.0)	0	(0.0)	1	(1.2)
Dyspnoea	0	(0.0)	0	(0.0)	1	(1.2)
Gastrointestinal toxicity	0	(0.0)	0	(0.0)	1	(1.2)
Intestinal perforation	0	(0.0)	1	(1.2)	0	(0.0)
Lower respiratory tract infection	0	(0.0)	0	(0.0)	1	(1.2)
Myocardial infarction	0	(0.0)	1	(1.2)	0	(0.0)
Nail toxicity	0	(0.0)	0	(0.0)	1	(1.2)
Neurotoxicity	0	(0.0)	0	(0.0)	1	(1.2)
Pleural effusion	0	(0.0)	1	(1.2)	0	(0.0)
Pulmonary embolism	0	(0.0)	1	(1.2)	0	(0.0)
Pulmonary toxicity	0	(0.0)	1	(1.2)	0	(0.0)
Respiratory failure	0	(0.0)	0	(0.0)	1	(1.2)
Respiratory tract infection	0	(0.0)	0	(0.0)	1	(1.2)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Segmental diverticular colitis	0	(0.0)	1	(1.2)	0	(0.0)

Every participant is counted a single time for each applicable row and column.

Non-serious adverse events occurring within 30 days after the last dose of study intervention and serious adverse events occurring within 90 days after the last dose of study intervention, or 30 days after the last dose of study intervention if a new anticancer therapy is initiated, whichever is earlier are included.

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

Adverse event terms are based on MedDRA version 25.1.

Database cutoff date: 26Jan2023

Source: [P002V01MK7684A: adam-adsl; adae]

Table 2-19
Adverse Event Summary
AEOSI Overall
(APaT Population)

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Participants in population	85		83		83	
with one or more adverse events	25	(29.4)	17	(20.5)	10	(12.0)
with no adverse event	60	(70.6)	66	(79.5)	73	(88.0)
with drug-related[a] adverse events	22	(25.9)	14	(16.9)	9	(10.8)
with toxicity grade 3-5 adverse events	13	(15.3)	2	(2.4)	2	(2.4)
with toxicity grade 3-5 drug-related adverse events	12	(14.1)	2	(2.4)	2	(2.4)
with serious adverse events	6	(7.1)	1	(1.2)	1	(1.2)
with serious drug-related adverse events	6	(7.1)	1	(1.2)	1	(1.2)
who died	2	(2.4)	0	(0.0)	0	(0.0)
who died due to a drug-related adverse event	2	(2.4)	0	(0.0)	0	(0.0)
discontinued any drug due to an adverse event	11	(12.9)	1	(1.2)	3	(3.6)
discontinued MK-7684A/PLACEBO	10	(11.8)	0	(0.0)	2	(2.4)
discontinued DOCETAXEL	7	(8.2)	0	(0.0)	2	(2.4)
discontinued MK-7684A	0	(0.0)	1	(1.2)	0	(0.0)
discontinued any drug due to a drug-related adverse event	10	(11.8)	1	(1.2)	3	(3.6)
discontinued MK-7684A/PLACEBO	9	(10.6)	0	(0.0)	2	(2.4)
discontinued DOCETAXEL	7	(8.2)	0	(0.0)	2	(2.4)
discontinued MK-7684A	0	(0.0)	1	(1.2)	0	(0.0)
discontinued any drug due to a serious adverse event	6	(7.1)	0	(0.0)	1	(1.2)
discontinued MK-7684A/PLACEBO	6	(7.1)	0	(0.0)	1	(1.2)
discontinued DOCETAXEL	4	(4.7)	0	(0.0)	1	(1.2)

Adverse Event Summary
AEOSI Overall
(APaT Population)

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
discontinued MK-7684A	0	(0.0)	0	(0.0)	0	(0.0)
discontinued any drug due to a serious drug-related adverse event	6	(7.1)	0	(0.0)	1	(1.2)
discontinued MK-7684A/PLACEBO	6	(7.1)	0	(0.0)	1	(1.2)
discontinued DOCETAXEL	4	(4.7)	0	(0.0)	1	(1.2)
discontinued MK-7684A	0	(0.0)	0	(0.0)	0	(0.0)

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

Non-serious adverse events occurring within 30 days after the last dose of study intervention and serious adverse events occurring within 90 days after the last dose of study intervention, or 30 days after the last dose of study intervention if a new anticancer therapy is initiated, whichever is earlier are included.

Grades are based on NCI CTCAE version 5.0.

Adverse event terms are based on MedDRA version 25.1.

Database cutoff date: 26Jan2023

Source: [P002V01MK7684A: adam-adsl; adae]

Table 2-20
Participants With Adverse Events of Special Interest (AEOSI) by All Risk Category by Decreasing Incidence
(Incidence >0% in One or More Treatment Groups)
(APaT Population)

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Participants in population	85		83		83	
with one or more adverse events of special interest	25	(29.4)	17	(20.5)	10	(12.0)
with no adverse events of special interest	60	(70.6)	66	(79.5)	73	(88.0)
Severe Skin Reactions	8	(9.4)	2	(2.4)	0	(0.0)
Pneumonitis	6	(7.1)	6	(7.2)	5	(6.0)
Hypothyroidism	5	(5.9)	4	(4.8)	1	(1.2)
Hyperthyroidism	4	(4.7)	3	(3.6)	2	(2.4)
Infusion Reactions	4	(4.7)	2	(2.4)	2	(2.4)
Adrenal Insufficiency	2	(2.4)	0	(0.0)	0	(0.0)
Colitis	2	(2.4)	1	(1.2)	1	(1.2)
Hypophysitis	1	(1.2)	0	(0.0)	0	(0.0)
Vasculitis	0	(0.0)	1	(1.2)	0	(0.0)

Every participant is counted a single time for each applicable row and column.
Non-serious adverse events occurring within 30 days after the last dose of study intervention and serious adverse events occurring within 90 days after the last dose of study intervention, or 30 days after the last dose of study intervention if a new anticancer therapy is initiated, whichever is earlier are included.
Adverse event terms are based on MedDRA version 25.1.
Database cutoff date: 26Jan2023

Source: [P002V01MK7684A: adam-adsl; adae]

Table 2-21
Participants With Adverse Events of Special Interest (AEOSI) by Decreasing Incidence by Maximum Toxicity Grade
(Incidence >0% in One or More Treatment Groups)
(APaT Population)

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Participants in population	85		83		83	
with one or more adverse events	25	(29.4)	17	(20.5)	10	(12.0)
Grade 1	6	(7.1)	6	(7.2)	4	(4.8)
Grade 2	6	(7.1)	9	(10.8)	4	(4.8)
Grade 3	11	(12.9)	2	(2.4)	1	(1.2)
Grade 4	0	(0.0)	0	(0.0)	1	(1.2)
Grade 5	2	(2.4)	0	(0.0)	0	(0.0)
with no adverse events	60	(70.6)	66	(79.5)	73	(88.0)
Adrenal Insufficiency	**2**	**(2.4)**	**0**	**(0.0)**	**0**	**(0.0)**
Grade 2	2	(2.4)	0	(0.0)	0	(0.0)
Adrenal insufficiency	2	(2.4)	0	(0.0)	0	(0.0)
Grade 2	2	(2.4)	0	(0.0)	0	(0.0)
Colitis	**2**	**(2.4)**	**1**	**(1.2)**	**1**	**(1.2)**
Grade 1	0	(0.0)	0	(0.0)	1	(1.2)
Grade 2	0	(0.0)	1	(1.2)	0	(0.0)
Grade 3	2	(2.4)	0	(0.0)	0	(0.0)
Colitis	1	(1.2)	1	(1.2)	1	(1.2)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Colitis	1	(1.2)	1	(1.2)	1	(1.2)
Grade 1	0	(0.0)	0	(0.0)	1	(1.2)
Grade 2	0	(0.0)	1	(1.2)	0	(0.0)
Grade 3	1	(1.2)	0	(0.0)	0	(0.0)
Immune-mediated enterocolitis	1	(1.2)	0	(0.0)	0	(0.0)
Grade 3	1	(1.2)	0	(0.0)	0	(0.0)
Hyperthyroidism	**4**	**(4.7)**	**3**	**(3.6)**	**2**	**(2.4)**
Grade 1	4	(4.7)	2	(2.4)	2	(2.4)
Grade 2	0	(0.0)	1	(1.2)	0	(0.0)
Hyperthyroidism	4	(4.7)	2	(2.4)	2	(2.4)
Grade 1	4	(4.7)	2	(2.4)	2	(2.4)
Basedow's disease	0	(0.0)	1	(1.2)	0	(0.0)
Grade 2	0	(0.0)	1	(1.2)	0	(0.0)
Hypophysitis	**1**	**(1.2)**	**0**	**(0.0)**	**0**	**(0.0)**
Grade 3	1	(1.2)	0	(0.0)	0	(0.0)
Hypophysitis	1	(1.2)	0	(0.0)	0	(0.0)
Grade 3	1	(1.2)	0	(0.0)	0	(0.0)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Hypothyroidism	**5**	**(5.9)**	**4**	**(4.8)**	**1**	**(1.2)**
Grade 1	2	(2.4)	2	(2.4)	0	(0.0)
Grade 2	3	(3.5)	1	(1.2)	1	(1.2)
Grade 3	0	(0.0)	1	(1.2)	0	(0.0)
Hypothyroidism	5	(5.9)	4	(4.8)	1	(1.2)
Grade 1	2	(2.4)	2	(2.4)	0	(0.0)
Grade 2	3	(3.5)	1	(1.2)	1	(1.2)
Grade 3	0	(0.0)	1	(1.2)	0	(0.0)
Infusion Reactions	**4**	**(4.7)**	**2**	**(2.4)**	**2**	**(2.4)**
Grade 1	1	(1.2)	0	(0.0)	1	(1.2)
Grade 2	2	(2.4)	2	(2.4)	0	(0.0)
Grade 3	1	(1.2)	0	(0.0)	1	(1.2)
Hypersensitivity	2	(2.4)	1	(1.2)	0	(0.0)
Grade 2	1	(1.2)	1	(1.2)	0	(0.0)
Grade 3	1	(1.2)	0	(0.0)	0	(0.0)
Infusion related hypersensitivity reaction	1	(1.2)	0	(0.0)	0	(0.0)
Grade 1	1	(1.2)	0	(0.0)	0	(0.0)
Infusion related reaction	1	(1.2)	1	(1.2)	1	(1.2)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Infusion related reaction	1	(1.2)	1	(1.2)	1	(1.2)
Grade 1	0	(0.0)	0	(0.0)	1	(1.2)
Grade 2	1	(1.2)	1	(1.2)	0	(0.0)
Drug hypersensitivity	0	(0.0)	0	(0.0)	1	(1.2)
Grade 3	0	(0.0)	0	(0.0)	1	(1.2)
Pneumonitis	**6**	**(7.1)**	**6**	**(7.2)**	**5**	**(6.0)**
Grade 1	0	(0.0)	3	(3.6)	1	(1.2)
Grade 2	2	(2.4)	3	(3.6)	3	(3.6)
Grade 3	2	(2.4)	0	(0.0)	0	(0.0)
Grade 4	0	(0.0)	0	(0.0)	1	(1.2)
Grade 5	2	(2.4)	0	(0.0)	0	(0.0)
Pneumonitis	3	(3.5)	5	(6.0)	5	(6.0)
Grade 1	0	(0.0)	3	(3.6)	1	(1.2)
Grade 2	2	(2.4)	2	(2.4)	3	(3.6)
Grade 4	0	(0.0)	0	(0.0)	1	(1.2)
Grade 5	1	(1.2)	0	(0.0)	0	(0.0)
Interstitial lung disease	2	(2.4)	0	(0.0)	0	(0.0)
Grade 3	1	(1.2)	0	(0.0)	0	(0.0)
Grade 5	1	(1.2)	0	(0.0)	0	(0.0)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Immune-mediated lung disease	1	(1.2)	1	(1.2)	0	(0.0)
Grade 2	0	(0.0)	1	(1.2)	0	(0.0)
Grade 3	1	(1.2)	0	(0.0)	0	(0.0)
Severe Skin Reactions	**8**	**(9.4)**	**2**	**(2.4)**	**0**	**(0.0)**
Grade 1	1	(1.2)	0	(0.0)	0	(0.0)
Grade 2	1	(1.2)	1	(1.2)	0	(0.0)
Grade 3	6	(7.1)	1	(1.2)	0	(0.0)
Pruritus	3	(3.5)	0	(0.0)	0	(0.0)
Grade 3	3	(3.5)	0	(0.0)	0	(0.0)
Rash	2	(2.4)	1	(1.2)	0	(0.0)
Grade 3	2	(2.4)	1	(1.2)	0	(0.0)
Dermatitis exfoliative generalised	1	(1.2)	0	(0.0)	0	(0.0)
Grade 1	1	(1.2)	0	(0.0)	0	(0.0)
Pemphigoid	1	(1.2)	0	(0.0)	0	(0.0)
Grade 3	1	(1.2)	0	(0.0)	0	(0.0)
Rash maculo-papular	1	(1.2)	0	(0.0)	0	(0.0)
Grade 3	1	(1.2)	0	(0.0)	0	(0.0)
Toxic skin eruption	1	(1.2)	1	(1.2)	0	(0.0)
Grade 2	1	(1.2)	1	(1.2)	0	(0.0)

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

	MK-7684A + Docetaxel		MK-7684A		Placebo + Docetaxel	
	n	(%)	n	(%)	n	(%)
Vasculitis	**0**	**(0.0)**	**1**	**(1.2)**	**0**	**(0.0)**
Grade 1	0	(0.0)	1	(1.2)	0	(0.0)
Vasculitis	0	(0.0)	1	(1.2)	0	(0.0)
Grade 1	0	(0.0)	1	(1.2)	0	(0.0)

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 NCI CTCAE version 5.0.

Non-serious adverse events occurring within 30 days after the last dose of study intervention and serious adverse events occurring within 90 days after the last dose of study intervention, or 30 days after the last dose of study intervention if a new anticancer therapy is initiated, whichever is earlier are included.

Adverse event terms are based on MedDRA version 25.1.

Database cutoff date: 26Jan2023

Source: [P002V01MK7684A: adam-adsl; adae]