A clinical study of pembrolizumab and chemotherapy with other treatments for non-small cell lung cancer (MK-3475-01A)

Protocol title: KEYMAKER-U01 Substudy 1: A Phase 2, Umbrella Study with Rolling Arms of Investigational Agents with Pembrolizumab in Combination with Chemotherapy in Treatment-Naive Patients with Advanced Non-small Cell Lung Cancer (NSCLC)

Why is this study needed?

Researchers are looking for new ways to treat advanced non-small cell lung cancer (NSCLC) that has not been treated. **NSCLC** is the most common type of lung cancer. **Advanced** means the cancer has spread to other parts of the body (metastatic) and cannot be removed with surgery.

A standard treatment for NSCLC includes immunotherapy and chemotherapy. **Immunotherapy** is a treatment that helps the immune system fight cancer. **Pembrolizumab** is a type of immunotherapy. **Chemotherapy** is a medicine that destroys cancer cells or stops them from growing.

Researchers want to know if adding other treatments to pembrolizumab and chemotherapy can treat advanced NSCLC.

The goal of this study is to learn the number of people whose cancer responds (gets smaller or goes away) after treatment.

Who will take part in this study?

About 360 people with advanced NSCLC will be in this study. They will be at least 18 years old and:

- Have either squamous or non-squamous advanced NSCLC
- Have not yet received treatment for advanced NSCLC
- Do not have another type of lung cancer

What treatments are being given during the study?

Everyone will receive **pembrolizumab and chemotherapy.** People will also receive one of these treatments:

- **Vibostolimab** – an immunotherapy
- **Boserolimab** – an immunotherapy
- **MK-4830** – an immunotherapy
- **MK-0482** – an immunotherapy

People will receive treatments through a vein by intravenous (IV) infusion every 3 or 6 weeks.

People will receive pembrolizumab, vibostolimab, boserolimab, MK-4830, and MK-0482 for up to 2 years or until the cancer gets worse or people do not tolerate them.

The researcher will choose the chemotherapy a person will receive based on their type of NSCLC. How long they receive chemotherapy will depend on the type of chemotherapy.

How is this study designed?

People will have an equal chance of being assigned to one of these treatment groups:

- **Group A**: Pembrolizumab and chemotherapy with vibostolimab
- **Group B**: Pembrolizumab and chemotherapy with boserolimab
- **Group C**: Pembrolizumab and chemotherapy with MK-4830
- **Group D**: Pembrolizumab and chemotherapy with MK-0482

Both the people in the study and the researcher will know which study treatment a person is getting (called an open-label study).

People may have urine, blood, tumor, and imaging tests, and physical examinations during the study.

People may be in this study for about 2 and a half years.

What are the goals of this study and how will they be measured?

Main goal	How it will be measured
To learn about the **objective response rate (ORR)** for people in Groups A, B, C, and D	**ORR** is the number of people whose cancer responds (cancer gets smaller or goes away) to treatment during the study
Other goals	**How they will be measured**
To learn about the **progression-free survival (PFS)** for people in Groups A, B, C, and D	**PFS** is the length of time from the start of treatment until the cancer gets worse or death from any cause
To learn about the **safety** of the treatments in Groups A, B, C, and D and how well people **tolerate** them	The number of people who: • Have an **adverse event (AE).** An AE is a health problem that happens or worsens during a study • Stop treatment due to an AE

What are the possible benefits and risks?

People may or may not benefit from the treatment received during the study. More information about the benefits and risks is in the Protocol.