Protocol Plain Language Summary

A clinical study of MK-2870 and chemotherapy to treat lung cancer (MK-2870-009)

Protocol Title: A Randomized, Open-label, Phase 3 Study of MK-2870 vs. Platinum Doublets in Participants with EGFR-mutated, Advanced Nonsquamous Non-small Cell Lung Cancer (NSCLC) Who Have Progressed on Prior EGFR Tyrosine Kinase Inhibitors

Why is this study needed?

Researchers are looking for new ways to treat **advanced non-small cell lung cancer (NSCLC)** with a gene mutation called EGFR (epidermal growth factor receptor). **Advanced** means the cancer has spread to the lymph nodes or other parts of the body and cannot be removed with surgery. A **gene mutation** is a change in the order of DNA.

Standard treatments for advanced NSCLC with an EGFR mutation may not work for some people. **MK-2870**, the study medicine, is an antibody drug conjugate (ADC). An **ADC** attaches to specific targets on cancer cells and delivers treatment to destroy those cells. This clinical study will compare MK-2870 to chemotherapy. **Chemotherapy** is medicine that destroys cancer cells or stops them from growing.

Researchers want to learn if people who receive MK-2870 live longer overall and without the cancer getting worse compared to people who receive chemotherapy.

Who will take part in this study?

About 520 people with advanced NSCLC will be in this study. They will be at least 18 years old and:

- Have an EGFR mutation
- Had the cancer get worse after treatment with a targeted therapy called EGFR tyrosine kinase inhibitor (TKI)
- Have not had other certain types of cancer in the past 3 years

What treatments are being given during the study?

People will have an equal chance of receiving one of these treatments through a needle into a vein as an intravenous (IV) infusion:

- **MK-2870**, the study medicine
- **Chemotherapy**

People will receive MK-2870 once every 2 weeks until the cancer gets worse, or they don't tolerate it. People will receive 2 types of chemotherapy (platinum and pemetrexed) once every 3 weeks:

- Both types for about 2 months
- Then pemetrexed until the cancer gets worse, or the person doesn't tolerate it

How is this study designed?

Both the people in the study and the researcher will know which study treatment a person is getting (open-label study). During the study, people will give urine, blood, and tumor samples, have imaging tests and physical examinations, and answer questions about how they are feeling and their ability to carry out daily tasks.

A person may be in this study for up to about 6 years.

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

Main goals	How they will be measured
To learn if the **progression-free survival (PFS)** of people who receive MK-2870 is longer than those who receive chemotherapy	**PFS** is the length of time from when the person starts treatment until the cancer grows or spreads, or death from any cause
To learn if the **overall survival (OS)** of people who receive MK-2870 is longer than those who receive chemotherapy	**OS** is the length of time from when the person starts treatment until death from any cause
Other goals	**How they will be measured**
To compare the **cancer response** in people who receive MK-2870 to those who receive chemotherapy	During the study, researchers will measure: • **Objective response rate (ORR)**: the number of people whose cancer responds to treatment (gets smaller or goes away) • **Duration of response (DOR)**: the length of time from when the cancer first responds to treatment until the cancer grows, spreads, or death occurs from any cause
To compare the **quality of life (QoL)** of people who receive MK-2870 to those who receive chemotherapy	People will answer sets of questions to measure their **QoL**, including questions about their overall health, lung cancer symptoms, and their ability to carry out daily tasks. Researchers will measure: • The change in the scores during the study • The length of time from when the person starts treatment until their QoL gets worse
To learn about the **safety** of MK-2870 and how well people **tolerate** it	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. This study has an external group of experts who oversee the overall risk and benefit. If this group of experts decides that the study treatment is not safe or does not show benefit, the study can be stopped.

More information about the benefits and risks is in the protocol.