Protocol Plain Language Summary

A clinical study of MK-1200 to treat advanced solid tumors (MK-1200-002)

Protocol Title: A Phase 1/2 Open-label Study to Evaluate the Safety and Efficacy of MK-1200 in Participants with Advanced Solid Tumors

Why is this study needed?

Researchers are looking for new ways to treat people with advanced cancer in solid tumors. **Solid tumors** are mostly in body organs and tissues, not in the blood or other body liquids. **Advanced** means that the cancer has spread to other parts of the body (metastatic) or cannot be removed with surgery.

MK-1200, the study medicine, is designed to treat advanced solid tumors. MK-1200 is a type of targeted therapy. A **targeted therapy** is a treatment that works to control how specific cancer cells grow and spread.

The main goal of this study is to learn about the safety of MK-1200 and how well people tolerate it.

Who will take part in this study?

About 304 people with advanced solid tumors will be in this study. They will be at least 18 years old and:

- Have one of these types of cancer:
  - Stomach
  - Esophagus (tube that connects the throat to the stomach)
  - Bile duct (small tubes that carry the digestive fluid bile)
  - Pancreatic duct (small tubes that carry digestive fluid out of the pancreas)
- Have received standard treatment for advanced solid tumors, or did not tolerate standard treatment
- Not have heart disease

What treatments are being given during the study?

People will be assigned to take 1 of up to 8 different dose levels of MK-1200 given through a needle into a vein as an intravenous (IV) infusion. People will receive MK-1200 every 2 weeks.

How is this study designed?

There are 2 parts to this study. A person will be in either Part 1 or Part 2.

In **Part 1**, people will be assigned to receive 1 of up to 8 different dose levels of MK-1200. Researchers will start by giving people the lowest dose level. Researchers will check to see if there are any safety concerns before giving the next higher dose of MK-1200. Researchers will pick 2 doses of MK-1200 from Part 1 for Part 2 (**selected doses**).

In **Part 2**, researchers will assign people to 1 of 2 groups based on the type of cancer they have:

- **Group 1**: people who have stomach cancer will have an equal chance of receiving 1 of the 2 selected doses of MK-1200

- **Group 2**: people who have esophagus, bile duct, or pancreatic duct cancer will receive only 1 selected dose of MK-1200

Both the people in the study and the researcher will know which study treatment a person is getting (**open-label study**). People may give blood and urine samples, have imaging tests, and physical examinations during the study.

A person may be in this study for up to about 2 years.

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

Main goal	How it will be measured
To learn about **safety** of MK-1200 and how well people **tolerate** it	The number of people who: • Had a **dose limiting toxicity (DLT)** during the first 4 weeks (Part 1 only) – A **DLT** is a medical problem related to study treatment that prevents giving a higher dose • Had an **adverse event (AE)** up to about 1 month after the last dose – An AE is a health problem that happens or worsens • Stopped treatment due to an AE
Other goals	**How they will be measured**
To learn how many people who receive MK-1200 have an **objective response (OR)**	**OR** rate is the number of people whose cancer responds to treatment (the cancer gets smaller or goes away) during the study
To learn what happens to different dose levels of MK-1200 in the body over time	Researchers will measure the amount of MK-1200 in people's blood samples at different times during the study
To learn how the cancer **responds** after receiving MK-1200	During the study, researchers will measure: • **Duration of response**: the length of time from when cancer first responds to treatment until the cancer grows, spreads, or death from any cause • **Progression-free survival**: the length of time from when the person starts in the study until the cancer grows or spreads, or death from any cause • **Overall survival**: the length of time from when the person starts in the study until death from any cause

What are the possible benefits and risks?

People may or may not benefit from the treatment received during the study. People may benefit because the treatment may treat the cancer or stop it from getting worse. There may be risks because the treatment may not work or may cause health problems. If people in this study have questions about the benefits and risks, they can talk to their study doctor. More information about the benefits and risks is in the Protocol and Informed Consent documents.