A clinical study of MK-2870 alone or with chemotherapy to treat gastrointestinal cancers (MK-9999-02A)

Protocol Title: A Phase 1/2 Study to Evaluate the Safety and Efficacy of MK-2870 Monotherapy or in Combination With Other Anticancer Agents in Gastrointestinal Cancers

Why is this study needed?

Researchers are looking for new ways treat certain **advanced gastrointestinal (GI) cancers**. **Advanced** means the cancer has spread to other parts of the body. **GI cancers** affect the digestive system.

Advanced GI cancers may be treated with chemotherapy. **Chemotherapy** is medicine that destroys cancer cells or stops them from growing. **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.

Researchers want to learn if MK-2870 alone or with chemotherapy can treat certain advanced GI cancers. The goals of this study are to learn:

- About the safety and how well people tolerate MK-2870 alone or with chemotherapy
- How many people have the cancer **respond** (get smaller or go away) to treatment

Who will take part in this study?

About 130 people will be in this study. They will be at least 18 years old and:

- Have a certain type of advanced GI cancer, such as colon or bile duct cancer
- Have received chemotherapy to treat the cancer
- Have not had other certain types of cancer in the past 3 years

What treatments are being given during the study?

People will receive one or both of these treatments:

- **MK-2870,** the study medicine
- **Chemotherapy** (5-fluorouracil and leucovorin)

People will receive their treatment once every 2 weeks through a needle into a vein as an intravenous (IV) infusion. People will continue their treatment until the cancer gets worse or they don't tolerate it.

How is this study designed?

People will be assigned to 1 of 2 groups:

- **Group A:** People will receive MK-2870 with chemotherapy
- **Group B:** People will receive MK-2870 alone

Researchers will first give a few people in Group A a certain dose level of MK-2870 with chemotherapy. They will check for any safety concerns or medical problems and adjust the dose level of MK-2870 if needed. This will help researchers decide which dose level of MK-2870 with chemotherapy to give to the rest of the people in Group A.

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, and have imaging tests and physical examinations.

A person may be in this study for about 5 years.

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

Main goals	How they will be measured
To learn about the **safety** and how well people **tolerate** MK-2870 alone or with chemotherapy	The number of people who: • Have an **adverse event (AE)**—An AE is a health problem that happens or worsens during the study • Stop treatment due to an AE • Have a **dose-limiting toxicity (DLT)** during the first 4 weeks of treatment. A DLT is a medical problem related to the study medicine that prevents giving a higher dose or may prevent giving the same dose. This will be measured only for the few people in Group A that first receive a certain dose level
To learn about the **objective response rate (ORR)** of people who receive MK-2870 alone or with chemotherapy	**ORR** is the number of people whose cancer responds (gets smaller or goes away) to treatment during the study

Other goal	How it will be measured
To learn how long the **cancer responds** in people who receive MK-2870 alone or with chemotherapy	During the study, researchers will measure: • **Duration of response (DOR):** the length of time from when the cancer first responds to treatment until the cancer grows, spreads, or death from any cause • **Progression-free survival (PFS)**: the length of time from when the person starts treatment until the cancer grows or spreads, or death from any cause • **Overall survival (OS):** the length of time from when the person starts treatment 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.

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