A clinical study of MK-7240 for the treatment of ulcerative colitis (MK-7240-001)

Protocol Title: A Phase 3, Randomized, Double-Blind, Placebo-Controlled Program to Evaluate the Efficacy and Safety of MK-7240 in Participants with Moderately to Severely Active Ulcerative Colitis

Why is this study needed?

Researchers are looking for a new way to treat people with **moderate to severe ulcerative colitis (UC)** that is causing symptoms (called **active**). UC is an **inflammatory bowel disease (IBD)** that causes swelling and ulcers (sores) in the digestive tract. UC affects the inner lining of the large intestine (called the colon) including the rectum (last part of the digestive tract). UC symptoms often come and go, with periods of few or no signs or symptoms of UC (called **remission**) between periods of UC symptoms.

MK-7240 is a study medicine designed to treat active, moderate to severe UC. The goal of this study is to learn about the safety of MK-7240 and how well people tolerate it. Researchers also want to learn how well MK-7240 works to treat UC and if people who take MK-7240 have remission after treatment compared to people who took placebo. A **placebo** looks like the study medicine but has no study medicine in it. Using a placebo helps researchers better understand the effects of a study treatment.

Who will take part in this study?

About 1,020 people with active, moderate to severe UC will be in the study. They will be ages 16 to 75 years and:

- Have had UC for at least 3 months
- Do not have Crohn's disease (CD) or other type of IBD
- Have taken other medicines that either did not help their UC or they did not tolerate the medicine

What treatments are being given during the study?

People will receive one or both treatments:

- **MK-7240**, the study medicine, at different dose levels
- **Placebo**

MK-7240 and placebo will be given through a needle in a vein as an intravenous (IV) infusion or as a shot given under the skin (subcutaneous or SC).

How is this study designed?

This study is made up of 2 studies (Study 1 and Study 2). People will be assigned to a group in 1 of the 2 studies.

Study 1: 720 people will have an equal chance to be assigned to 1 of 4 groups:

Treatment group	Study 1 treatment periods		
	Period 1 3 months	**Period 2 10 months**	**Optional Period 3 3 months**
Groups 1, 2 and 3	MK-7240 as IV a total of 4 times on: • Day 1 • Weeks 2, 6, and 10	MK-7240 as SC	MK-7240 as IV a total of 4 times on: • Day 1 • Weeks 2, 6, and 10
Group 4	Placebo as IV a total of 4 times on: • Day 1 • Weeks 2, 6, and 10	Placebo as SC	

Study 2: People will have an equal chance to be assigned to 1 of 3 groups:

Treatment group	Study 2 treatment periods	
	Period 1 3 months	**Optional Period 2 3 months**
Groups 1 and 2	MK-7240 as IV a total of 4 times on: • Day 1 • Weeks 2, 6, and 10	MK-7240 as IV a total of 4 times on: • Day 1 • Weeks 2, 6, and 10
Group 3	Placebo as IV a total of 4 times on: • Day 1 • Weeks 2, 6, and 10	

During Study 1, neither the people in the study nor the researchers will know which treatment a person is taking during treatment Periods 1 and 2 of Study 1 and Period 1 of Study 2 (**double-blind**). Both the people in the study and the researchers will know which treatment a person is taking during treatment Period 3 of Study 1 and Period 2 of Study 2 (**open-label**).

For both studies, people whose UC signs and symptoms are better after treatment may receive treatment with MK-7240 as SC for another 3 years (called an **extension**).

During both studies, people will give blood, urine, stool, and colon tissue samples, have the inside of their cheek swabbed, have physical examinations, answer questions, and have imaging tests (including an **endoscopy,** in which a doctor uses a thin, flexible lighted tube with a camera to look at the inside of a person's digestive tract).

A person may be in Study 1 for up to about 4 years and 7 months. A person may be in Study 2 for up to about 3 years and 7 months.

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

Main goals	How they will be measured
To learn if more people who take MK-7240 have **remission** compared to people who take placebo	Researchers will measure the number of people who have remission at: • 3 months in Study 1 (end of treatment Period 1) • 12 months in Study 1 (end of treatment Period 2) • 3 months in Study 2 (end of treatment Period 1)
To learn about the **safety** of MK-7240 and how well people **tolerate** treatment	During each study, the number of people who: • Had an **adverse event (AE)** – 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 if more people who take MK-7240 **respond to treatment** compared to those who take placebo	Respond to treatment means improved symptoms or signs of UC. Researchers will measure this at different times during the study.

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 that will oversee the overall risk and benefit. If this group of experts decides that the study treatment is not safe the study can be stopped.

More information about the benefits and risks is in the Investigator Brochure, Protocol, and Informed Consent documents.