Protocol Plain Language Summary

A clinical study of MK-0616 in people who have a high risk of having major heart-related events and take medicine to lower cholesterol (MK-0616-015)

Protocol title: A Phase 3 Randomized, Placebo-Controlled Clinical Study to Evaluate the Efficacy and Safety of MK-0616 in Reducing Major Adverse Cardiovascular Events in Participants at High Cardiovascular Risk

Why is this study needed?

Researchers are looking for new ways to prevent **major heart-related events** (such as heart attack, stroke, or death) in people who:

- Had heart-related events in the past or are at high risk of having a first heart-related event
- Are currently taking medicine called **statins**, which are medicines that lower **low-density lipoprotein cholesterol (LDL-C).** LDL-C is sometimes called "bad cholesterol." Cholesterol is a type of fat in a person's blood

Some people who take statins can still have high cholesterol after taking them.

MK-0616 (the study medicine) is in a class of medicines that have been shown to lower the amount of **LDL-C** in a person's blood. High levels of LDL-C can cause fatty deposits (called plaque) that sticks to the walls of blood vessels and can lead to major heart-related events. MK-0616 is different from the other medicines in this class because it is taken as a tablet by mouth and not an injection.

The goal of the study is to learn if MK-0616 works better than **placebo** on increasing the time to the first major heart-related event. A placebo looks like the study medicine but has no study medicine in it. Researchers use a placebo to better understand the actual effects of the study medicine.

Who will take part in this study?

About 14,550 people with high levels of LDL-C will be in this study. They will be at least 18 years old and:

- Have had a major heart-related event in the past or have a high risk of having a first heart-related event
- Are currently taking a statin
- Do not have certain types of heart disease or other certain health conditions

What treatments are being studied?

People will have an equal chance of receiving one of these treatments as a tablet by mouth once a day:

- **MK-0616**
- **Placebo**

People must take the treatment on an empty stomach and must not eat or drink anything, except small amounts of water, for 8 hours before and 30 minutes after taking the treatment.

How is this study designed?

People may be in this study for up to around 6 years.

Neither the people in the study nor the researchers will know if a person gets MK-0616 or placebo (called a double-blind study).

During the study, people may have blood and urine tests, tests to measure electrical activity in the heart (called electrocardiogram or ECG) and have physical examinations.

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

Main goal	How they will be measured
To learn if MK-0616 works better than placebo in delaying the first **major heart-related event**	The length of time from the start of the study until people have any of these: • Death from heart disease • Heart attack • Stroke • Loss of blood flow to arms or legs or surgery to remove an arm or leg • An urgent procedure to restore blood flow in blocked blood vessels
Other goals	**How they will be measured**
To learn if MK-0616 works better than placebo in delaying the first **major heart-related event**. Researchers will put the major heart-related events into different groups and also look at each type of event individually.	The length of time from the start of the study until: • Death from heart disease or disease of the blood vessels • Heart attack • Stroke • Loss of blood flow to arms or legs or surgery to remove an arm or leg • An urgent procedure to restore blood flow in blocked blood vessels
To learn if MK-0616 works better than placebo in delaying **death** from any cause	The length of time from the start of the study until death from any cause.
To learn if MK-0616 and placebo lower cholesterol (LDL-C and non-HDL-C). HDL-C is high-density lipoprotein cholesterol, sometimes called "good cholesterol." Non-HDL-C is cholesterol other than HDL-C	The change in the amount of LDL-C and non-HDL-C in a person's blood from the start of the study to Week 52.
To learn if MK-0616 and placebo lower apolipoprotein B (ApoB) and lipoprotein (a) (Lp(a)). ApoB and Lp(a) are types of fat (lipid) and protein bound together	The change in the amount of ApoB and Lp(a) in a person's blood from the start of the study to Week 52.
To learn about **safety** and how well people **tolerate** MK-0616	The number of people who: • Had an **adverse event** (**AE**). An AE is a health problem that happens or worsens during a study. • Stopped treatment due to an AE

What are the possible benefits and risks?

People in this study may or may not benefit from the treatment. This study has an external group of experts that oversees 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 benefits and risks may be found in the protocol.