Protocol Plain Language Summary

A clinical study of islatravir and MK-8507 for people with HIV-1 (MK-8591-013)

Protocol Title: A Phase 2b, Randomized, Active-Controlled, Double-Blind, Dose-Ranging Clinical Study to Evaluate a Switch to Islatravir (ISL) and MK-8507 Once-Weekly in Adults with HIV-1 Virologically Suppressed on Bictegravir/Emtricitabine/Tenofovir Alafenamide (BIC/FTC/TAF) Once-Daily

Why is this study needed?

Researchers are looking for new treatments for people living with **HIV-1** (Human Immunodeficiency Virus Type 1). HIV-1 is the most common type of HIV, which is a virus that attacks cells of the immune system.

HIV-1 treatments, called antiretroviral therapy or **ART**, are medicines that lower the amount of HIV-1 virus in the body (viral load). **Standard ART** helps people live longer, but it may include taking medicines every day. This may make it hard for some people to follow their treatment plan.

Researchers are looking for new ART that is safe, can be taken less often, and can be taken for a long time. The **study ART**, islatravir (ISL) and MK-8507**,** is 2 medicines taken once a week.

The goal of this study is to learn about the safety and how well people tolerate the study ART.

By December 2021, the study was redesigned by the sponsor. All people stopped their assigned treatment. People assigned to standard ART were no longer in the study. People assigned to study ART were switched to **non-study ART** (ART that is not the study ART). They were followed for at least 6 months and may be able to continue the study.

Who will take part in this study?

About 161 people with HIV-1 will be in this study. They will be at least 18 years old and:

- Have a HIV-1 viral load of less than 50 **copies**—viral load is measured as the number of virus "copies" in a small amount of blood
- Taking a standard ART called **BIC/FTC/TAF** (bictegravir, emtricitabine, and tenofovir alafenamide) for at least 6 months
- Not have HIV-2

How is this study designed?

Prior to redesign:

People will have an equal chance to be assigned to one of these treatment groups:

- **Group A:** study ART (ISL and **low dose level** of MK-8507) and placebo
- **Group B:** study ART (ISL and **medium dose level** of MK-8507) and placebo
- **Group C:** study ART (ISL and **high dose level** of MK-8507) and placebo
- **Group D:** standard ART and placebo

After each group takes their assigned treatment for 1 year, researchers will review the safety of each dose level. Neither the people in the study nor the researchers will know which study treatments a person is getting (double-blind study). During the study, people will give urine and blood samples, and have physical examinations.

After redesign:

Group D will no longer be in the study.

Groups A, B, and C will take non-study ART. They will be followed for at least 6 months. People will give blood samples and have physical examinations.

What treatments are being given during the study?

Prior to redesign:

People will take one of these treatments by mouth:

- **Study ART**, which is a combination of 2 medicines, taken once a week:
  - **ISL**, a capsule at one dose level (amount)
  - **MK-8507**, a tablet at different dose levels
- **Standard ART**— called **BIC/FTC/TAF**, which combines the 3 medicines into one tablet, taken once a day

To make sure people do not know which treatment or treatments they are receiving, everyone will also take placebo tablets and capsules with their treatment. A **placebo** looks like the study medicine but has no study medicine in it.

After redesign:

People will only take non-study ART and will not take placebo.

What is the goal of this study and how will it be measured?

Main goal	How it will be measured
To learn about the **safety** and how well people **tolerate** the study ART	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?

Clinical studies may have benefits and risks. People may benefit because the study ART may treat HIV-1 or stop it from getting worse. There may be risks because the study ART may not work or may cause health problems.

This study has a group of experts, separate from the researchers, who oversee the benefits and risks. After a review by the group of experts, the sponsor decided to redesign the study. All people stopped their assigned treatment. People assigned to standard ART were no longer in the study. People assigned to study ART were switched to non-study ART. They were followed for at least 6 months and may be able to continue the study.

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