Protocol Plain Language Summary

A clinical study of people with HIV-1 who received previous treatment with doravirine and islatravir (MK-8591A-054)

Protocol title: A Phase 3 Open-label Clinical Study of Doravirine/Islatravir (DOR/ISL [100 mg/0.25 mg]) Once Daily for the Treatment of HIV-1 Infection in Participants Who Previously Received DOR/ISL (100 mg/0.75 mg) QD in a Phase 3 Clinical Study

Why is this study needed?

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

HIV-1 treatments, called **ART** (antiretroviral therapy), involve taking medicines to lower the amount of HIV-1 virus in the body.

The purpose of this study is for people from prior studies to continue getting **study ART** but at a lower dose. Also, researchers will try to better understand how well the lower dose of study ART works in controlling HIV-1.

Who will take part in this study?

About 650 people with HIV-1 will take part in this study. They will be at least 18 years old and:

- Taking the study ART at a higher dose in another study
- Not have a HIV-1 viral load of 200 **copies** or more
- Have not had another ART stop working for them

How is this study designed?

Each person will be in the study and take the study ART for about 2 years. Both the people in the study and the researchers will know the treatment a person will take (open-label study).

A person may give urine samples, have blood tests and physical examinations during the study. After finishing the study, people may continue to take the study ART for up to 5 years.

What treatments are given during this study?

The **study ART** combines 2 medicines called **doravirine (DOR)** and **islatravir (ISL).** It's taken by mouth as 1 tablet once a day.

Protocol Plain Language Summary

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

Main goal	How it will be measured
To learn about the safety and how well people manage **(tolerate)** the study ART	By Week 96, the number of people who: • Have an **adverse event (AE)** – an AE is a health problem that happens or worsens during a study • Stop the study ART due to an AE
Other goals	**How they will be measured**
To learn how well the study ART works to treat HIV-1	At Week 96, the number of people who have an HIV-1 viral load of: • 50 copies or more • Less than 50 copies • 200 copies or more A lower viral load of HIV-1 in the blood is better. The viral load is measured as the number of "**copies**" in a small amount of blood (milliliter).
To learn if the study ART stops working for people	The number of people who have an HIV-1 viral load of 200 copies or more at any time during the study

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 Investigator Brochure, Protocol, and Informed Consent documents.