

## What are the different phases of the study?

**Screening (up to 45 days):** You will receive medical tests to see if you are eligible to take part in the study. If you are eligible, you may choose to participate and move to the next phase.

**Study treatment (up to 96 weeks, or about 2 years):** You will visit the study site for medical tests up to about 11 times during this phase.

**Follow-Up:** You may have 1 follow-up visit about 6 weeks after your last dose of the study medicine.

## Why participate in this study?

- Your participation may help researchers learn more about what happens when people with HIV-1 start taking a 2-drug medicine (investigational medicine) compared to the standard 3-drug medicine.
- Participation is voluntary, and you are free to stop at any time.
- You will receive the study medicine and attend the study visits at no charge. You may receive reimbursement for study-related travel and expenses.



**Together we can advance HIV research**

Learn more about this study and whether you may be able to participate.

**For more information, including the possible risks and benefits of being in this study, please contact:**

The MK8591A-053 research study is testing an investigational medicine in people living with HIV-1 who have never taken any antiretroviral therapy (ART) to treat their HIV. This study is an important step in testing what happens when people with HIV-1 take a 2-drug regimen rather than a 3-drug regimen to treat their HIV.



A research study tries to answer questions about how medicines work in the people who take them. Researchers run studies to test whether an investigational medicine is safe and effective. These studies may help doctors find new ways to help prevent, detect, or treat health problems.

## About the investigational medicine

The investigational medicine is a tablet taken once a day by mouth. It is a combination of 2 drugs:

- Doravirine, which is approved by some health authorities for treating HIV-1 (though it may not be approved in your country)
- Islatravir, an experimental drug that has not been approved



## About this study

This study is testing the investigational medicine in people living with HIV-1 who have never received any ART to treat their HIV. Researchers will assess the safety and tolerability of the investigational medicine, see how well it slows the growth of the HIV virus, and how it works in the body compared to an approved 3-drug medicine.

All participants in this study will have their health closely monitored by an experienced study team.

## There are 2 groups in this study

People in this study will be randomly placed (like flipping a coin) into 1 of 2 groups:

- Group 1 will get the investigational medicine (DOR/ISL) and a placebo
- Group 2 will get the approved drug (BIC/FTC/TAF) and a placebo

You have an equal chance of being put into either study medicine group. You and the study team will not know which group you are in.

Some of the tests that take place during the study include:

- Physical exams
- Blood and urine tests



- Vital signs (pulse, blood pressure, body temperature, breathing rate)
- Questionnaire completion by the participant
- Electrocardiogram (ECG)
- DEXA (bone density) scans (if applicable)

Approximately 500 people will be in this study. If you are eligible and choose to participate, your time in this study will last approximately 2 years and 2 months.

## Can I take part in this study?

You may be eligible to take part in this study if you are at least 18 years of age and:

- Are HIV-1 positive
- Have not taken any ART since your diagnosis of HIV
- Have not taken long-acting medications, such as cabotegravir or lenacapavir, to prevent HIV at any time

The study team will discuss other study criteria with you.