This document provides a short summary of this study for a general audience. You can find more information in the scientific summary of the study. A link to the summary is provided at the end of this document.

Study names

Short Title: A study to see how well cabotegravir and rilpivirine work when given once every two months to adults living with HIV.

Full Scientific Title: A phase IIB, multicentre, open-label, rollover study evaluating the efficacy, safety, and tolerability of long-acting cabotegravir plus long-acting rilpivirine administered every two months in HIV-1 infected adults who are virologically suppressed and participated in Study LAI116482.

ViiV Healthcare Study Number: 209035

Who sponsored this study?

ViiV Healthcare
GSK Clinical Support Help Desk
Website: clinicalsupporthd.gsk.com/contact.html
Email: GSKClinicalSupportHD@gsk.com

General information about the clinical study

When was this study done?

The study started in August 2018. Enrolment is closed, but the study was ongoing when this summary was finalised. Data collected up to March 2020 are included in this summary. This is called the data cut-off.

What was the main objective of this study?

Human immunodeficiency virus type 1 (HIV) damages the body's defence system (immune system). It weakens the ability to fight infections and increases the risk of developing diseases. Doctors monitor the amount of HIV in the body (viral load) by measuring HIV RNA levels in the blood.

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Antiretroviral medicines treat HIV infection by controlling the viral load. Researchers consider that these medicines worked well if the participants' viral loads remained undetectable (less than 50 copies per millilitre [c/mL]).

In this study, researchers wanted to see how well cabotegravir (CAB) and rilpivirine (RPV) injections maintained viral loads when given once every two months to adults living with HIV who had an undetectable viral load. Researchers also assessed the safety of these medicines.

Which medicines were studied?

On Day 1 of this study, participants who had received daily CAB and RPV tablets in Study LAI116482 could choose to be in one of the following two treatment groups:

- CAB and RPV group: Participants received CAB and RPV injections into the muscle once every two months.
- Dolutegravir (DTG) and RPV group: Participants received a tablet containing DTG and RPV once daily.

After Month 12, participants who chose to receive CAB and RPV injections could choose to continue receiving them until these were available in their country. Participants who chose to receive DTG and RPV could remain in the study only up to Month 12.

Which participants were included in this study?

Studies have a list of requirements for participants who can enrol (inclusion criteria) and those who can't (exclusion criteria). For this study, the main inclusion and exclusion criteria are listed below.

Men and women were included in the study if they:

- Were at least 18 years old.
- Received daily CAB and RPV tablets for six years as part of Study LAI116482.
- Had an undetectable viral load at least 12 weeks before Day 1.

Men and women were excluded from the study if they had:

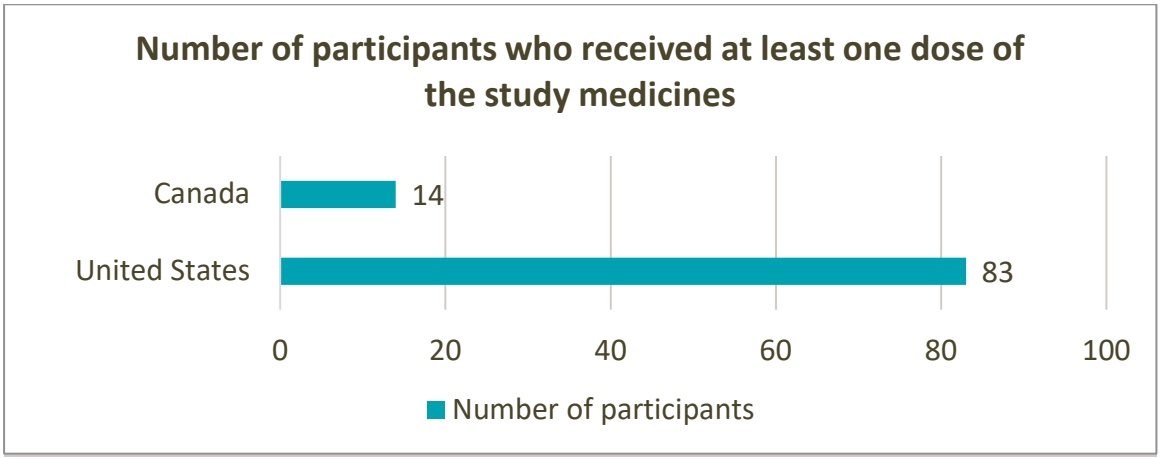
- A viral load of 50 c/mL or more at least twice within six months before Day 1.
- A viral load of 200 c/mL or more at least once within six months before Day 1.
- Any other disease(s), abnormal blood test results, or taken any medicine(s) that the study doctor thought would affect the results of the study.

Overall, 97 participants received at least one dose of the study medicines. The study included 95 participants (98%) who were assigned male at birth and 2 participants (2%) who were assigned female at birth. Of these, 94 participants identified as male and 3 participants identified as female. The average age was 42 years. The youngest participant was 25 years old and the oldest participant was 63 years old.

For more detailed information about the participants included in this study, see the scientific results summary (a link to the summary is provided at the end of this document).

Where was this study done?

Study sites were in two countries.



What were the main results of the study?

Study doctors collected blood samples and measured participants' viral loads.

The table below shows the results for participants who had viral load assessed as:

- Detectable: 50 c/mL or more at Month 12 or at their last test before they stopped taking part in the study.
- Undetectable: Less than 50 c/mL at Month 12.

Number of participants (percent) by viral load		
	CAB and RPV 90 participants	**DTG and RPV 7 participants**
50 c/mL or more	0	0
Less than 50 c/mL	88 (98%)	7 (100%)

More information about the study results is available in the scientific results summary (a link to the summary is provided at the end of this document).

What were the side effects?

Unwanted medical events (adverse events) can happen to people when they receive a medicine. Study doctors record these events. A summary of these events can be found in the scientific results summary (a link to the summary is provided at the end of this document).

If the study doctor thinks that the event was caused by the study medicine, they record this as a possible side effect (adverse reaction).

In this summary, side effects refer to those events that the study doctor thinks may have been caused by the study medicines and/or injections. The side effects in this summary may be different to those in the Informed Consent for this study or other documents related to the study medicines.

The side effects in this summary have been collected from Day 1 to the data cut-off.

Injection-related side effects were collected only for participants in the CAB and RPV group as DTG and RPV were given as a tablet.

Serious side effects

No serious side effects were reported in the DTG and RPV group.

One of 90 participants in the CAB and RPV group reported an injection-related serious side effect of partial injection of the study medicine into blood vessel.

Non-serious side effects

A non-serious side effect of headache was reported in 1 of 7 participants in the DTG and RPV group.

Non-serious side effects were reported by 65 of 90 participants in the CAB and RPV group. The table below shows the non-serious side effects that were reported by 5% or more of participants in the CAB and RPV group.

Number of participants (percent) with non-serious side effects reported by 5% or more of participants in the CAB and RPV group	
	CAB and RPV 90 participants
Injection-related non-serious side effects	
Pain	59 (66%)
Discomfort	8 (9%)
Lump	5 (6%)
Swelling	5 (6%)
Study medicine-related non-serious side effects	
Fever	7 (8%)

How has this study helped participants and researchers?

Adults living with HIV, who were taking daily CAB and RPV tablets previously, took part in this study. Almost all participants chose to receive CAB and RPV injections given once every two months. At Month 12, all participants in the study maintained undetectable viral load levels. The side effects reported in this study were as expected and limited in number.

Are there plans for further studies?

Other studies of CAB and RPV in adults living with HIV have been conducted and some are ongoing or planned.

Where can I find more information about this study?

Clinical studies have other unique study numbers that are included in publications and other information about the study. The unique study number associated with this study is shown below with an internet link to the scientific summary.

The scientific summary includes more details about the requirements for study enrolment, the study visit schedule, results from other endpoints, and more detailed information about adverse events. When the study is complete, final results will be available in the scientific summary.

Organisation and Website	Study Number
United States National Institutes of Health (NIH) (www.clinicaltrials.gov)	NCT03639311[1]

Your doctor can help you understand more about this study and the results. Speak to your doctor about the treatment options available in your country. You should not make changes to your care based on the results of this or any single study. Keep taking your current treatment unless instructed by your doctor.

We would like to thank the participants who contributed to this study. The results of this study will help answer scientific questions about treating adults living with HIV.

The content for this document was finalised by ViiV Healthcare on 2 September 2021. The information in this summary does not include additional information available after this date.

[1] https://clinicaltrials.gov/ct2/show/study/NCT03639311