LAPaL
THE LONG-ACTING THERAPEUTICS PATENTS AND LICENCES DATABASE

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CAB LA + rHuPH20

LAPaL
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STRUCTURE PLACEHOLDER

cabotegravir PH20

Developer(s)

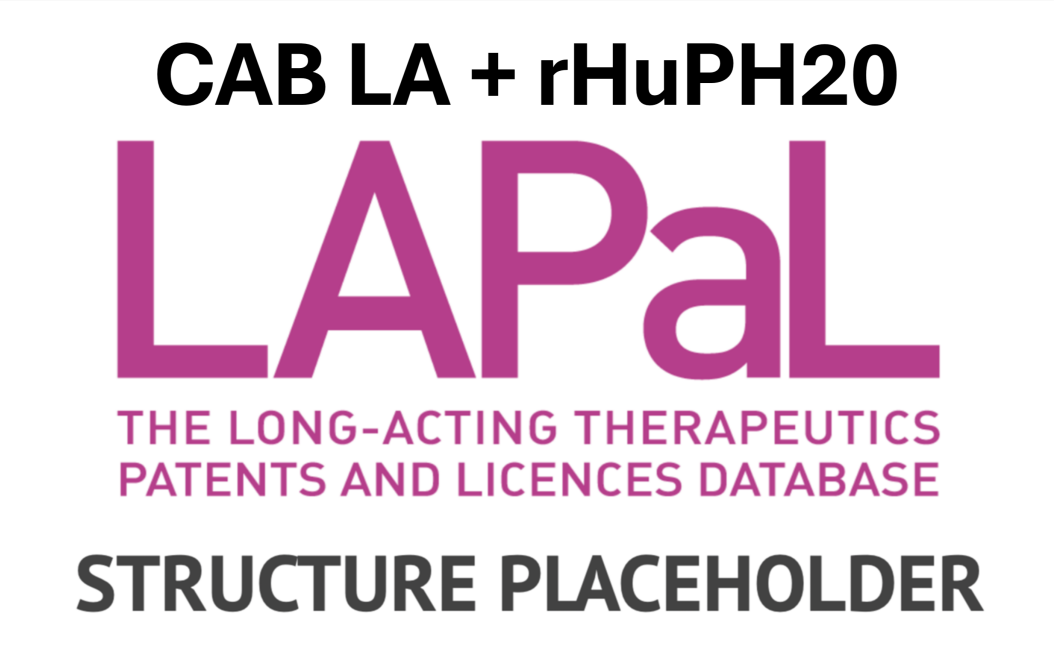
ViiV Healthcare

Originator

https://viivhealthcare.com/

United Kingdom

Drug structure



CAB LA and hyaluronidase placeholder

Drug information

Associated long-acting platforms

Aqueous drug particle suspension

Administration route

Subcutaneous, Intramuscular, To be determined

Therapeutic area(s)

HIV

Use case(s)

Pre-Exposure Prophylaxis (PrEP)
Treatment
Prevention

Use of drug

Ease of administration

Administered by a community health worker
Administered by a nurse
To be determined

User acceptance

Not provided

Dosage

Available dose and strength

Not provided

Frequency of administration

Not provided

Maximum dose

Not provided

Recommended dosing regimen

Not provided

Additional comments

Not provided

Dosage link(s)

Not provided

Drug information

Drug's link(s)

Not provided

Generic name

long-acting cabotegravir coadministered with recombinant human hyaluronidase PH20 (rHuPH20)

Brand name

Not provided

Compound type

Not provided

Summary

Not provided

Approval status

Unknown

Regulatory authorities

Unknown

Delivery device(s)

Not provided

Scale-up and manufacturing prospects

Scale-up prospects

Not provided

Tentative equipment list for manufacturing

Not provided

Manufacturing

Not provided

Specific analytical instrument required for characterization of formulation

Not provided

Clinical trials

219406

Identifier

NCT06033547

Link

https://clinicaltrials.gov/study/NCT06033547

Phase

Phase I

Status

Not provided

Sponsor

ViiV Healthcare

More details

The primary purpose of the study is to investigate the safety, tolerability, and pharmacokinetic (PK) profiles of two different cabotegravir formulations in healthy adult participants. The study will initially start with the assessment of Cabotegravir Formulation F. Once the clinical batch of Cabotegravir Formulation G is available, this formulation will be assessed.

Purpose

A Study to Investigate the Pharmacokinetics, Safety, and Tolerability of Two Different Formulations of Long-acting Cabotegravir in Healthy Adult Participants

Interventions

Not provided

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2023-09-12

Anticipated Date of Last Follow-up

2025-01-17

Estimated Primary Completion Date

2025-07-25

Estimated Completion Date

2025-07-25

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Adults

Genders

- All

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

Yes

Comments about the studied populations

Inclusion Criteria: * Participants who are overtly healthy as determined by medical evaluation including medical history, physical examination, laboratory tests, and cardiac monitoring * Body weight =\>40 kilogram (kg) and body mass index (BMI) within the range =\>18 to =\<32 kilogram per meter square (kg/m\^2) * Participants who are negative on a single test for Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)(approved molecular polymerase chain reaction \[PCR\] laboratory or point of care test) performed on the day of admission. A negative result is required prior to the administration of study intervention on Day 1. * Contraceptive use by men and women should be consistent with local regulations regarding the methods of contraception for those participating in clinical stud

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

56

Allocation

Not provided

Intervention model

Sequential assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Not provided

Studied LA-formulation(s)

Not provided

Studied route(s) of administration

Not provided

Use case

Not provided

Key results

Not provided

218012

Identifier

NCT05418868

Link

https://clinicaltrials.gov/study/NCT05418868

Phase

Phase I

Status

Recruiting

Sponsor

ViiV Healthcare

More details

This is an open-label, dose-escalation study to investigate the safety, tolerability and pharmacokinetics (PK) of single subcutaneous (SC) administration of long acting (LA) Cabotegravir (CAB) 200 milligrams per milliliter (mg/mL) with Recombinant Human Hyaluronidase PH20 (rHuPH20) (Part A), a single SC or intramuscular (IM) administration of LA CAB (greater than or equal to) \>=400 mg/mL with and without rHuPH20 (Parts C and D), LA CAB Formulation I (Part C Cohort C8) and a single-dose or repeat-dose IM administration of rilpivirine (RPV) (Part E). Part A of the study (CAB 200 mg/mL with rHuPh20) has been closed to further enrolment based on preliminary results.

Purpose

A Study to Investigate Pharmacokinetics, Safety and Tolerability of Long-Acting

Cabotegravir Plus Recombinant Human Hyaluronidase PH20 in Healthy Adult Participants

Interventions

Not provided

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2022-06-14

Anticipated Date of Last Follow-up

2025-02-17

Estimated Primary Completion Date

2026-07-06

Estimated Completion Date

2027-11-02

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Adults

Genders

- All

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

Yes

Comments about the studied populations

Inclusion Criteria: * At the time of obtaining informed consent, participants age should be greater than or equal to (\>=)18 years and less than or equal to (\<=) 55 years. * Participants who are overtly healthy as determined by medical evaluation including medical history, physical examination, laboratory tests, and cardiac monitoring. * Body weight \>=40 kilogram (kg) and body mass index (BMI) within the range \>=18 to \<=32 kilogram per meter square (kg/m\^2). * Participants who are negative on a single test for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (approved molecular polymerase chain reaction \[PCR\] laboratory or point of care test), performed on the day of admission. A negative result is required prior to the administration of study intervention on Day 1. * C

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

180

Allocation

Not provided

Intervention model

Sequential assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Not provided

Studied LA-formulation(s)

Not provided

Studied route(s) of administration

Not provided

Use case

Not provided

Key results

Not provided

Excipients

Proprietary excipients used

Not provided

Novel excipients or existing excipients at a concentration above Inactive Ingredients Database (IID) for the specified route of administration

Not provided

Residual solvents used

Not provided

Patent info

There are either no relevant patents or these were not yet submitted to LAPaL

Supporting material

Publications

There are no publication

Additional documents

No documents were uploaded

Useful links

There are no additional links

Access principles

Collaborate for development

Consider on a case by case basis, collaborating on developing long acting products with potential significant public health impact, especially for low- and middle-income countries (LMICs), utilising the referred to long-acting technology

Not provided

Share technical information for match-making assessment

Provide necessary technical information to a potential partner, under confidentiality agreement, to enable preliminary assessment of whether specific medicines of public health importance in LMICs might be compatible with the referred to long-acting technology to achieve a public health benefit

Not provided

Work with MPP to expand access in LMICs

In the event that a product using the referred to long-acting technology is successfully developed, the technology IP holder(s) will work with the Medicines Patent Pool towards putting in place the most appropriate strategy for timely and affordable access in low and middle-income countries, including through licensing

Not provided

Comment & Information

Not provided