LAPaL
THE LONG-ACTING THERAPEUTICS PATENTS AND LICENCES DATABASE

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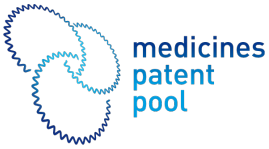

GS-4182 COMPOUND

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STRUCTURE PLACEHOLDER

GS-4182

Developer(s)

Gilead

Originator

https://www.gilead.com/

United States

Drug structure

not disclosed yet

Drug information

Associated long-acting platforms

Oral solid form

Administration route

Oral

Therapeutic area(s)

HIV

Use case(s)

Treatment

Use of drug

Ease of administration

Self-administered

User acceptance

Not provided

Dosage

Available dose and strength

300mg is the investigated dose

Frequency of administration

once a week oral dosing with GS-1720 is the investigated schedule

Maximum dose

600mg is the investigated loading dose (2 tablets)

Recommended dosing regimen

In the phase 2/3 study (NCT06613685), participants will receive a 1-day loading dose of GS-1720 (1300 mg) and GS-4182 (600 mg) on Day 1.Thereafter, participants will take weekly doses of single agent GS-1720 (650 mg) and GS-4182 (300 mg) co-administered for at least 48 weeks.

Additional comments

Not provided

Dosage link(s)

Not provided

Drug information

Drug's link(s)

Not provided

Generic name

GS-4182

Brand name

investigational

Compound type

Small molecule

Summary

GS-4182 is an investigational lenacapavir prodrug with improved bioavailability and potential for oral weekly administration. The chemical structure of GS-4182 is not yet available in the public domain. GS-4182 is studied in combination with GS-1720, a new oral INSTI. Phase II/III WONDERS trials are currently underway using the GS-4182+GS-1720 combination. If successful, a weekly oral HIV treatment could provide a valuable alternative for PLHIV.

Approval status

GS-4182 is currently in clinical development and not yet approved in any jurisdiction.

Regulatory authorities

GS-4182 is currently in clinical development and not yet approved in any jurisdiction.

Delivery device(s)

Not provided

Scale-up and manufacturing prospects

Scale-up prospects

Detailed manufacturing information is not currently available for this compound.

Tentative equipment list for manufacturing

Detailed manufacturing information is not currently available for this compound.

Manufacturing

Detailed manufacturing information is not currently available for this compound.

Specific analytical instrument required for characterization of formulation

Detailed manufacturing information is not currently available for this compound.

Clinical trials

WONDERS2

Identifier

NCT06613685

Link

https://clinicaltrials.gov/study/NCT06613685

Phase

Phase II/III

Status

Recruiting

Sponsor

Gilead Sciences

More details

The goal of this clinical study is to learn more about the experimental drugs GS-1720 (an oral, long-acting integrase strand transfer inhibitor (INSTI)) and GS-4182 (a prodrug of Lenacapavir (LEN)); to compare the combination of GS-1720 and GS-4182 with the current standard-of-care treatment bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) (Biktarvy), to see if the combination of GS-1720 and GS-4182 is safe and if it works for treating human immunodeficiency virus type 1 (HIV-1) infection in treatment-naive people with HIV-1 (PWH). This study has two phases: Phase 2 and Phase 3. The primary objectives of this study are: Phase 2: To evaluate the efficacy of oral weekly GS-1720 coadministered with GS-4182 versus continuing Biktarvy (BVY) in

treatment-naive PWH at Week 24. Phase

Purpose

Study of Oral Weekly GS-1720 and GS-4182 Compared With Biktarvy in People With HIV-1 Who Have Not Been Treated

Interventions

Intervention 1
GS-1720

Intervention 2
GS-4182

Intervention 3
Bictegravir/emtricitabine/tenofovir alafenamide

Intervention 4
GS-1720/GS-4182 FDC

Intervention 5
Placebo to Match BVY

Countries

United States of America
Canada
Germany
Poland
Portugal
Puerto Rico
Romania
South Africa
Spain

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2024-10-21

Anticipated Date of Last Follow-up

2025-04-11

Estimated Primary Completion Date

2029-01-01

Estimated Completion Date

2030-08-01

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Adults
- Older Adults

Genders

- All

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

No

Comments about the studied populations

Key Inclusion Criteria: * HIV-1 RNA ≥ 500 copies/mL at screening. * Antiretroviral (ARV) treatment-naive, except the use of oral pre-exposure prophylaxis (PrEP) or postexposure prophylaxis (PEP) with emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) or F/TAF, up to 1 month prior to screening. Key Exclusion Criteria: * Prior use of any long acting parenteral antiretrovirals (ARVs) such as monoclonal antibodies, broadly neutralizing antibodies targeting HIV-1, LEN, injectable cabotegravir (including oral cabotegravir lead-in), and/or injectable rilpivirine. * Documented resistance to the integrase strand-transfer inhibitor class, specifically, resistance-associated mutations E92G/Q, G118R, F121Y, Y143C/H/R, S147G, Q148H/K/R, N155H/S, or R263K in the integrase gene. * Any of the follow

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

675

Allocation

Randomized

Intervention model

Sequential assignment

Intervention model description

Not provided

Masking

Double-blind masking

Masking description

Not provided

Frequency of administration

Weekly

Studied LA-formulation(s)

Tablet

Studied route(s) of administration

Oral

Use case

Treatment

Key resources

Not provided

WONDERS1

Identifier

NCT06544733

Link

https://clinicaltrials.gov/study/NCT06544733

Phase

Phase II/III

Status

Active, not recruiting

Sponsor

Gilead Sciences

More details

The goal of this clinical study is to learn more about the experimental drugs GS-1720 and GS-4182; to compare the combination of GS-1720 and GS-4182 with the current standard-of-care treatment bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF, BVY), to see if the combination of GS-1720 and GS-4182 is safe and if it works for treating human immunodeficiency virus type 1 (HIV-1) infection. This study has two phases: Phase 2 and Phase 3. The primary objectives of this study are: Phase 2: To evaluate the efficacy of switching to oral weekly GS-1720 in combination with GS-4182 versus continuing BVY in virologically suppressed people with HIV-1 (PWH) at Week 24. Phase 3: To evaluate the efficacy of switching to oral weekly GS-1720/GS-4182 Fixed-dose combination (FDC) tablet regimen ve

Purpose

Study of Oral Weekly GS-1720 and GS-4182 Versus Biktarvy in People With HIV-1 Who Are Virologically Suppressed

Interventions

Intervention 1

GS-1720

Intervention 2

GS-4182

Intervention 3

Placebo to Match BVY

Intervention 4

Bictegravir/emtricitabine/tenofovir alafenamide

Intervention 5

GS-1720/GS-4182 FDC

Countries

United States of America
Puerto Rico

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2024-08-20

Anticipated Date of Last Follow-up

2024-12-26

Estimated Primary Completion Date

2028-01-01

Estimated Completion Date

2029-06-01

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Adults
- Older Adults

Genders

- All

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

No

Comments about the studied populations

Key Inclusion Criteria: * Documented plasma HIV-1 RNA \< 50 copies/mL for ≥ 24 weeks before and at screening. * Receiving BVY for ≥ 24 weeks prior to screening. Key Exclusion Criteria: * Prior use of, or exposure to LEN, GS-1720, or GS-4182. * History of

virologic failure while on an integrase strand-transfer inhibitor (INSTI)-based regimen. * Documented integrase strand-transfer inhibitor (INSTI) resistance, specifically, resistance-associated mutations (RAMs) E92G/Q, G118R, F121Y, Y143C/H/R, S147G, Q148H/K/R, N155H/S, or R263K in the integrase gene. * Prior use of any long-acting (LA) parenteral antiretrovirals (ARV) such as monoclonal antibodies (mAbs) or broadly neutralizing antibodies (bNAbs) targeting HIV-1, injectable cabotegravir (including oral cabotegravir lead-in), or injecta

Health status

Not provided

Study type

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Enrollment

675

Allocation

Randomized

Intervention model

Sequential assignment

Intervention model description

Not provided

Masking

Double-blind masking

Masking description

Not provided

Frequency of administration

Weekly

Studied LA-formulation(s)

Tablet

Studied route(s) of administration

Oral

Use case

Treatment

Key resources

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