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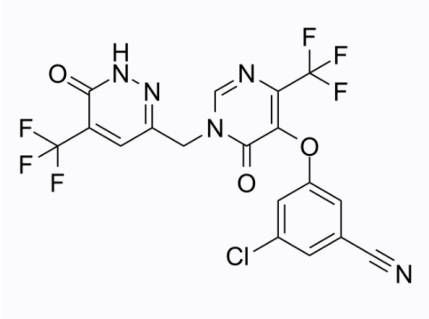


Ulonivirine (MK-8507)

Developer(s)

MSD

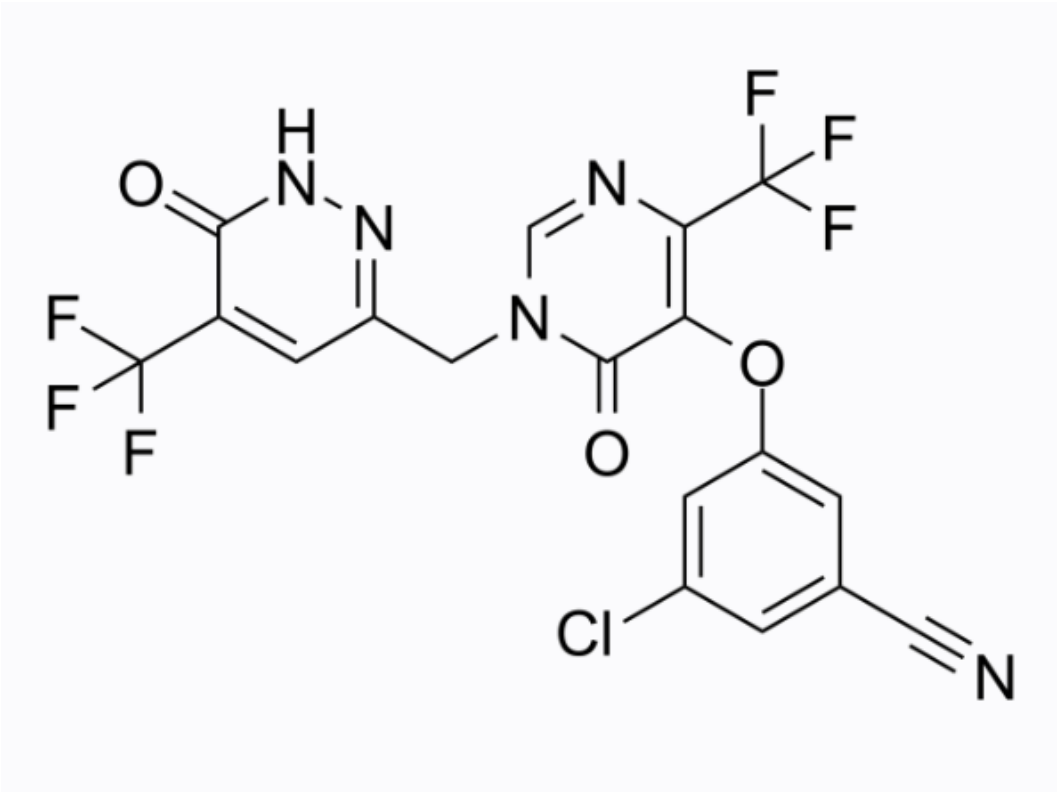
Originator

https://www.msd.com/

United States

Merck & Co., Inc. is an American multinational pharmaceutical company known as Merck Sharp & Drone (MSD) in territories outside of the USA and Canada. Merck was originally established in 1891, and is currently headquartered in Rahway, New Jersey. The company is particularly well known for developing and manufacturing biologic therapies, vaccines, medicines and animal health products.

Drug structure



MK-8507 Chemical Structure

Sourced from https://www.medchemexpress.com/ulonivirine.html

Drug information

Associated long-acting platforms

Oral solid form

Administration route

Oral

Therapeutic area(s)

HIV

Use case(s)

Pre-Exposure Prophylaxis (PrEP)
Treatment
Prevention

Use of drug

Ease of administration

Self-administered

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)

https://go.drugbank.com/drugs/DB18787

Generic name

MK-8507

Brand name

Not provided

Compound type

Small molecule

Summary

MK-8507, also known as Ulonivirine, is a selective, potent and novel non-nucleoside reverse transcriptase inhibitor (NNRTI) currently in clinical development for the treatment of HIV-1. MK-8507 inhibits HIV-1 allosterically through the classic NNTRI binding location adjacent to the polymerase active site. Preclinical research indicates that MK-8507 displays activity against the most common resistance mutations associated with NNRTIs (e.g. Y181C and K103N) and possesses strong antiviral effects. The pharmacokinetics of MK-8507 support once-weekly oral administration. In Nov 2021, Merck announced the pausing of MK-8507 development following reduced CD4+ T-cell and lymphocyte counts in participants enrolled in combination drug trials (MK-8507 + Islatravir).

Approval status

Ulonivirine (previously known as MK 8507) is an orally-administered investigational non-nucleoside reverse transcriptase inhibitor (NNRTI) being developed by MSD for the treatment of HIV-1 infection.

Regulatory authorities

Unknown

Delivery device(s)

No delivery device

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

8507-003

Identifier

NCT02174159

Link

https://clinicaltrials.gov/study/NCT02174159

Phase

Phase I

Status

Completed

Sponsor

Merck Sharp & Dohme LLC

More details

The study will evaluate the safety, tolerability, pharmacokinetics, and antiretroviral activity of a single dose of ulonivirine in antiretroviral therapy (ART)-naive, HIV-1 infected participants. The hypothesis tested in the study is that at a safe and well-tolerated dose, ulonivirine has superior antiretroviral activity to a historical placebo control, as measured by change from baseline in plasma HIV-1 ribonucleic acid (RNA) at 168 hours postdose.

Purpose

Evaluation of Safety, Tolerability, Pharmacokinetics, and Antiretroviral Activity of Ulonivirine (MK-8507) in Human Immunodeficiency Virus (HIV-1)-Infected Participants (MK-8507-003)

Interventions

Intervention 1

Ulonivirine

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2014-09-15

Anticipated Date of Last Follow-up

2023-04-06

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2015-07-16

Actual Completion Date

2015-07-23

Studied populations

Age Cohort

- Adults

Genders

- All

Accepts pregnant individuals

No

Accepts lactating individuals

No

Accepts healthy individuals

No

Comments about the studied populations

Inclusion Criteria: * Male, or non-pregnant and non-breastfeeding female, or postmenopausal or surgically sterile female (confirmed with medical records, examination, or laboratory test). Male participants with female partner of childbearing potential agrees to use a medically acceptable method of contraception during the study and 90 days after receiving study drug. * Body mass index \<=35 kg/m\^2 * Other than HIV infection, baseline health judged to be stable at screening and/or prior to administration of study drug * No clinically-significant electrocardiogram abnormality * Documented to be HIV-1 positive as determined by a positive enzyme-linked immunosorbent assay (ELISA) or quantitative polymerase chain reaction (PCR) result with confirmation * Has a screening plasma Cluster of Diff

Health status

Negative to : HBV

Positive to : HIV

Study type

Interventional (clinical trial)

Enrollment

18

Allocation

Not provided

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Open label

Masking description

None (Open Label)

Frequency of administration

Other : "Single dose "

Studied LA-formulation(s)

Tablet

Studied route(s) of administration

Oral

Use case

Treatment

Key results

Type of key results	Title	Website link
Article	Single Oral Doses of MK-8507, a Novel Non-Nucleoside Reverse Transcriptase Inhibitor, Suppress HIV-1 RNA for a Week.	https://doi.org/10.1097/qai.0000000000

8507-014

Identifier

NCT05093972

Link

https://clinicaltrials.gov/study/NCT05093972

Phase

Phase I

Status

Not yet recruiting

Sponsor

Merck Sharp & Dohme LLC

More details

The purpose of this study is to evaluate pharmacokinetics (PK) and safety of a single oral dose of ulonivirine in participants with mild or moderate hepatic impairment (HI). It is hypothesized that the area under the plasma concentration-time curve from dosing to (extrapolated) infinity (AUC0-∞) in participants with mild or moderate HI is similar to that of healthy control participants.

Purpose

Ulonivirine (MK-8507) in Participants With Mild or Moderate Hepatic Impairment (MK-8507-014)

Interventions

Intervention 1

Ulonivirine

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

2026-04-07

Actual Start Date

2025-04-07

Anticipated Date of Last Follow-up

2025-02-14

Estimated Primary Completion Date

2026-09-10

Estimated Completion Date

2026-09-10

Actual Primary Completion Date

2024-05-10

Actual Completion Date

2025-09-10

Studied populations

Age Cohort

- Adults
- Older Adults

Genders

- All

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

Yes

Comments about the studied populations

Inclusion Criteria: Mild and Moderate HI (Panels A and B): * Has a diagnosis of chronic (\>6 months), stable HI with features of cirrhosis due to any etiology (stability of hepatic disease should correspond to no acute episodes of illness within the previous 2 months due to deterioration in hepatic function) Healthy Controls (Panel C): * Is in good health All Participants (Panels A to C): * Has a body mass index (BMI) ≥18.5 and ≤40 kg/m\^2, inclusive * If male, uses contraception in accordance with local regulations * If female, is not pregnant or breastfeeding and one of the following applies: 1) is not a woman of childbearing potential (WOCBP), or 2) is a WOCBP and is abstinent/uses acceptable contraception, has a negative highly sensitive pregnancy test within 24 hours of receivin

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

22

Allocation

Not provided

Intervention model

Parallel 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

Treatment

Key results

Not provided

8591-013

Identifier

NCT04564547

Link

https://clinicaltrials.gov/study/NCT04564547

Phase

Phase II

Status

Completed

Sponsor

Merck Sharp & Dohme LLC

More details

This is a randomized, controlled, double-blind, study to evaluate the safety and tolerability of islatravir (ISL) + ulonivirine based on review of the accumulated safety data, in adult participants with human immunodeficiency virus type 1 (HIV-1) who have been virologically suppressed for ≥6 months on bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) once-daily.

Purpose

Dose Ranging, Switch Study of Islatravir (ISL) and Ulonivirine (MK-8507) Once-Weekly in Virologically-Suppressed Adults With Human Immunodeficiency Virus Type 1 (HIV-1) [MK-8591-013]

Interventions

Intervention 1

Islatravir

Intervention 2

Ulonivirine

Intervention 3

BIC/FTC/TAF

Intervention 4

Placebo to ISL

Intervention 5

Placebo to Ulonivirine

Countries

United States of America

France

Switzerland

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2021-03-09

Anticipated Date of Last Follow-up

2025-02-10

Estimated Primary Completion Date

2020-09-25

Estimated Completion Date

2020-09-25

Actual Primary Completion Date

2025-01-30

Actual Completion Date

2025-01-30

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

Inclusion Criteria: * Is HIV-1 positive with plasma HIV-1 RNA \<50 copies/mL at screening * Has been virologically suppressed on BIC/FTC/TAF for ≥6 months * Has a screening CD4+ T-cell count \>200 cells/mm\^3 (completed by the central laboratory) * Is male or female, at least 18 years of age, at the time of signing the informed consent * female participant is eligible to participate if she is not pregnant or breastfeeding, and at least one of the following conditions applies: * Is not a woman of childbearing potential (WOCBP) * Is a WOCBP and using a contraceptive method that is

highly effective (with a failure rate of \<1% per year), or be abstinent from heterosexual intercourse as their preferred and usual lifestyle (abstinent on a long term and persistent basis) Exclusion Criteria: *

Health status

Positive to : HIV
Negative to : HBV, HCV

Study type

Interventional (clinical trial)

Enrollment

161

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Triple-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 results

Not provided

8507-016

Identifier

NCT06619678

Link

https://clinicaltrials.gov/study/NCT06619678

Phase

Phase I

Status

Completed

Sponsor

Merck Sharp & Dohme LLC

More details

The main goals of this study are to learn what happens to Islatravir or MK-8507 in a person's body over time. Researchers will compare Islatravir given alone to Islatravir given with MK-8507. Researchers will also compare MK-8507 given alone to MK-8507 given with Islatravir.

Purpose

A Study of MK-8507 and Islatravir (MK-8591) in Healthy Adult Participants (MK-8507-016)

Interventions

Intervention 1

MK-8507+islatravir

Countries

United States of America

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2024-01-17

Anticipated Date of Last Follow-up

2024-09-27

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2024-06-23

Actual Completion Date

2024-06-23

Studied populations

Age Cohort

- Adults
- Older Adults

Genders

- All

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

Yes

Comments about the studied populations

Inclusion Criteria: The key inclusion criteria include but are not limited to the following: * Is in good health before randomization * Has a body mass index (BMI) ≥18 and ≤32 kg/m\^2, inclusive Exclusion Criteria: The key exclusion criteria include but are not limited to the following: * Has a history of clinically significant endocrine, gastrointestinal (GI), cardiovascular, hematological, hepatic, immunological, renal, respiratory, genitourinary, or major neurological (including stroke and chronic seizures) abnormalities or diseases * Has a history of cancer with protocol specified exceptions

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

36

Allocation

Not provided

Intervention model

Sequential assignment

Intervention model description

Experimental: Islatravir+MK-8507 Period 1: Participants receive single dose of Islatravir on Day 1. Period 2: Participants receive single dose of MK-8507 on Days 1 and Days 8. Period 3: Participants receive single dose of Islatravir and single dose of MK-8507 on Day 1, 7 days after the Day 8 dose of MK-8507, during Period 2. Participants will receive additional MK-8507 single doses on Days 8, 15, 22, and 29.

Masking

Open label

Masking description

Not provided

Frequency of administration

Once

Studied LA-formulation(s)

Tablet

Studied route(s) of administration

Oral

Use case

Treatment

Key results

Not provided

8591B-060

Identifier

NCT06891066

Link

https://clinicaltrials.gov/study/NCT06891066

Phase

Phase II

Status

Recruiting

Sponsor

Merck Sharp & Dohme LLC

More details

Investigators are trying to find better treatments for people with HIV-1. In this clinical study, investigators want to see how well a new treatment called ISL+ULO, taken once a week, works compared to an existing treatment called BIC/FTC/TAF, which is taken every day. Investigators will check how many people still have a high level of the virus in their blood after 24 weeks. The investigators also want to understand if the new treatment, MK-8591B, is safe and how well people can handle it.

Purpose

A Study of Islatravir (ISL) and Ulonivirine (ULO) Once Weekly (QW) in Virologically Suppressed Adults With Human Immunodeficiency Virus Type 1 (HIV-1) (MK-8591B-060)

Interventions

Intervention 1

ISL

Intervention 2

ULO

Intervention 3

BIC/FTC/TAF

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

2025-04-21

Actual Start Date

2025-04-14

Anticipated Date of Last Follow-up

2025-05-10

Estimated Primary Completion Date

2027-09-24

Estimated Completion Date

2027-09-24

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

Inclusion: The main inclusion criteria include but are not limited to the following: - Has been receiving Bictegravir/Emtricitabine/Tenofovir alafenamide (BIC/FTC/TAF) therapy with documented viral suppression \[Human immunodeficiency virus type 1 (HIV-1) ribonucleic acid (RNA) \<50 copies/mL\] for ≥6 months prior to providing documented informed consent and has no history of prior virologic treatment failure on any past or current regimen. Exclusion: The main exclusion criteria include but are not limited to the following: * Has Human immunodeficiency virus type 2 (HIV-2) infection. * Has a diagnosis of an active Acquired immune deficiency syndrome (AIDS)-defining opportunistic infection. * Has active hepatitis C virus (HCV) coinfection. * Has hepatitis B virus (HBV) coinfection. * H

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

150

Allocation

Randomized

Intervention model

Parallel 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

Type of key results	Title	Website link
Article	Merck's link to clinical trial NCT06891066	https://www.merckclinicaltrials.com/tria

MK-8507-015

Identifier

EUCT2023-506697-12-00

Link

https://euclinicaltrials.eu/ctis-public/view/2023-506697-12-00?lang=en

Phase

Phase I

Status

Completed

Sponsor

Merck Sharp & Dohme LLC, Merck Sharp & Dohme LLC

More details

Not provided

Purpose

MK-8507 Extended Multiple Dose Study

Interventions

Not provided

Countries

Belgium

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

2023-10-20

Actual Start Date

2023-10-20

Anticipated Date of Last Follow-up

Not provided

Estimated Primary Completion Date

Not provided

Estimated Completion Date

2024-06-07

Actual Primary Completion Date

Not provided

Actual Completion Date

2024-05-31

Studied populations

Age Cohort

- Adults

Genders

- All

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

Yes

Comments about the studied populations

Healthy volunteers

Health status

Not provided

Study type

Not provided

Enrollment

Not provided

Allocation

Not provided

Intervention model

Not provided

Intervention model description

Not provided

Masking

Not provided

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

Description

Prodrugs of HIV reverse transcriptase inhibitors

Brief description

Ulonivirine prodrugs

Representative patent

WO2015153304

Category

Compound (prodrug)

Patent holder

Merck Sharp & Dohme Corp.

Exclusivity

Not provided

Expiration date

March 27, 2035

Status

Granted in Brazil, China, India, US, Europe

Description

Ulonivirine (MK-8507) - 5-phenoxy-3H-pyrimidin-4-one derivates and their use as HIV reverse transcriptase inhibitors

Brief description

Ulonivirine compound and analogues and their use as HIV reverse transcriptase inhibitors

Representative patent

WO2014058747

Category

compound

Patent holder

Merck Sharp & Dohme Corp.

Exclusivity

Not provided

Expiration date

September 29, 2033

Status

Granted in: AR, ARIPO (BW, GH, KE, NA), BR, CL, CN, CO, CR, DZ, EAPO (AM, AZ, BY, KZ, RU) EP, GE, GT, ID, IN, IR, KR, MA, MN, MX, NG, PE, PH, UA, US, VN, ZA Pending in: DO, NI, PK, SV, TH, VE

Supporting material

Publications

Fluoride Pharmacokinetics in Urine and Plasma Following Multiple Doses of MK-8507, an Investigational, Oral, Once-Weekly Nonnucleoside Reverse Transcriptase Inhibitor. Gillespie G. et al., J Clin Pharmacol. 2022 Feb;62(2):199-205. doi: https://doi.org/10.1002%2Fjcph.1957. Epub 2021 Nov 12. PMID: 34435371; PMCID: PMC9298720.

MK-8507 is an investigational HIV-1 nonnucleoside reverse transcriptase inhibitor being developed for the treatment of HIV-1 infection. MK-8507 contains 2 trifluoromethyl groups that may result in fluoride release through metabolism, but the extent of MK-8507–related fluoride release in humans has yet to be determined. This double-blind, placebo-controlled, 2-period, parallel-group, multiple-dose trial in healthy participants without HIV-1 who were administered a fluoride-restricted diet and once-weekly doses of MK-8507 aimed to estimate the relationship between MK-8507 dose and fluoride exposure. A total of 15 adult male and 3 adult female (of non-childbearing potential) participants were randomized to receive MK-8507 200 mg (n = 6), MK-8507 800 mg (n = 6), or placebo (n = 6). Change from baseline in mean daily fluoride excretion averaged over 7 days following the administration of MK-8507 200 mg resulted in a net mean increase of 19.8 µmol (90% confidence interval, 12.2-27.4) relative to placebo and did not exceed 57 µmol, a threshold related to the mean difference between the daily reference dose set by the US Environmental Protection Agency and the average dietary fluoride intake in the United States. However, daily urinary fluoride excretion exceeded the threshold following administration of 800 mg MK-8507 (75.1 µmol [90% confidence interval, 67.5-82.7]). Assuming a linear relationship between MK-8507 dose and estimated mean daily fluoride released at steady-state, data interpolation suggests that the US Environmental Protection Agency reference dose for fluoride would not be exceeded in

most patients when administering MK-8507 at doses currently under clinical investigation (≤400 mg once weekly).

Pharmacokinetic and Safety Profile of the Novel HIV Nonnucleoside Reverse Transcriptase Inhibitor MK-8507 in Adults without HIV. Ankrom W et al., Antimicrob Agents Chemother. 2021 Nov 17;65(12):e0093521. doi: https://doi.org/10.1128%2FAAC.00935-21. Epub 2021 Sep 13. PMID: 34516246; PMCID: PMC8597757.

MK-8507 is a novel HIV-1 nonnucleoside reverse transcriptase inhibitor in clinical development with potential for once-weekly oral administration for the treatment of HIV-1 infection. Two randomized, double-blind, placebo-controlled phase 1 studies in adults without HIV-1 evaluated the safety, tolerability, and pharmacokinetics of single and multiple doses of MK-8507; drug interaction with midazolam (a cytochrome P450 3A4 substrate) and food effect were also assessed. In study 1, 16 participants received oral ascending single doses of MK-8507 (2 to 400 mg) or placebo in an alternating fashion. In study 2, 24 participants received ascending single doses of MK-8507 (400 to 1,200 mg) or placebo and multiple doses (once weekly for 3 weeks) of MK-8507 (100 to 400 mg) or placebo. MK-8507 pharmacokinetics were approximately dose proportional at 2 to 1,200 mg. MK-8507 had a time to maximum concentration of 2 to 7 h and a mean terminal half-life of ~58 to 84 h. MK-8507 doses of ≥100 mg achieved a plasma concentration at 168 h postdose (7 days) associated with antiviral efficacy. A high-fat meal had no clinically meaningful effect on MK-8507 pharmacokinetics, and MK-8507 400 mg once weekly had no clinically meaningful effect on midazolam pharmacokinetics. Single and multiple doses of MK-8507 were generally well tolerated. No trends with dose and no clinically meaningful changes were observed in vital signs, electrocardiograms, and laboratory safety tests. The pharmacokinetics and safety data are supportive of once-weekly oral administration and support further clinical investigation of MK-8507 for the treatment of HIV-1 infection.

Single Oral Doses of MK-8507, a Novel Non-Nucleoside Reverse Transcriptase Inhibitor, Suppress HIV-1 RNA for a Week. Schürmann D. et al. *J Acquir Immune Defic Syndr*.

2022;89(2):191-198. doi:10.1097/QAI.0000000000002834

Background: MK-8507 is a novel HIV-1 non-nucleoside reverse transcriptase inhibitor being developed for treatment of HIV-1 infection. MK-8507 has high antiviral potency in vitro and pharmacokinetic (PK) properties that support once-weekly dosing.

Setting: A phase 1, open-label, proof-of-concept study was conducted in treatment-naive adults with HIV-1 infection to assess monotherapy antiviral activity.

Methods: In 3 sequential panels, participants aged 18-60 years with baseline plasma HIV-1 RNA ≥10,000 copies/mL and CD4+ T-cell count >200/mm3 received a single oral dose of 40, 80, or 600 mg MK-8507 in the fasted state. Participants were assessed for HIV-1 RNA for at least 7 days, PKs for 14 days, and safety and tolerability for 21 days postdose.

Results: A total of 18 participants were enrolled (6 per panel). The mean 7-day postdose HIV-1 RNA reduction ranged from ~1.2 to ~1.5 log10 copies/mL across the doses assessed. One patient had a viral rebound associated with emergence of an F227C reverse transcriptase variant (per chain-termination method sequencing) 14 days postdose; this variant was found in a second participant by ultra-deep sequencing as an emerging minority variant. MK-8507 PKs were generally dose-proportional and similar to observations in participants without HIV-1 infection in prior studies; mean MK-8507 half life was 56-69 hours in this study. MK-8507 was generally well tolerated at all doses.

Conclusions: The robust antiviral activity, PK, and tolerability of MK-8507 support its continued development as part of a complete once weekly oral regimen for HIV-1 treatment; combination therapy could mitigate the emergence of resistance-associated variants.

Li G, Wang Y, De Clercq E. Approved HIV reverse transcriptase inhibitors in the past decade [published correction appears in Acta Pharm Sin B. 2023 Aug;13(8):3581. doi: 10.1016/j.apsb.2023.06.004.]. *Acta Pharm Sin B*. 2022;12(4):1567-1590. doi:10.1016/j.apsb.2021.11.009

HIV reverse transcriptase (RT) inhibitors are the important components of highly active antiretroviral therapies (HAARTs) for anti-HIV treatment and pre-exposure prophylaxis in clinical practice. Many RT inhibitors and their combination regimens have been approved in the past ten years, but a review on their drug discovery, pharmacology, and clinical efficacy is lacking. Here, we provide a comprehensive review of RT inhibitors (tenofovir alafenamide, rilpivirine, doravirine, dapivirine, azvudine and elsulfavirine) approved in the past decade, regarding their drug discovery, pharmacology, and clinical efficacy in randomized controlled trials. Novel RT inhibitors such as islatravir, MK-8504, MK-8507, MK8583, IQP-0528, and MIV-150 will be also highlighted. Future development may focus on the new generation of novel antiretroviral inhibitors with higher bioavailability, longer elimination half-life, more favorable side-effect profiles, fewer drug-drug interactions, and higher activities against circulating drug-resistant strains.

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