LAPaL
THE LONG-ACTING THERAPEUTICS PATENTS AND LICENCES DATABASE

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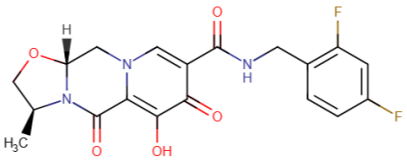


Cabotegravir Stearate (M2CAB)

Developer(s)

Exavir Therapeutics, Inc.

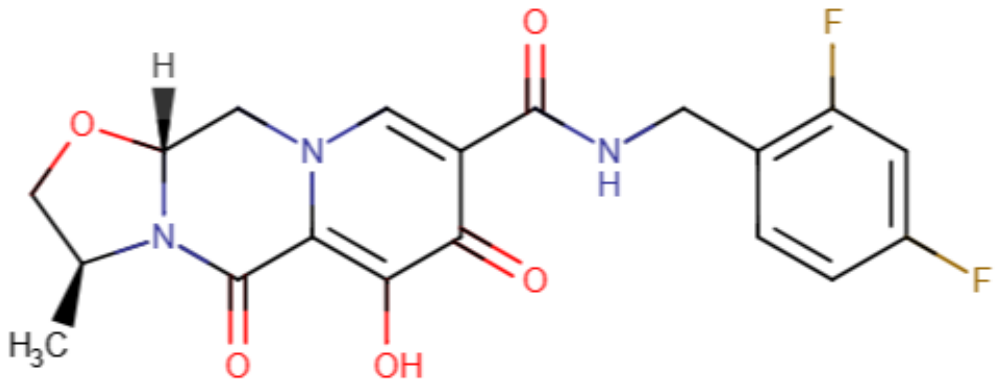
Originator

https://exavirtherapeutics.com/

United States

Exavir Therapeutics is a biopharmaceutical company focused on developing ultra-long-acting therapeutics for chronic viral infections and CNS disorders. Headquartered in San Francisco, CA, they utilize prodrug nano-formulation technology to extend the half-life of drugs. Their current research focus primarily targets HIV, with the goal of improving treatment adherence and patient outcomes.

Drug structure



Cabotegravir Chemical Structure (Stearate not pictured)

Sourced from DrugBank

Drug information

Associated long-acting platforms

Aqueous drug particle suspension, Nanocrystal Suspension

Administration route

Intramuscular

Therapeutic area(s)

HIV

Use case(s)

Pre-Exposure Prophylaxis (PrEP)
Treatment

Use of drug

Ease of administration

Administered by a community health worker
Administered by a nurse
Administered by a specialty health worker

User acceptance

Not provided

Dosage

Available dose and strength

Not yet available

Frequency of administration

Preliminary preclinical data indicates once or twice yearly administration.

Maximum dose

Not yet available

Recommended dosing regimen

M2CAB is formulated as a nanocrystalline intramuscular long-acting injectable suspension (XVIR-110) that has the potential to be dosed once or twice yearly in humans based on pharmacokinetic modelling

Additional comments

The estimated elimination half-life of CAB from XVIR-110 is ~120 days (~17 weeks or ~4 months) and provided mean CAB concentrations greater than 10x & 4x the PB-IC90 for more than 6 months & 1 year.

Dosage link(s)

Not yet available

Drug information

Drug's link(s)

Not provided

Generic name

Cabotegravir Stearate

Brand name

Not provided

Compound type

Small molecule

Summary

Cabotegravir Stearate (M2CAB) is a novel prodrug of the HIV-1 integrase strand transfer inhibitor (INSTI) cabotegravir (CAB). CAB is indicated as single agent pre-exposure prophylaxis (PrEP) for HIV prevention and is utilised in combination with Rilpivirine (a non-nucleoside reverse transcriptase inhibitor, NNRTI) for HIV treatment. M2CAB is formulated as a nanocrystalline intramuscular long-acting injectable suspension (XVIR-110) that could potentially be dosed once or twice yearly in humans based on pharmacokinetic modelling. M2CAB forms macrophage-distributed and local depots with an apparent protracted elimination half-life resulting in "flip-flop" plasma pharmacokinetics. In preclinical studies, XVIR-110 showed sustained CAB exposures and a favourable injection site reaction profile.

Approval status

Cabotegravir Stearate (M2CAB) is currently in preclinical development and is not yet approved.

Regulatory authorities

Unknown

Delivery device(s)

No delivery device

Scale-up and manufacturing prospects

Scale-up prospects

Cabotegravir stearate (M2CAB) is currently in preclinical development, therefore detailed manufacturing and scale-up prospects are not currently available. One formulation (XVIR-110) is a nanocrystalline cabotegravir prodrug that achieves and maintains sustained cabotegravir exposures which support its ongoing development as a potential ultra-long-acting INSTI for HIV PrEP and in-combination for treatment.

Tentative equipment list for manufacturing

Not provided

Manufacturing

Not provided

Specific analytical instrument required for characterization of formulation

Not provided

Clinical trials

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

- Cabotegravir Stearate (XVIR-110) an Integrase Strand Transfer Inhibitor (InSTI) Prodrug Poster
- Cabotegravir Stearate (XVIR-110), an InSTI Prodrug, Provides Ultra-Long Acting Cabotegravir Exposure

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