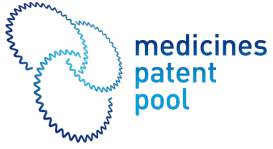
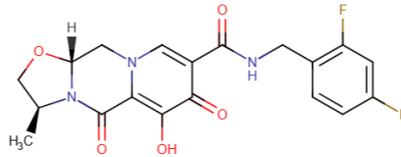


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## Cabotegravir Stearate (M2CAB)

## Developer(s)

Exavir Therapeutics, Inc.

Originator

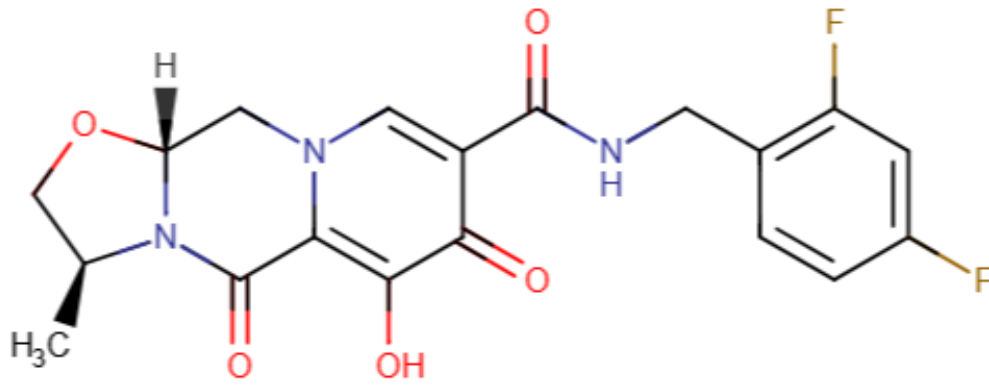
<https://exavirtherapeutics.com/>

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