medicines patent pool

WATCHLIST

CABOTEGRAVIR + RILPIVIRINE LONG-ACTING FORMULATION

HIV TREATMENT

ViiV & Janssen

DISEASE BURDEN

In 2022, 39.0 million people globally were living with HIV and 1.3 million people became newly infected, most of which occurred in LMICs.

CLINICAL RELEVANCE

Cabotegravir and rilpivirine are the only injectable long-acting regimen for HIV approved so far, which has been shown to be safe and efficacious for HIV treatment. Their use is currently not included in WHO guidelines for HIV treatment.

INTELLECTUAL PROPERTY LANDSCAPE

Primary patents on cabotegravir have been granted in many LMICs and are expected to expire in 2026. Secondary patents on the long-acting parenteral composition as well as intermediates and processes are expected to expire in 2031. MPP holds a licence with ViiV Healthcare for the use of cabotegravir for HIV PrEP.
Rilpivirine primary patent has expired except in a few countries where the term has been extended until 2026-2027. Secondary patents on the formulation are present in many LMICs and are expected to expire in 2027.

SERVICE DELIVERY ENABLERS

Cabotegravir is used in combination with rilpivirine as a long-acting injectable for the treatment of HIV. Rilpivirine has a cold chain requirement, limiting its potential for impact in LMICs. Transitioning to long-acting HIV treatment has adherence benefits, but the health system requirements may be higher than a daily oral regimen at primary healthcare or community levels.

REGULATORY

Product approved by stringent regulatory authorities. Potential sublicensees of lenacapavir could rely on mechanisms like USFDA Paragraph III through PEPFAR (if included), Swissmedic MAGHP or EU-M4all or WHO Prequalification (if included) for quality assurance . Pharmacokinetics (PK)-based bioequivalence studies will be required. Bioequivalence studies will be complex and long since it is a long-acting injectable. Biowaiver is not possible.

MANUFACTURING

The product requires sterile long-acting injectable nanosuspension formulation with specific requirements in terms of technology and manufacturing equipment. No challenges with respect to excipients. Requires special packaging for the medical device. Due to complex manufacturing technology special manufacturing facility requirements. Shelf life is 3 years with refrigeration.

MARKET

Cabotegravir and rilpivirine long-acting combination for HIV treatment has been registered in very few LMICs. Implementation trials are ongoing. Access plans are not yet known.