medicines patent pool

PRIORITY LIST

DISEASE BURDEN

In 2022, 39 million people globally were living with HIV and 1.3 million people became newly infected, most of which occurred in LMICs.

CLINICAL RELEVANCE

Lenacapavir is a first-in-class capsid inhibitor, studied for HIV PrEP as a sub-cutaneous injection every 6 months. Interim results from the PURPOSE 1 study indicated full protection from HIV acquisition in young women and adolescent girls. Further data on safety and efficacy in other populations are expected soon.

INTELLECTUAL PROPERTY LANDSCAPE

Lenacapavir primary patents have been filed or granted in several LMICs and are expected to expire between 2034 and 2037. Gilead also holds secondary patents that may provide exclusivity until 2038 in many LMICs.

LENACAPAVIR

HIV PREVENTION

Gilead

SERVICE DELIVERY ENABLERS

Lenacapavir for PrEP would not require companion drugs. While it may have advantages in terms of adherence, health system requirements might be higher compared to once-daily oral PrEP options such as TDF/FTC. However, the upcoming access to long-acting cabotegravir for PrEP in LMICs will likely pave the way for a successful lenacapavir implementation, if proven safe and effective.

REGULATORY

While lenacapavir for PrEP is not approved by regulatory authorities yet, the formulation appears to be the same as the approved injectable treatment. Bioequivalence studies are necessary for oral solid formulations. Biowaivers will not be an option for oral solid formulations. There is a possibility of biowaiver for injectable products.

MANUFACTURING

Assuming the formulation is the same as the approved treatment: a spray-drying process is adopted for oral formulation. Injectable product is a standard solution, terminally sterilised. Standard excipients are used. The injectable formulation contains a specialised syringe along with vials. Shelf life is two years at room temperature for the tablets and the injectable product.

MARKET

This medicine is still investigational for the PrEP indication, and therefore little is known about its potential positioning in HIV prevention protocols, pricing, and overall access plans.

LAPaL
THE LONG-ACTING THERAPEUTICS PATENTS AND LICENCES DATABASE

June 2024

medicines patent pool

PRIORITY LIST

DISEASE BURDEN

In 2022, 39 million people globally were living with HIV and 1.3 million people became newly infected, most of which occurred in LMICs.

CLINICAL RELEVANCE

Lenacapavir is a first-in-class capsid inhibitor, already approved for the treatment of multi-drug-resistant HIV infection in adults as a subcutaneous injection every 6 months in combination with other daily ARVs. It has a promising safety profile studied as a weekly oral HIV treatment in combination with islatravir (results are expected in 2024), as daily oral regimen with bictegravir, or as sub-cutaneous injections in association with monoclonal antibodies every 6 months.

INTELLECTUAL PROPERTY LANDSCAPE

Lenacapavir primary patents have been filed or granted in several LMICs and are expected to expire between 2034-2037. Gilead also holds secondary patents that may provide exclusivity until 2038 in many LMICs.

LENACAPAVIR

HIV TREATMENT

Gilead

SERVICE DELIVERY ENABLERS

Lenacapavir's possible companion drugs are still under study. A six-monthly injectable regimen could aid adherence but may conflict with efforts to simplify and decentralize HIV treatment due to healthcare providers training requirements for injections.

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. Bioequivalence studies are necessary for oral solid formulations. Biowaivers will not be an option for oral solid formulations. There is a possibility of biowaiver for injectable products.

MANUFACTURING

A spray drying process is adopted for the oral formulation. Injectable product is a standard solution, terminally sterilized. Standard excipients are used. The injectable formulation contains a specialised syringe along with vials. Shelf life is two years at room temperature for the tablets and the injectable product.

MARKET

While lenacapavir is currently approved by some major regulatory authorities for heavily treatment-experienced adults, it is not yet registered (and is therefore not available) in LMICs. Access plans for lenacapavir in LMICs are not yet known. A long-acting companion injectable allowing for a full injectable regimen would considerably increase market size.

LAPaL
THE LONG-ACTING THERAPEUTICS PATENTS AND LICENCES DATABASE

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