LENACAPAVIR

HIV PREVENTION

Gilead

CLINICAL RELEVANCE

Lenacapavir is a first-in-class capsid inhibitor, approved for treatment of multi-drug resistant HIV infection in adults. It is studied for HIV PrEP as a sub-cutaneous injection every 6 months and has a promising safety profile. Results are expected by September 2024.

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.

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.

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 successful lenacapavir implementation, if proven safe and effective.

REGULATORY

While lenacapavir for PrEP is not approved regulatory authorities yet, the formulation appears to be the same as the approved treatment.

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 2 years at room temperature for tablets and injectable product.

MARKET

This medicine is still in the R&D pipeline and therefore little is known about its potential positioning in treatment protocols, pricing, and overall access plans.

LENACAPAVIR

HIV TREATMENT

Gilead

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. It has a promising safety profile studied as a weekly oral HIV treatment in combination with islatravir (results are expected in 2024), as an oral daily treatment in combination with other ARVs, 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.

SERVICE DELIVERY ENABLERS

study. While an oral long-acting HIV treatment aligns with differentiated service delivery, its advantage over daily regimens is unclear. A six-monthly injectable regimen could aid adherence but may conflict with efforts to simplify and decentralize HIV treatment due to healthcare workers 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 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 2 years at room temperature for tablets and 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 any LMICs. access plans for lenacapavir in LMICs are not yet known.