ISLATRAVIR

HIV

Merck

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

Islatravir is a first-in-class nucleoside reverse transcriptase translocation inhibitor (NRTTI) that is not yet approved. It is studied as a weekly oral HIV treatment in combination with lenacapavir and as an oral daily treatment in combination with doravirine.

INTELLECTUAL PROPERTY LANDSCAPE

While islatravir primary patent is expected to expire in 2025, it has been granted in few HICs only. There are secondary patents on a dosing regimen (less frequent than once-daily) in many LMICs with an expected expiry in 2037.

SERVICE DELIVERY ENABLERS

Islatravir's current companion drugs being explored for HIV treatment, doravirine and lenacapavir, are not recommended by WHO for HIV treatment and may not be readily available in LMICs. An oral long-acting HIV treatment regimen could be an important option that would align with decentralized service delivery efforts.

REGULATORY

The product does not have regulatory approval yet and there is insufficient data to determine bioequivalence studies requirements or the likelihood of a biowaiver.

MANUFACTURING

No adequate data to assess manufacturing complexity, apparently seems like immediate release tablets.

MARKET

Access plans for islatravir (and its investigated combinations) in LMICs are not yet known.