

DISEASE BURDEN

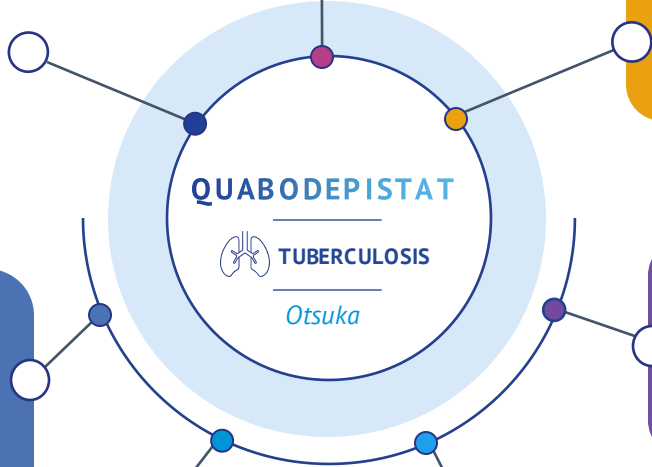
In 2023, an estimated 10.8 million people fell ill with TB worldwide. About 1.25 million people died from TB in 2023. Most of the people who fall ill with TB live in LMICs. TB is a leading cause of death from a single infectious agent – including in people with HIV- and a major cause of deaths related to antimicrobial resistance.

CLINICAL RELEVANCE

Quabodepistat is a DprE1 inhibitor investigated for tuberculosis treatment, as part of a regimen. This oral drug is in clinical development under the Project to Accelerate New Treatments for Tuberculosis (PAN-TB) program in combination with delamanid, bedaquiline, and sutezolid (DBQS) and in combination with pretomanid, bedaquiline and sutezolid (PBQS). It is also studied in combination with delamanid and bedaquiline without sutezolid. If successful, the PAN-TB regimens should provide improved safety and tolerability, a shorter duration, and be simpler to use than existing tuberculosis treatment options.

INTELLECTUAL PROPERTY LANDSCAPE

The primary patent on quabodepistat has been granted in many LMICs and is expected to expire in 2035. There are secondary patents on intermediates and combinations that may provide exclusivity until 2037-2039 in many LMICs.



SERVICE DELIVERY ENABLERS

The availability of fully-oral TB treatments regimens has simplified service delivery, but there remains health system requirements for diagnosis and monitoring and the implementation of directly-observed therapy (DOT); and while TB treatment has shortened in recent years, it still takes several months, which is challenging for adherence. A fully oral and shorter pan-TB regimen could be game changing.

REGULATORY

Quabodepistat has not yet been approved by any regulatory authority and there is insufficient data to determine bioequivalence studies requirements or the likelihood of a biowaiver.

MANUFACTURING

There is limited data at this stage to assess manufacturing complexity of quabodepistat.

MARKET

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