

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 being investigated for tuberculosis treatment as part of a regimen. It exhibits potent antituberculosis activity and has a favorable safety profile. Despite the premature termination of PAN-TB Consortium trials involving quabodepistat—since the trial did not support the investigational regimens in achieving the objective of identifying a new three-month tuberculosis treatment—Otsuka plans to study the drug alongside bedaquiline and delamanid in phase 3 trials.

INTELLECTUAL PROPERTY LANDSCAPE



The primary patent on quabodepistat has been granted in more than 50 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.

QUABODEPISTAT



SERVICE DELIVERY ENABLERS



The availability of fully-oral TB treatment regimens simplifies service delivery and improves adherence, but there remains health system requirements for diagnosis and monitoring and the implementation of directly-observed therapy (DOT). While TB treatment has shortened in recent years, it still takes several months, which is challenging for adherence. A fully oral and shorter (ideally 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.