



### **CLINICAL RELEVANCE**

Quabodepistat is an investigational DprE1 inhibitor. 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 (DBOS) and in combination with pretomanid, bedaquiline and sutezolid (PBOS). 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 treatment options.



# **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.

**MANUFACTURING** 

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



### **DISEASE BURDEN**

In 2021, an estimated 10.6 million people fell ill with TB worldwide, of which 450 000 incident cases of rifampicin-resistant or multidrug-resistant TB. About 1.5 million people die from TB each year. Most of the people who fall ill with TB live in LMICs.



# **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.





Otsuka

# 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.



# 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.



