Pharmacokinetic Study to Evaluate Anti-mycobacterial Activity of TMC207 in Combination With Background Regimen (BR) of Multidrug Resistant Tuberculosis (MDR-TB) Medications for Treatment of Children/Adolescents With Pulmonary MDR-TB

NCT02354014

Status	RECRUITING
Phase	Phase 2
Sponsor	Janssen Research & Development, LLC
Enrollment	60 participants

Key Eligibility Criteria

Inclusion (8)

- Participant must be a boy or girl, aged from birth (0 months) to less than (\<) 18 years at screening. Participants in Cohort 4 who are \<6 months of age at screening, gestational age at birth had to be greater than or equal to (\>=) 37 weeks
- Participant must weigh \>3 kilogram (kg) at baseline and be within the 5th and 95th percentiles (inclusive) for the participant's age, based on the World Health Organization (WHO) child growth standards; Body Mass Index (BMI) for age. In Cohorts 3 and 4, weight for height/length may be used instead of BMI for age according to the local standard of care. Per WHO guidance, for participants aged \< 2 years in Cohort 4, length will be used to calculate the BMI instead of height
- For Cohorts 1 and 2 only: Heterosexually active girls may participate if they are of non-childbearing potential, or if they are using effective birth control methods and are willing to continue practicing birth control methods throughout Multidrug Resistant Tuberculosis (MDR-TB) treatment and for 6 months after stopping TMC207 treatment, or if they are non-heterosexually active or willing to practice sexual abstinence throughout MDR-TB treatment
- For Cohorts 1 and 2 only: Boys who engage in sexual activity that could lead to pregnancy of the female partner must use at minimum a male condom throughout MDR-TB treatment and for 3 months after stopping TMC207 treatment
- Participant must have confirmed or probable (clinically diagnosed or presumed) pulmonary and/or non-severe extrapulmonary MDR-TB, including pre-extensively drug-resistant TB (pre- extensively drug resistant \[XDR\]-TB) or XDR-TB infection, based on the case definitions of pediatric pulmonary and non-severe extrapulmonary TB as described in the International (WHO) guidelines and in accordance with the local standard of care

... and 3 more (see full listing online)

Exclusion (4)

- Participant has a clinically significant active medical condition or the presence of any concomitant severe illness or rapidly deteriorating health condition, including immune deficiency (except HIV infection), which in the opinion of the investigator would prevent appropriate participation in the study, or that would make implementation of the protocol or interpretation of the study results difficult, or otherwise make the subject a poor candidate for a clinical study
- Participant is a girl who is pregnant, or breast-feeding, or planning to become pregnant while enrolled in this study or within 6 months after stopping TMC207 treatment
- Participant has known or presumed forms of extrapulmonary TB, other than: Lymphadenopathy (peripheral nodes or isolated mediastinal mass without significant airway compression); Pleural effusion or pleural fibrotic lesions
- Participant has a significant cardiac arrhythmia that requires medication or risk factors for Torsade de Pointes, example heart failure, hypokalemia, known personal or family history of Long QT Syndrome, and untreated hypothyroidism

Locations (11 total)

Hospital Geral da Polana Caniço, Maputo, Mozambique
De La Salle Health Sciences Institute- DLSUMC, Dasmariñas, Philippines
Lung Center Of The Philippines, Quezon City, Philippines
... and 8 more locations

https://clinicaltrials.gov/study/NCT02354014