

Note from the Sponsor: cancelled trial

Sponsor name:	Janssen Infectious Diseases BVBA
EudraCT number:	2011-000653-23
Protocol number:	TMC207-TiDP13-C210
Clinical trial title:	A Phase III placebo-controlled, double-blind, randomized trial to evaluate the efficacy and safety of TMC207 in subjects with sputum smear-positive pulmonary infection with multi-drug resistant Mycobacterium Tuberculosis (MDR-TB)
Reasons for the cancellation:	<p>Bedaquiline received conditional approval in Europe in March 2014 based on the data from phase 2b studies. The post-authorization measures include confirmation of efficacy and safety of bedaquiline as part of a randomized phase 3 study. Initially, a large placebo-controlled study, TMC207-TiDP13-C210, was planned for, where bedaquiline or placebo was added to a background regimen for a treatment duration of 9 months, with the aim to show superiority vs placebo. However, the field had evolved significantly since negotiations with the CHMP on the design of the Phase 3 study had been initiated, and the need for treatment simplification and treatment shortening had become even more apparent. In addition, with Sirturo being approved in the US and additional important approvals expected in 4Q2013 in high recruiting countries like China, South Africa and Russia, recruitment of a large placebo-controlled Phase III trial would've been challenging. Therefore, another confirmatory phase 3 study was proposed to and accepted by the CHMP, where the Bangladesh regimen (Van Deun 2010) is compared to two different, simplified, bedaquiline-based regimens. This is done as part of the study called STREAM Stage 2.</p>