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Janssen seeks approval for drug resistant TB drug in EU

04 September 2012 | Regulatory | By BioSpectrum Bureau

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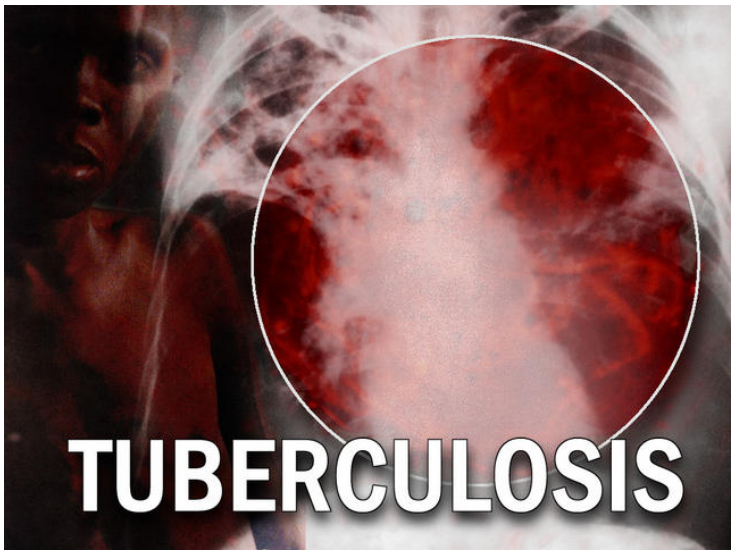

Singapore: Janssen-Cilag International NV (Janssen) submitted a marketing authorization application to the European Medicines Agency (EMA) seeking conditional approval for the use of the investigational drug bedaquiline (TMC207) as an oral treatment, to be used as part of combination therapy for pulmonary, multi-drug resistant tuberculosis (MDR-TB) in adults.

Dr Wim Parys, head, infectious diseases, Janssen, said that, "MDR-TB is a growing threat to public health and it presents a significant new treatment challenge in controlling this serious and deadly disease. This filing underscores our commitment to discover and develop novel medicines and solutions for serious unmet medical needs, and we hope this new treatment will become an important option for patients with MDR-TB."

The discovery of bedaquiline (formerly R207910) and its unique mechanism of action were announced in a Science article by scientists at Janssen. The antibiotic kills the bacterium that causes tuberculosis (Mycobacterium tuberculosis) by targeting adenosine triphosphate (ATP) synthase, an enzyme that is essential to generate its energy.

The regulatory submission is supported by 24-week data from the phase II clinical development program, which includes an open-label study and a controlled, randomized trial that evaluated the safety and efficacy of bedaquiline versus placebo in the treatment of patients with pulmonary MDR-TB in combination with a background regimen.

Janssen also submitted a new drug application (NDA) to the US FDA for bedaquiline in June 2012, under priority review status.