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ASIA EDITION

J&J seeks resistant TB drug approval

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Singapore: Janssen Research and Development has submitted a new drug application (NDA) to the US Food and Drug Administration (FDA) seeking accelerated 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. If approved by the FDA, bedaquiline would be the first drug with a new mechanism of action for TB in more than 40 years and the first and only one specifically indicated for MDR-TB.

"The emergence of multi-drug resistant strains of TB is a growing problem that impacts people around the world and is posing a significant new treatment challenge in controlling this serious and deadly disease," said Paul Stoffels, worldwide chairman, pharmaceuticals, Johnson & Johnson.

"Although tuberculosis kills approximately 1.4 million people per year and current therapies do not provide adequate control of resistant strains, there have been no new treatment options to treat TB in the last 40 years. We believe the NDA submission for bedaquiline is an exciting milestone in the development of new TB drugs."

Bedaquiline was discovered by scientists at Janssen, a Johnson & Johnson company. Its unique mechanism of action targets adenosine triphosphate (ATP) synthase, which *Mycobacterium tuberculosis*, requires 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.

"This is a critically important milestone in the development of bedaquiline and an important step forward in the development of new treatments for TB," said Mr Wim Parys, MD, head of the infectious diseases therapeutic area at Janssen. "It 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 multi-drug resistant TB. This first submission will be followed by others in high-burden countries."

The phase III trial TMC207-C210 a double-blind study comparing nine months of treatment with bedaquiline versus placebo (both with a background regimen) is planned to start recruiting in Q4 2012. This study will evaluate a new regimen of seven drugs for a shorter treatment duration (nine months of treatment) than the current 18 to 24 months WHO standard of care.