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Janssen MDR-TB drug gets FDA nod

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Singapore: Janssen Therapeutics received US FDA accelerated approval to Sirturo (bedaquiline) Tablets for the treatment of pulmonary multi-drug resistant tuberculosis (MDR-TB) as part of combination therapy in adults. The accelerated approval is based on the surrogate endpoint of time to sputum culture conversion.

Sirturo inhibits mycobacterial ATP (adenosine 5'-triphosphate) synthase, an enzyme that is essential for the generation of energy in Mycobacterium tuberculosis. Sirturo is a diarylquinoline antimycobacterial drug indicated as part of combination therapy in adults (greater than or equal to 18 years) with pulmonary MDR-TB. Sirturo should be administered by directly observed therapy (DOT).

This indication is based on analysis of time to sputum culture conversion from two controlled phase II trials in patients with pulmonary MDR-TB. The safety and efficacy of Sirturo for the treatment of latent infection due to Mycobacterium tuberculosis has not been established. The safety and efficacy of Sirturo for the treatment of drug-sensitive TB has not been established.

In addition, there are no data on the treatment with Sirturo of extra-pulmonary TB (e.g., central nervous system). Therefore, use of Sirturo in these settings is not recommended. The most common adverse drug reactions were nausea, arthralgia and headache. Additional adverse events were hemoptysis and chest pain. Please see Important Safety Information below for more details.

Dr Paul Stoffels, chief scientific officer and worldwide chairman, pharmaceuticals, Johnson & Johnson, "The accelerated approval of Sirturo is a significant step in the fight against MDR-TB, which is a more difficult to treat form of TB that affects approximately 630,000 people in the world and is on the rise in many areas worldwide."