

'Miracle drug' for resistant TB to roll out for trial today

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A 'miracle drug' to battle multi-drug resistant tuberculosis MDR-TB, and extensively-drug resistant TB (XDR-TB) will be rolled out on Monday, in six public hospitals across the country, as part of a coordinated programme between the government and Johnson & Johnson. The drug, 'Bedaquiline', manufactured by Johnson & Johnson's pharma arm Janssen will be made available at these centres, with initially 600 courses being provided to people suffering from drug resistant forms of the disease.

Significantly, Bedaquiline (trade name Sirturo) is perhaps the first drug in decades, with potential to dramatically improve MDR-TB treatment outcomes, and reduce the number of deaths due to the disease.

This is perhaps the first instance when a multinational has partnered with the government to roll out treatment for a disease showing an alarming spread. India is the world's TB hotspot as it accounts for around 23% of global cases and most deaths—220,000 in 2014—from the bacterial lung disease that spreads through coughs and sneezes. The estimated TB prevalence in India is over 2.2 million, with over 70,000 cases of MDR-TB patients.

The treatment rolled out under the Revised National Tuberculosis Control Programme will be available at hospitals, including Mumbai's Sewri Hospital, Delhi's National Institute of TB and Respiratory Diseases, and Ahmedabad-based BJ Medical College & Hospital, among others (see graphic). "We are ready with the roll-out of the drug through the government-run control programme, for which 600

BREAKTHROUGH IN TAKING ON A GIANT KILLER

➤ Nearly half a million people develop MDR-TB each year, only half of these are treated successfully

➤ For the first time in over 40 years, new TB drug 'Bedaquiline' is available and was granted 'accelerated' approval by US FDA in Dec 2012

➤ Information on new drug limited as it has only been through Phase II b trials for safety and efficacy

➤ WHO provides 'interim policy guidance' in June 2013 on use of Sirturo (Bedaquiline), as part of combination treatment for pulmonary MDR-TB in adults

➤ Bedaquiline gets approval in Jan 2015 from Drugs Controller General in India

➤ Only to be administered as part of MDR-TB regimen by directly observed therapy (DOT)

➤ To be rolled out at six govt hospitals in India in 2016 (under the state-run TB control programme)

➤ Drug won't be made available in retail market



CENTRES ADMINISTERING NEW DRUG BEDAQUILINE

✓ National Institute of Research in Tuberculosis/ Government Hospital for Thoracic Medicine, **Chennai**

✓ National Institute of TB and Respiratory Diseases, **New Delhi**

✓ Rajan Babu Institute for Pulmonary Medicine and Tuberculosis, **New Delhi**

✓ Sewri Hospital (KEM Hospital), **Mumbai**

✓ BJ Medical College & Hospital, **Ahmedabad**

✓ Government Medical College, **Guwahati**

patients will be enrolled across the country, over the next six to nine months, after the required tests. Upon review of clinical data after two years, the access programme will be expanded nationwide", Sanjiv Navangul, Janssen India MD told TOI in an exclusive interview.

"We will sit across the table (with government) to discuss pricing. This (therapy) is not a business (for the company) and not about revenues, and we will be flexible about pricing (the drug)", he added. Meanwhile, there is global concern on the pricing of new TB drugs, including Bedaquiline and Delamanid. WHO reportedly estimates the existing cost per patient for MDR-TB typically at \$5000-10,000, around 10 times that of the treatment for TB, which burdens the already-struggling

national control programmes. Janssen is believed to be offering the drug through a tiered-pricing structure, which includes \$3,000 in middle-income countries, and \$900 in low-income countries. Adding the price of \$3,000 (of the new drug) to the existing treatment of \$5,000 per patient, a course of MDR-TB could cost around \$8,000 per patient, experts say.

So the MDR-TB regimen is likely to cost around Rs 5 lakh per patient in developing countries. "Recognizing the high burden of disease, India will be placed in the lowest-price tier for Bedaquiline", Navangul said, without giving details about pricing. A similar programme launched in South Africa is already seeing success, the company claims.

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