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Dishman has been awarded manufacture of SIRTURO® (bedaquiline) API

Dishman Pharmaceuticals and Chemicals Limited (Dishman), a leading global manufacturer of pharmaceutical active ingredients, announced today that it holds a license agreement from Janssen Pharmaceutica NV, one of the Janssen Pharmaceutical Companies of **Johnson & Johnson** (Janssen) to produce the Active Pharmaceutical Ingredient (API) of SIRTURO® (bedaquiline), a medicine used in the treatment of Multi-Drug Resistant Tuberculosis (MDR-TB).

In 2008 Janssen had contracted Dishman to conduct full chemical synthesis of this API at their manufacturing facility in Bavla, India. Janssen subsequently registered Dishman as a manufacturer of API with the USFDA, European Medicines Agency and several other Asian regulatory authorities. Recently, Dishman has started supplying Janssen with the global demand of this API.

Speaking on behalf of the company Dishman Chairman, Mr. J R Vyas, said: *"We are extremely proud of the responsibility entrusted to our team and the important role we are able to play in combatting MDR-TB. India is a country significantly burdened by this disease and we fully understand its devastating impact on people's lives. Our team are working diligently to ensure we are well placed to support Janssen in addressing the demand for bedaquiline in high-burden TB areas."*

Tuberculosis (TB) is a major public health concern in India with the World Health Organization estimating there are more than 2.8 million cases of TB.[i] In particular, the burden of MDR-TB in India, is among the most significant in the world with an estimated 64,000 cases[ii], and for those diagnosed with this deadly disease, fewer than half are treated successfully[iii].

In January 2015, SIRTURO® (bedaquiline) received approval from the Drugs Controller General of India for use in adults (>18 years) as part of combination therapy of pulmonary tuberculosis due to multidrug-resistant Mycobacterium tuberculosis when an effective treatment regimen cannot otherwise be provided. This approval provides for access to bedaquiline under the Revised National TB Control Program through its Programmatic Management of Drug Resistant TB framework in order to ensure appropriate

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About Multidrug-Resistant Tuberculosis (MDR-TB)

MDR-TB is a particularly complicated form of TB characterised by resistance to at least two of the standard four-drug, anti-TB drugs.[iv] Inadequately treated patients are likely to increase selective pressure, allowing resistant bacteria to thrive and pose a significant transmission risk to the general population. Without significant public health intervention, MDR-TB is projected to infect more than two million people between 2011 and 2015.[v]

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[i] Ministry of Health and Family Welfare. TB India 2014 – Annual Status Report. Available at http://www.tbcindia.nic.in/pdfs/TB%20INDIA%202014.pdf. Accessed January 2015.

[ii] Ministry of Health and Family Welfare. TB India 2014 – Annual Status Report. Available at http://www.tbcindia.nic.in/pdfs/TB%20INDIA%202014.pdf. Accessed January 2015.

[iii] WHO. Global Tuberculosis Report 2014. Available at http://apps.who.int/iris/bitstream/10665/137094/1/9789241564809_eng.pdf?ua=1. Accessed January 2015

[iv] WHO. Multidrug-Resistant Tuberculosis, Online Q&A. February 2012. Available at http://www.who.int/features/qa/79/en/index.html. Accessed October 2014.

[v] WHO. Partners call for increased commitment to tackle MDR-TB. 23 March 2011. Available at http://www.who.int/mediacentre/news/releases/2011/TBday_20110322/en/index.html. Accessed October 2014

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