Janssen India SIRTURO® (bedaquiline) donation in support of conditional access program for multidrug-resistant tuberculosis

Introduction of bedaquiline via Revised National Tuberculosis Control Program will provide free access to bedaquiline through six public hospitals and institutes of national importance in treatment of multi-drug resistant tuberculosis

New Delhi, India, March 22, 2016: Janssen India, the pharmaceutical division of Johnson & Johnson Pvt Ltd. confirmed today that it has donated 600 courses of SIRTURO® (bedaquiline) to the Revised National Tuberculosis Control Program (RNTCP) of India for use as part of a conditional access program. Bedaquiline was approved for conditional use by the Drugs Controller General of India (DCGI) in 2015, for use in adults (>18 years) as part of combination therapy of pulmonary tuberculosis (TB) due to multidrug-resistant Mycobacterium TB (MDR-TB) when an effective treatment regimen cannot otherwise be provided.

The introduction of bedaquiline will be managed by the RNTCP and will provide approximately 600 patients with free access to bedaquiline through six public hospitals and institutes of national importance in the treatment of MDR-TB. After review of clinical and outcome data, Janssen India will work with the RNTCP to discuss opportunities to expand the program to include more patients.

The hospitals and institutions are:

- National Institute of Research in Tuberculosis (NIRT) / Government Hospital for Thoracic Medicine, Chennai
- National Institute of TB and Respiratory Diseases (NITRD), New Delhi
- Rajan Babu Institute for Pulmonary Medicine and Tuberculosis, New Delhi
- Sewri Hospital / KEM Hospital, Mumbai
- B.J. Medical College & Hospital, Ahmedabad
- Government Medical College, Guwahati

MDR-TB is a particularly complicated form of TB to treat and is characterized by resistance to the two most powerful drugs in the first-line regimen, isoniazid and rifampicin[1]. To date, anti-TB regimens have included drugs that were approved before the 1960s, and only limited treatment options are available for patients with MDR-TB. Discovered by Janssen researchers, bedaquiline is a therapy with a novel mechanism of action against TB, and addresses a significant unmet need for patients with MDR-TB.

The increase in bacterial resistance to antibiotics has been dramatic, and combating this growth is a top priority for global policy and public health. There is a particular concern that antibiotics are losing effectiveness faster than they are being replaced by new, innovative drugs.

Specifically in MDR-TB, antimicrobial resistance is one of the world's most serious public health threats. The World Health Organization (WHO) estimates that there are approximately 2,500,000 people with TB in India, with 71,000 estimated cases of MDR-TB and 24,000 MDR-

TB patients enrolled on treatment in 2014. For those diagnosed with MDR-TB, fewer than half are currently treated successfully[2].

As bedaquiline is a therapy with a new mechanism of action, national TB programs have to take many steps to ensure it is used appropriately and in a way that does not rapidly lead to the development of further resistance.

“Janssen believes that appropriate use is an integral aspect of the introduction of new TB regimens, and we take seriously our obligation to ensure that bedaquiline provides utility for patients today as well as tomorrow,” commented Sanjiv Navangul, Managing Director, Janssen India. “As part of our TB program, we are wholeheartedly committed to working with the RNTCP and other relevant stakeholders to ensure access to bedaquiline for MDR-TB patients, as part of national efforts to combat one of the oldest of diseases.”

Introducing bedaquiline via the RNTCP and its Programmatic Management of Drug Resistant TB (PMDT) framework will enable the RNTCP to capture real world evidence and enable further assessment of the role of bedaquiline in treating patients more broadly across India.

The DCGI approved bedaquiline, for its use under a conditional access program, in January 2015, based on 24-week data from the Phase 2 clinical development program, which included 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 and an open-label study. In Phase 2 studies, the bedaquiline treatment group had a decreased time to culture conversion and improved culture conversion rates compared to the placebo treatment group.

On the basis of the WHO definition of cure, nearly twice as many patients in the bedaquiline group as in the placebo group were cured, a finding that addresses the unmet need for improved long-term treatment outcomes in patients with multidrug-resistant tuberculosis[3].

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Notes to Editors

About bedaquiline

Discovered by Janssen researchers, bedaquiline is a therapy with a novel mechanism of action against TB, and addresses a significant unmet need for patients with MDR-TB. It has a unique mechanism of action that inhibits mycobacterial ATP (adenosine 5’-triphosphate) synthase, an enzyme that is essential for the generation of energy in *Mycobacterium tuberculosis*.

Bedaquiline was granted accelerated approval by the U.S. FDA in December 2012 and has also received conditional approval in the European Union, is registered in the Russian Federation through a partner for the Russian Federation and CIS countries, JSC Pharmstandard and is approved in India, as well as Armenia, Macau, Peru, the Philippines, South Africa, South Korea, Taiwan, Turkmenistan and Uzbekistan. Regulatory filings have also been submitted in China, Colombia, Thailand, Vietnam, Indonesia and Bangladesh. Pharmstandard has submitted additional regulatory filings in Kazakhstan, Azerbaijan, Kyrgyzstan and Georgia.

About Janssen India

Janssen, the pharmaceutical division of Johnson & Johnson, is dedicated to addressing and solving some of the most important unmet medical needs of our time in India, in oncology, immunology, neurosciences & analgesia, dermatology, infectious diseases and metabolic diseases. Driven by a strong commitment to the health and well-being of patients, 3

Janssen India brings innovative products, services and solutions to people throughout the world. Janssen recognizes the impact of serious conditions on people's lives, and aims to empower people through disease awareness, education and access to quality care in these six therapeutic areas.

References

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