CHINA FOOD AND DRUG ADMINISTRATION APPROVES SIRTURO® (BEDAQUILINE) FOR PATIENTS WITH PULMONARY MULTI-DRUG RESISTANT TUBERCULOSIS (MDR-TB)

December 2, 2016 – Xian Janssen Pharmaceutical Ltd. today announced that the China Food and Drug Administration (CFDA) has approved SIRTURO® (bedaquiline) for use as part of combination therapy in adult patients (18 years and older) with pulmonary multi-drug resistant tuberculosis (MDR-TB).

Discovered by Janssen Pharmaceutica N.V., SIRTURO® is a therapy with a novel mechanism of action against TB and it addresses the large unmet need of patients with MDR-TB by significantly improving treatment outcomes.

MDR-TB is a form of TB characterized by resistance to the two most powerful drugs in the first-line regimen, isoniazid and rifampicin[1], meaning patients have considerably reduced options for tackling the disease. SIRTURO® is an antibiotic that inhibits mycobacterial ATP (adenosine 5'-triphosphate) synthase, an enzyme that is essential for the generation of energy in *Mycobacterium tuberculosis*.

"MDR-TB occurs in patients who are infected with a drug-resistant strain of TB, or because of unsuccessful prior treatment regimens," said Chu Naihui, director of TB department of the Beijing Chest Hospital. "MDR-TB places a significant burden on patients, and is a particular problem in China, which accounts for almost 15 percent of the world's MDR-TB cases[2]. Due to its unique mechanism of action, SIRTURO® represents a major advancement in the fight against MDR-TB."

Tuberculosis, and particularly MDR-TB, represents one of the world's top health challenges, and is a serious burden and threat for China. The World Health Organization estimates that among the 1 million new TB cases in China every year, there are 70,000 cases of MDR-TB.[3]

Globally in 2015, an estimated 10.4 million people fell ill with TB, and an estimated 1.4 million people died from the disease worldwide[4]. By 2050, MDR-TB could incur more than $16 trillion

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[1] Centers for Disease Control and Prevention, Provisional CDC guidelines for the use and safety monitoring of bedaquiline fumarate (Sirturo) for the treatment of multidrug-resistant tuberculosis. MMWR Recomm Rep. 2013 Oct 25;62(RR-09):1-12. http://www.ncbi.nlm.nih.gov/pubmed/24157696. Accessed December 2016

[2] World Health Organization, Global Tuberculosis Report 2016. Available at: http://apps.who.int/iris/bitstream/10665/250441/1/9789241565394-eng.pdf?ua=1 .Accessed December 2016.

[3] World Health Organization, Global Tuberculosis Report 2016. Available at: http://apps.who.int/iris/bitstream/10665/250441/1/9789241565394-eng.pdf?ua=1 Accessed December 2016.

[4] World Health Organization, Global Tuberculosis Report 2016. Available at: http://apps.who.int/iris/bitstream/10665/250441/1/9789241565394-eng.pdf?ua=1 Accessed December 2016.

in costs for governments across the world[5], making it a large and growing public health and economic threat.

To date, anti-TB regimens have been focused on drugs that were approved before the 1960s, and have included limited treatment options for patients with MDR-TB.

"SIRTURO®, taken together with appropriate background regimens, has been shown to increase culture conversion rates and decrease time to culture conversion in patients diagnosed with pulmonary MDR-TB when compared with a placebo," said Avery Ince MD PhD, Vice President of Medical Affairs at Xian Janssen Pharmaceutical Ltd. "Our focus now is to work together with multiple stakeholders across China to ensure appropriate use of SIRTURO® and to support efforts that will help overcome this deadly disease."

Culture conversion from positive to negative, is now being used as an interim outcome for predicting treatment success in MDR-TB[6].

SIRTURO® also represents an important tool in support of global public health efforts to tackle bacterial resistance to antibiotics. In September, world leaders used the United Nations high level meeting on antimicrobial resistance to call for a multi-sectoral approach towards tackling the issue[7], and it is in this spirit that Xian Janssen will work to introduce the medicine in China.

Appropriate use of SIRTURO® is fundamental to Xian Janssen's efforts to overcome MDR-TB, and the company is working with partners, including those on the frontline in the battle against TB, to establish a robust access program to ensure appropriate programmatic use of SIRTURO® in China. This program will enable patients to use SIRTURO® both safely and appropriately while also reducing the likelihood of further resistant forms of TB bacteria emerging.

"Xian Janssen understands the significant unmet medical needs and challenges surrounding the treatment of MDR-TB in China, and we are committed to working with our partners to introduce and support access to SIRTURO®," added Asgar Rangoonwala, President of Xian Janssen Pharmaceutical Ltd. "Appropriate use is an integral aspect of the introduction of new TB treatment regimens and we take very seriously our obligation to ensure that SIRTURO® provides utility for patients today and in the future."

About BEDAQUILINE

Discovered by Janssen researchers, bedaquiline is the first therapy with a novel mechanism of action against TB approved in several decades. It has a unique mechanism of action that

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[5] The TB Alliance, "The Pandemic," 2016. http://www.tballiance.org/why-new-tb-drugs/global-pandemic. Accessed December 2016.

[6] Brust JC, et al. Culture conversion among HIV co-infected multidrug-resistant tuberculosis patients in Tugela Ferry, South Africa. PLoS One. 2011;6(1):e15841.

[7] General Assembly of the United Nations, "High-level Meeting on Antimicrobial Resistance." http://www.un.org/pga/71/event-latest/high-level-meeting-on-antimicrobial-resistance/ Accessed December 2016.

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, received conditional approval in the European Union, and is registered in the Russian Federation through a partner for the Russian Federation and CIS countries, JSC Pharmstandard. In addition, bedaquiline is approved in China, Armenia, Hong Kong, India, New Zealand, Peru, the Philippines, South Africa, South Korea, Taiwan, Turkmenistan and Uzbekistan. Regulatory filings have also been submitted in Bangladesh, Burundi, Colombia, Ghana, Indonesia, Kenya, Mexico, Rwanda, Tanzania, Thailand, Turkey, Uganda, and Vietnam. Pharmstandard has submitted an additional regulatory filing in Moldova.

About the Janssen Pharmaceutical Companies

At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science. We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at www.janssen.com.

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[5] The TB Alliance, "The Pandemic," 2016. http://www.tballiance.org/why-new-tb-drugs/global-pandemic. Accessed December 2016.

[6] Brust JC, et al. Culture conversion among HIV co-infected multidrug-resistant tuberculosis patients in Tugela Ferry, South Africa. PLoS One. 2011;6(1):e15841.

[7] General Assembly of the United Nations, "High-level Meeting on Antimicrobial Resistance." http://www.un.org/pga/71/event-latest/high-level-meeting-on-antimicrobial-resistance/ Accessed December 2016.

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