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SIRTURO® (bedaquiline) Receives Conditional Approval in the European Union for the Treatment of Multi-Drug Resistant Tuberculosis

Beerse, Belgium, (March 06, 2014) - Janssen-Cilag International NV (Janssen) announced today that the European Commission (EC) has granted conditional approval to SIRTURO® (bedaquiline) in the European Union, for use as part of an appropriate combination regimen for pulmonary multi-drug resistant tuberculosis (MDR-TB) in adult patients, when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability.

The decision from the EC follows a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommending the approval of bedaquiline on December 20, 2013.

"We are delighted that SIRTURO® has been approved for use in the European Union, as it represents a significant step forward in helping address a very serious global public health issue," said Wim Parys, Head R&D, Global Public Health at Janssen. "We will continue to work with partners and relevant authorities to ensure SIRTURO® is used correctly and appropriately, and we recognise the importance of educational efforts in informing physicians and patients about appropriate use."

SIRTURO® was discovered by scientists at Janssen and 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*. The conditional approval by the EC is supported by 24-week data from the Phase 2 clinical development programme, which included a controlled, randomised trial that evaluated the safety and efficacy of SIRTURO® versus placebo in the treatment of patients with pulmonary MDR-TB in combination with a background regimen (TMC207-C208) and an open-label study (C209). The durability of effect was supported by 120-week data from the Phase 2 controlled, randomised trial.[1]

In Phase 2 studies, the SIRTURO® treatment group had a decreased time to culture conversion and improved culture conversion rates compared to the placebo treatment group. The median time to culture conversion was 83 days for the SIRTURO® treatment group, compared to 125 days for the placebo treatment group at week 24 (TMC207-C208). At week 120, treatment with SIRTURO® continued to result in a significantly improved culture conversion rate versus the placebo treatment group.

Furthermore, based on WHO-recommended treatment outcome definitions applied to week 120 final data, the proportion of patients defined as cured at 120 weeks was 57.6% in the SIRTURO® arm vs. 31.8% in the placebo arm (p=0.003).[2]

"MDR-TB is associated with a high mortality rate and poses a significant public-health threat, as individuals infected with drug-resistant strains are often unable to receive adequate treatment and can potentially spread their infection," said Professor Martin Grobusch, Head of the Center for Tropical Medicine and Travel Medicine, University of Amsterdam. "Today's approval is a critical step forward in tackling this rapidly growing disease and speeding up patient access to much needed treatment."

Under the provisions of the conditional approval, Janssen commits to support a Phase 3 study to further substantiate the benefit-risk for SIRTURO® and define its optimal use, with regards to the number and types of agents that are needed in combination, and its optimal treatment duration.

To date, SIRTURO® has received accelerated approval in the United States and has been registered in the Russian Federation by JSC Pharmstandard, the company Janssen signed a license agreement with in 2013 for Russia and the Commonwealth of Independent States. Regulatory filings have also been submitted in South Africa, China, India, Thailand, Vietnam, Colombia, and South Korea.

About Multi-Drug 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.[3] Inadequately treated patients are likely to increase selective pressure, allowing resistant bacteria to thrive and pose a significant transmission risk to the general population.[4] Without significant public health intervention, MDR-TB is projected to infect more than two million people between 2011 and 2015.[4]

About The Clinical Development Program

The clinical development program includes two Phase 2 studies in patients with MDR-TB. TMC207-C208 was conducted in two independent stages: Stage 1 was a controlled, randomised, exploratory trial and Stage 2 was a controlled, randomised superiority trial in MDR-TB patients. Stage 2 compared time to culture conversion following the use of SIRTURO® (400 mg once daily for two weeks followed by 200 mg three times a week for 22 weeks) versus placebo in combination with a standardised background regimen for MDR-TB. The study enrolled 161 patients who received treatment for 24 weeks followed by continuation of the background therapy for an additional 12 to 18 months. Results were presented in 2010 at the 41st Union World Conference on Lung Health in Berlin, Germany.[5] Results from Stage 1 were published in *The New England Journal of Medicine*[5] in 2009. The submission contains 120 week data from TMC207-C208 Stage 2, the results of which were published in 2013 at the 44th Union World Conference of Lung Health in Paris, France.[1]

TMC207-C209 is a Phase 2 open-label trial in MDR-TB patients, in which SIRTURO® was administered as 400 mg once daily for two weeks followed by 200 mg three times weekly for 22 weeks in combination with an individualised background regimen for MDR-TB, followed by continued administration of the background regimen for 12 to 18 months. A total of 233 patients from 11 countries were enrolled in the trial, designed to evaluate the safety and efficacy of SIRTURO® in treatment-experienced patients, including 25% with pre-extensively drug-resistant TB (pre-XDR) and 21% with XDR-TB. Results were presented in 2011 at the 42nd Union World Conference on Lung Health in Lille, France.[7]

Janssen will conduct a Phase 3 study to further substantiate the benefit-risk for SIRTURO® and define the optimal use of SIRTURO®, with regards to the number and types of agents that are needed in combination, and the optimal treatment duration.

About Janssen Global Public Health
Janssen Global Public Health (Janssen GPH) complements the groundbreaking science of the Janssen Pharmaceutical companies of Johnson & Johnson with innovative strategies that improve access to medicines, foster collaborations, and support public health solutions to sustainably advance health care worldwide. Current focus includes multi-drug resistant tuberculosis (MDR-TB); human immunodeficiency virus (HIV); elephantiasis and river blindness; intestinal worms; and use of mobile technologies (mHealth) to improve health outcomes.

(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Infectious Diseases-Diagnostics BVBA, any of the Janssen Pharmaceutical Companies and/or Johnson & Johnson.

Risks and uncertainties include, but are not limited to: economic factors, such as interest rate and currency exchange rate fluctuations; competition, including technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; challenges to patents; changes in behavior and spending patterns or financial distress of purchasers of health care products and services; changes to governmental laws and regulations and domestic and foreign health care reforms; general industry conditions including trends toward health care cost containment; and increased scrutiny of the health care industry by government agencies.

A further list and description of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 29, 2013, including in Exhibit 99 thereto, and our subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statements as a result of new information or future events or developments.)

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News Release

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