



December 20, 2013

SIRTURO® (bedaquiline) Receives Positive Opinion from the Committee for Medicinal Products for Human Use as Part of Combination Therapy to Treat Adults with Pulmonary Multi-Drug Resistant Tuberculosis

Beerse, Belgium, (December 20, 2013) - Janssen Infectious Diseases JCI today announced that the Committee for Medicinal Products for Human Use (CHMP), of the European Medicines Agency (EMA), adopted a positive opinion recommending the conditional marketing authorisation of bedaquiline tablets for use as part of a combination therapy 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 CHMP positive opinion is an important step in the conditional approval of bedaquiline, and will now be considered by the European Commission (EC), which has the authority to approve medicines for use throughout the European Union. The CHMP positive opinion was 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 bedaquiline versus placebo in the treatment of patients with pulmonary MDR-TB in combination with a background regimen (TMC207-C208 Study 1 and Study 2) and an open-label study (C209). The durability of effect was supported by 120-week data from the Phase 2 controlled, randomised trial¹.

In 2012, of the estimated 8.6 million reported new cases of TB globally, 3.6 per cent were MDR-TB². MDR-TB is a particularly complicated form of TB characterised by resistance to at least two of the standard four-drug, anti-TB drug regimen³ and is estimated to kill 150,000 people annually⁴ and projected to infect more than two million people between 2011 and 2015⁵.

Bedaquiline 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. In Phase 2 clinical trials, adding bedaquiline to the current standard of care resulted in significantly faster culture conversion and significantly higher proportion of culture conversion. The new mode of action of bedaquiline also minimises the potential cross-resistance with existing TB drugs.

Bedaquiline was granted accelerated approval by the U.S. Food and Drug Administration (FDA) in December 2012, based on TMC207-C208 Study 1 and Study 2, which shows that significantly more patients were cured following treatment with bedaquiline versus placebo. In addition, the World Health Organization (WHO) also recently issued interim policy guidance on the use of bedaquiline in the treatment of pulmonary MDR-TB, as part of combination therapy in adults. This underscores the critical unmet need for new MDR-TB treatment options and the need to prevent uncontrolled and potentially irresponsible use of the treatment.

About Janssen

Janssen is committed to making a meaningful difference in global public health. Inspired by the legacy of Dr. Paul Janssen, we work passionately to discover and responsibly deliver innovative medicines and vaccines that address serious unmet health needs, including HIV, tuberculosis, intestinal worms and neglected tropical diseases. We collaborate with members of the global healthcare community, including the Bill and Melinda Gates Foundation, TB Alliance, DNDi, the International Partnership for Microbicides, and many others, to bring new solutions that deliver years of life and quality of life for people around the world.

World Health Organization Interim Guidance on Bedaquiline

On June 17, 2013, the World Health Organization (WHO) issued [interim policy guidance](#) on the use of bedaquiline in the treatment of pulmonary MDR-TB as part of combination therapy in adults. The guidance culminates a rigorous review process by internal and external TB experts convened by the WHO and drew upon available Phase 2 safety and efficacy data, a cost-effectiveness assessment and independent analysis to review the six-month surrogate endpoint.

(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, general industry conditions and competition; economic factors, such as interest rate and currency exchange rate fluctuations; 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; 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 Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 30, 2012. Copies of this Form 10-K, as well as subsequent 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 undertake to update any forward-looking statements as a result of new information or future events or developments.)

¹Diacon A, et al. OP-176-02: Final 120-week results of a Phase II randomised, double-blind, placebo-controlled study of 24-weeks

bedaquiline treatment for MDR-TB (C208). *Int J Tuberc Lung Dis* 2013;17 (Suppl 2):S234.

²World Health Organization. Global Tuberculosis Report 2013. Available at; http://apps.who.int/iris/bitstream/10665/91355/1/9789241564656_eng.pdf. Accessed December 5 2013

³WHO. Multidrug-Resistant Tuberculosis, Online Q&A. February 2012. Available at <http://www.who.int/features/qa/79/en/index.html>.

Accessed December 5 2013

⁴WHO. Tuberculosis MDR-TB & XDR-TB 2011 Progress Report. Available at http://www.who.int/tb/challenges/mdr/factsheet_mdr_progress_march2011.pdf. Accessed December 5 2013.

⁵WHO. 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 December 5 2013

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