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Janssen Research & Development Submits New Drug Application to FDA for Investigational Multi-Drug Resistant Tuberculosis Treatment Bedaquiline (TMC207)

RARITAN, 2 July 2012 - Janssen Research & Development, LLC (Janssen) today announced it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking accelerated approval for the use of the investigational drug bedaquiline (TMC207) as an oral treatment, to be used as part of combination therapy for pulmonary, multi-drug resistant tuberculosis (MDR-TB) in adults. If approved by the FDA, bedaquiline would be the first drug with a new mechanism of action for TB in more than 40 years and the first and only one specifically indicated for MDR-TB.

"The emergence of multi-drug resistant strains of TB is a growing problem that impacts people around the world and is posing a significant new treatment challenge in controlling this serious and deadly disease," said Paul Stoffels, Worldwide Chairman, Pharmaceuticals, Johnson & Johnson. "Although tuberculosis kills approximately 1.4 million people per year and current therapies do not provide adequate control of resistant strains, there have been no new treatment options to treat TB in the last 40 years. We believe the NDA submission for bedaquiline is an exciting milestone in the development of new TB drugs."

Bedaquiline was discovered by scientists at Janssen, a Johnson & Johnson company. Its unique mechanism of action targets adenosine triphosphate (ATP) synthaseⁱ, which *Mycobacterium tuberculosis* (M.tb)--the bacterium that causes tuberculosis--requires to generate its energy.

The regulatory submission is supported by 24-week data from the Phase II clinical development program, which includes an open-label study and 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.

Among infectious diseases, tuberculosis is the second most common cause of adult deaths worldwideⁱⁱ. The World Health Organization (WHO) estimates approximately one-third of the world's population is infected with *M.tb* and the disease is responsible for nearly 3,800 deaths per day, worldwideⁱⁱⁱ. MDR-TB, which is characterized by resistance to at least two of the most powerful medicines in today's standard, four-drug regimen for drug-susceptible TB, is of particular concern given the alarming increase in antibacterial resistance throughout the world and the difficulties in treating it. In 2010, there was an estimated prevalence of 650,000 cases of MDR-TB, and in 2008 it was estimated there were 150,000 MDR-TB deaths annually^{iv}. The WHO issued a Call to Action in Beijing in 2009^v because of the growing public health threat it poses. In the United States, TB is an orphan disease, with approximately 100 to 130 MDR TB patients annually^{vi}.

"This is a critically important milestone in the development of bedaquiline and an important step forward in the development of new treatments for TB," said Wim Parys, M.D., Head of the Infectious Diseases therapeutic area at Janssen. "It underscores our commitment to discover and develop novel medicines and solutions for serious unmet medical needs and we hope this new treatment will become an important option for patients with multi-drug resistant TB. This first submission will be followed by others in high-burden countries."

About the clinical development program

The clinical development program includes two Phase II studies in patients with MDR-TB. TMC207-C208 was conducted in two independent stages: stage 1 was a controlled, randomized, exploratory trial and stage 2 was a controlled, randomized superiority trial in MDR-TB patients. Stage 2 compared time to culture conversion following the use of bedaquiline (400 mg once daily for two weeks followed by 200 mg three times a week for 22 weeks) versus placebo in combination with a standardized 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^{vi}. Results from stage 1 were published in *The New England Journal of Medicine*^{viii} in 2009. The submission contains 72 week data from TMC207-C208.

The submission is further supported by 24-week data from TMC207-C209, a Phase II open-label trial in MDR-TB patients, in which bedaquiline was administered as 400 mg once daily for two weeks followed by 200 mg three times weekly for 22 weeks in combination with an individualized 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 bedaquiline 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^{ix}.

The Phase III trial - TMC207-C210 - a double-blind study comparing nine months of treatment with bedaquiline versus placebo (both with a background regimen) is planned to start recruiting in Q4 2012. This study will evaluate a new regimen of seven drugs for a shorter treatment duration (nine months of treatment) than the current 18 to 24 months WHO standard of care.

About Janssen Research & Development, LLC

Janssen Research & Development, LLC is headquartered in Raritan, N.J. and has affiliated facilities in Europe, the United States and Asia. Janssen Research & Development is leveraging a combination of internal and external innovation to discover and develop novel medicines and solutions in five distinct therapeutic areas: Neuroscience, Oncology, Immunology, Infectious Diseases and Vaccines, and Cardiovascular and Metabolism. For more information about Janssen Research & Development, LLC visit www.janssenrmd.com.

Janssen Research & Development is part of the Janssen Pharmaceutical Companies of Johnson & Johnson. Driven by our commitment to patients, we work together to bring innovative ideas, products, services and solutions to address serious unmet medical needs around the world.

Forward looking statements:

(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 Research & Development, LLC 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 January 1, 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. Neither Janssen Research & Development, LLC nor Johnson & Johnson undertake to update any forward-looking statements as a result of new information or future events or developments.)

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ⁱ Andries et al. A Diarylquinoline Drug Active on the ATP Synthase of *Mycobacterium tuberculosis* *Science* 14 January 2005: Vol. 307. no. 5707, pp. 223 - 227

ⁱⁱ World Health Organization. "TBHIV Facts at a Glance." Accessed from <http://www.who.int/tb/challenges/hiv/facts/en/index.html>, and World Health Organization. Tuberculosis Fact Sheet. Accessed from <http://www.who.int/mediacentre/factsheets/fs104/en/index.html>

ⁱⁱⁱ Fact Sheet: http://www.who.int/tb/publications/2011/factsheet_tb_2011.pdf

^{iv} Ibid.

^v http://www.who.int/tb_beijingmeeting/media/en_call_for_action.pdf

^{vi} https://extranet.who.int/sree/Reports?op=vs&path=/WHO_HQ_Reports/G2/PROD/EXT/MDRTB_Indicators_charts"

^{vii} McNeeley DF, Diacon H, Pym A, et al. TMC-207 versus placebo plus OBT for the treatment of MDR-TB: a prospective clinical trial. Oral presentation at the 41st Union World Conference on Lung Health; November 11-15, 2010; Berlin, Germany, <http://uwclh.conference2web.com/content/all#/?search=mcneeley&sessions=35>

^{viii} Diacon et al. The Diarylquinoline TMC207 for Multidrug-Resistant Tuberculosis, in *The New England Journal of Medicine*, vol. 360 no. 23, June 4, 2009, <http://www.nejm.org/doi/full/10.1056/NEJMoa0808427>.

^{ix} 42nd Union World Conference on Lung Health in Lille, France, 46. Clinical trials of new drugs and regimens for MDR- and XDR-TB, October 30, 2011 15:00, http://www.worldlunghealth.org/confLille/images/stories/PDF_Symposias/Symposium_46.pdf.