September 25, 2013

Janssen R&D Ireland Announces Agreement with PATH for Early Development of Rilpivirine in Long-Acting Formulation for Potential Prophylactic Intervention

Cork, Ireland (25 September 2013) - Janssen R&D Ireland (Janssen) announced today it has signed a license agreement with PATH for the early development of the human immunodeficiency virus type 1 (HIV-1) medicine rilpivirine in a long-acting injection (depot formulation) as potential pre-exposure prophylaxis (PrEP) against HIV infection.

Under the terms of the agreement, a Drug Development program of PATH, an international nonprofit organization that transforms global health through innovation, has the right to develop rilpivirine long-acting formulation as a possible new way to prevent HIV infection. PATH has the intent to conduct prophylaxis clinical trials in collaboration with partners including the HIV Prevention Trials Network. Following the completion of the clinical Phase 2 program, PATH and Janssen will evaluate entering into a late stage development agreement covering the use of rilpivirine as PrEP for uninfected individuals at high risk of acquiring HIV.

"Rilpivirine is an important treatment option for patients today and we are pleased to work with PATH to evaluate it as an injectable depot formulation that may help to reduce the spread of infection," said Wim Parys, Global Head of Research & Development, Janssen Global Health. "We believe that evaluating a long acting formulation, which could help improve adherence in a PrEP regimen, is an important part of the Janssen commitment to the global fight against HIV and AIDS."

Rilpivirine is a non-nucleoside reverse transcriptase inhibitor (NNRTI). It is currently commercialized by Janssen for the oral, once daily treatment of HIV-1, in combination with other antiretroviral agents (ARVs), in ARV treatment-naïve adults, and in most countries, in patients with a viral load less than or equal to 100,000 HIV-1RNA copies/mL.

This license agreement with PATH does not impact the commercialization of rilpivirine by Janssen, and does not impact the use of rilpivirine in combination treatments.

About Janssen R&D Ireland
At Janssen, we are dedicated to addressing and solving some of the most important unmet medical needs of our time in oncology, immunology, neuroscience, infectious diseases, and cardiovascular and metabolic diseases.

We are further committed to making a meaningful difference in global public health. Inspired by the legacy of Dr. Paul Janssen and our commitment to patients, 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, the Global TB Alliance, the Drugs for Neglected Diseases Initiative, 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.

Janssen R&D Ireland is part of the Janssen Pharmaceutical Companies of Johnson & Johnson. Please visit http://www.janssenrnd.com for more information.

(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 R&D Ireland, any of the other 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.)

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