



## Janssen Announces License Agreement With Vertex to Develop Novel Treatment for Influenza A

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Titusville, United States, 18 June 2014 - Janssen Pharmaceuticals, Inc. (Janssen) announced today that it has entered into an exclusive license agreement with Vertex Pharmaceuticals for the worldwide development, manufacturing and commercialization of VX-787, a novel medicine in Phase II development for the treatment of influenza A.

VX-787 is an investigational medicine designed to directly inhibit replication of the influenza A virus, including recent H1 (pandemic) and H5 (avian) influenza strains, based on in-vitro data. Influenza is an acute viral infection that spreads easily through respiratory droplets produced when an infected person coughs or sneezes, or through contaminated hands and surfaces<sup>1</sup>. Universally, resistance has emerged to existing antivirals for influenza and, through the development of VX-787, Janssen hopes to provide an additional treatment option for patients.

"Influenza infection remains one of the most serious public health challenges globally. In addition to the burden of seasonal influenza, the pandemics of the 20th and 21st centuries exemplify the threat the influenza A virus presents," says Johan Van Hoof, Global TA Head Infectious Diseases and Vaccines, Managing Director, Crucell. "This agreement builds on Janssen's legacy of innovation and partnership, and we are proud to collaborate with Vertex on this novel medicine. This treatment has the potential to address a significant unmet medical need and to improve the well-being of patients everywhere."

The license agreement also grants Janssen rights to develop, manufacture and commercialize VX-787's back-up compound, VX-353, as well as rights to develop, manufacture and commercialize certain other back-up compounds for the prevention and/or treatment of influenza. The agreement is subject to the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act.

Vertex completed a Phase IIA study of VX-787 in 2013. The parties expect additional clinical trials to begin in the coming months.

#### **About VX-787**

VX-787 is a first-in-class, influenza A-specific, oral polymerase inhibitor. It is the first and most advanced example of a novel mode of action (MOA) direct acting antiviral working through the influenza virus PB2 polymerase subunit. Targeting an alternative part of the viral replication process may help ensure that this new medicine can successfully treat strains of the influenza virus which may be resistant to existing antiviral drugs with other MOAs.

VX-787 has demonstrated potent and rapid in-vitro antiviral activity on all Vertex tested influenza A strains to date, including oseltamivir (Tamiflu®) resistant strains<sup>2</sup>. Initial clinical assessments of VX-787 have also been promising. Phase I studies demonstrated the molecule was well tolerated in healthy volunteers providing a pharmacokinetic profile supportive of once daily dosing.<sup>2</sup> Vertex has also completed a Phase IIA challenge study that showed statistically significant improvements in viral and clinical measurements of influenza A infection and demonstrated clinical proof of concept.<sup>3</sup>

#### **About Influenza**

Influenza occurs globally, with an average of 5-10 percent of adults and 20-30 percent of children becoming infected with the virus each year. Worldwide, annual influenza epidemics are estimated to result in about 3 to 5 million cases of severe illness, and about 250,000 to 500,000 deaths<sup>4</sup>. Yearly influenza epidemics can seriously affect all populations, but the highest risk of complications occur among children younger than age 2 years, adults aged 65 years or older, pregnant women, and people of any age with certain medical conditions, such as chronic heart, lung, kidney, liver, blood or metabolic diseases (such as diabetes), or weakened immune systems.<sup>4</sup>

The treatment of influenza consists of antiviral medications that have been shown in clinical studies to shorten the disease and reduce the severity of symptoms if taken within two days of infection, however, there is a significant need for new medicines targeting flu that provide a wider treatment window, greater efficacy and faster onset of action.<sup>4</sup>

#### **About Janssen**

At Janssen, we are dedicated to addressing and solving some of the most important unmet medical needs of our time in infectious diseases and vaccines, oncology, immunology, neuroscience, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we develop innovative products, services and healthcare solutions to help people throughout the world.

Janssen Pharmaceuticals, Inc. is part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

*(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 Pharmaceuticals, Inc. 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](http://www.sec.gov), [www.inj.com](http://www.inj.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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<sup>1</sup> World Health Organization. Influenza. Available at: <http://www.euro.who.int/en/health-topics/communicable-diseases/influenza>. Last accessed June 2014

<sup>2</sup> Vertex: Data on file.

<sup>3</sup> Vertex. VX-787 Showed Significant Antiviral Activity and Reduced the Severity and Duration of Influenza Symptoms in Phase 2 Challenge Study. Available at: <http://investors.vrtx.com/releasedetail.cfm?releaseid=744857>. Last accessed June 2014.

<sup>4</sup> World Health Organization. Influenza (Seasonal). Available at: <http://www.who.int/mediacentre/factsheets/fs211/en/>. Last accessed June 2014.