December 21, 2017

U.S. FDA Grants Priority Review to Janssen for Apalutamide as a Treatment for Non-Metastatic Castration-Resistant Prostate Cancer

Apalutamide is the First Agent Submitted for Approval to Treat Earlier Stage Castration-Resistant Prostate Cancer at High Risk for Metastasis

HORSHAM, Pa., Dec. 21, 2017 /PRNewswire/ -- Janssen Biotech, Inc. (Janssen) today announced that the U.S. Food and Drug Administration (FDA) has granted Priority Review designation for the New Drug Application (NDA) for apalutamide, an investigational, next-generation oral androgen receptor (AR) inhibitor for the treatment of men with non-metastatic castration-resistant prostate cancer (CRPC). Currently, there are no FDA-approved treatments for patients with non-metastatic CRPC.

The FDA grants Priority Review designation to investigational therapies that, if approved, may offer significant improvements in the safety and effectiveness of the treatment, diagnosis or prevention of serious conditions when compared to standard applications.[1] This designation means the FDA's goal is to take action on an application within six months of receipt, compared to 10 months for Standard Review.[1] The FDA has assigned a Prescription Drug User Fee Act (PDUFA) target date of April 2018 to render a decision on the apalutamide application.

"The prognosis for men with prostate cancer is significantly worse once the cancer has spread to other parts of the body. Accordingly, men with non-metastatic castration-resistant prostate cancer need treatment options that can delay disease progression and improve long-term outcomes," said Craig Tendler, M.D., Vice President, Late Development and Global Medical Affairs, Oncology, Janssen Research & Development, LLC. "We are encouraged by the FDA's recognition, via the priority review designation, of the potential for apalutamide to provide such an option for these men."

The NDA submission for apalutamide, which was completed on October 10, 2017, was based on Phase 3 data from the pivotal ARN-509-003 (SPARTAN) clinical trial, which assessed the safety and efficacy of apalutamide versus placebo in men with non-metastatic CRPC who have a rapidly rising prostate specific antigen (PSA) despite receiving continuous androgen deprivation therapy (ADT).[2] These men with a rapidly rising PSA are at high risk for developing metastatic disease.[3,4] The primary endpoint of this study was metastasis-free survival (MFS).[2] MFS is the time from randomization to first evidence of confirmed metastasis, or time to death.[5] The SPARTAN study results have been accepted for oral presentation at the ASCO Genitourinary Cancers Symposium on Thursday, February 8, 2018, in San Francisco.

According to the American Cancer Society, prostate cancer is the most common cancer among American men, other than skin cancer.[6] More than 161,000 men are estimated to be diagnosed with prostate cancer in 2017.[6]

Non-metastatic castration-resistant prostate cancer refers to patients with CRPC who lack detectable distant metastatic disease.[7,8] These individuals have a rising PSA, serum testosterone level below 50 ng/dL and bone scan and computed tomography (CT) scans that show no evidence of spread to bones or visceral organs.[9] Men with rapidly rising PSA have a high unmet medical need, as these patients are at high risk for developing metastatic disease.[10]

Patients with non-metastatic prostate cancer receiving ADT will eventually become resistant to ADT, developing CRPC. It is estimated 10 to 20 percent of patients diagnosed with prostate cancer may develop CRPC within approximately five years of follow-up.[11]

About Apalutamide
Apalutamide is an investigational, next-generation oral androgen receptor inhibitor that inhibits the action of androgen in prostate cancer cells, and prevents binding of androgen to the androgen receptor, and translocation of the androgen receptor to the nucleus of the cancer cell.

About the Janssen Pharmaceutical Companies
At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science. We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at www.janssen.com. Follow us at www.twitter.com/JanssenUS and www.twitter.com/JanssenGlobal.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development of apalutamide. 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 known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Biotech, Inc., Janssen Research & Development, LLC and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions 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 January 1, 2017, including under "Item 1A. Risk Factors," its most recently filed Quarterly Report on Form 10-Q, including in the section captioned "Cautionary Note Regarding Forward-Looking Statements," and the company's 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. Neither the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

[1] Guidance for Industry Expedited Programs for Serious Conditions - Drugs and Biologics. Available at: https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm358301.pdf. Accessed in December 2017.

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