



Janssen Submits New Drug Application to U.S. FDA for Apalutamide (ARN-509) to Treat Men with Non-Metastatic Castration-Resistant Prostate Cancer

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HORSHAM, Pa., Oct. 11, 2017 /PRNewswire/ -- Janssen Biotech, Inc. today announced that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for apalutamide, an investigational, next generation oral androgen receptor (AR) inhibitor for men with non-metastatic castration-resistant prostate cancer (CRPC). Currently, there are no FDA approved treatments for patients with non-metastatic CRPC.



This submission is 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).¹ Men with non-metastatic CRPC with a rapidly rising PSA are at high risk for developing metastatic disease.^{2,3} The primary endpoint of this study was metastasis free survival (MFS).¹ MFS is the time from randomization to first evidence of confirmed metastasis, or time to death.⁴ The SPARTAN study results will be presented at a future medical meeting.

"The SPARTAN data lead the path towards a new approach to treating men with prostate cancer earlier in the disease course. We have demonstrated that treating patients before the disease has metastasized improves outcomes," said Peter Lebowitz, M.D., Ph.D., Global Therapeutic Area Head of Oncology at Janssen. "We are thrilled to have completed our submission of the SPARTAN data to the FDA and we look forward to a promising treatment that can provide new hope and expectations for men facing this disease."

Prostate cancer is the most common cancer among American men, other than skin cancer.⁵ According to the American Cancer Society, more than 161,000 men are estimated to be diagnosed with prostate cancer in 2017.⁵ Patients with non-metastatic prostate cancer receiving ADT will eventually become resistant to ADT, developing castration-resistant prostate cancer (CRPC). Data has estimated 10% to 20% of patients diagnosed with prostate cancer may develop CRPC within approximately 5 years.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, testosterone level below 50 ng/dl and bone scan and 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

About Apalutamide (ARN-509)

Apalutamide is an investigational, next generation oral androgen receptor inhibitor that inhibits the action of testosterone in prostate cancer cells and works by preventing androgen from binding to the androgen receptor.

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., any of the other Janssen Pharmaceutical Companies 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 Clinical trials gov. A Study of Apalutamide (ARN-509) in Men with Non-Metastatic Castration-Resistant Prostate Cancer (SPARTAN). Available at: <https://clinicaltrials.gov/ct2/show/NCT01946204>. Accessed September 2017.

² Smith MR, et al. Natural history of rising serum prostate-specific antigen in men with castrate nonmetastatic prostate cancer. *J Clin Oncol*. 2005;23:2918-2925.

³ Lin JH, et al. Association of prostate specific-antigen doubling time (PSADT) with metastasis-free survival (MFS) and overall survival (OS) in non-metastatic castration-resistant prostate cancer (nmCRPC). *J Clin Oncol* 2017;35(15 suppl). Abstract e16525.

⁴ Xie W, et al. Metastasis-Free Survival Is a Strong Surrogate of Overall Survival in Localized Prostate Cancer. *Journal of Clinical Oncology*. 2017; 0732-183X/17/3599-1.

⁵ American Cancer Society. Key Statistics for Prostate Cancer. Available at: <https://www.cancer.org/cancer/prostate-cancer/about/key-statistics.html>. Accessed September 2017.

⁶ Kirby M, Hirst C, Crawford ED. Characterising the castration-resistant prostate cancer population: a systematic review. *Int J Clin Pract*. 2011;65:1180-1192.

⁷ Scher HI, et al. Design and end points of clinical trials for patients with progressive prostate cancer and castrate levels of testosterone: recommendations of the Prostate Cancer Clinical Trials Working Group. *J Clin Oncol*. 2008;26:1148-1159.

⁸ Scher HI, et al. Trial Design and Objectives for Castration-Resistant Prostate Cancer: Updated Recommendations From the Prostate Cancer Clinical Trials Working Group 3. *J Clin Oncol*. 2016;34:1402-1418.

⁹ Virgo K, et al. Second-Line Hormonal Therapy for Men With Chemotherapy-Naïve, Castration-Resistant Prostate Cancer: American Society of Clinical Oncology Provisional Clinical Opinion. *Journal of Clinical Oncology*. 2017; 0732-183X/17/3599-1.

¹⁰ Modern Medicine. "Treatment of Nonmetastatic Castration-Resistant Prostate Cancer." Available at: <http://www.cancernetwork.com/oncology-journal/treatment-nonmetastatic-castration-resistant-prostate-cancer>. Accessed September 2017.

Media Inquiries:

Bernadette King
Phone: 1-215-325-2158
Mobile: 1-215-778-3027

Satu Glawe
Phone: +49 2638 947 9218
Mobile: +49 172 294 6264

Investor Relations:

Lesley Fishman
Phone: 1-732-524-3922

U.S. Medical Inquiries:

1-800-526-7736

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