Media Inquiries:
Bernadette King
Phone: 1-215-778-3027

Satu Glawe
Phone: +49 172 294 6264

Investor Relations:
Lesley Fishman
Phone: 1-732-524-3922

U.S. Medical Inquiries:
1-800-526-7736

ERLEADA™ (apalutamide), a Next-Generation Androgen Receptor Inhibitor, Lowered Risk of Metastasis or Death in Patients with Non-Metastatic Castration-Resistant Prostate Cancer

- *Phase 3 SPARTAN data showed ERLEADA™ improved median metastasis-free survival by more than two years*
- *Data featured as oral presentation at ASCO GU 2018 (Abstract #161) and published in* The New England Journal of Medicine

SAN FRANCISCO and RARITAN, NJ, February 8, 2018 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today new findings from the Phase 3 SPARTAN clinical trial that showed treatment with ERLEADA™, an investigational, next-generation[1] androgen receptor inhibitor, decreased risk of metastasis or death by 72 percent and improved median metastasis-free survival (MFS) by more than two years (difference of 24.3 months) in patients with non-metastatic castration-resistant prostate cancer (CRPC) whose prostate specific antigen (PSA) is rapidly rising, compared to placebo. The results were presented at the American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU) in San Francisco (Abstract #161) and were simultaneously published in *The New England Journal of Medicine*.

"While there have been advances in the treatment of prostate cancer over the years, metastatic castration-resistant prostate cancer is still a lethal disease. These compelling results are the first to show that metastases can be delayed in these patients," said Eric Small, M.D. FASCO, Professor of Medicine, and Chief of the Division of Hematology and Oncology at the University of California, San Francisco, and lead SPARTAN study investigator. "These data suggest that apalutamide could

potentially be a new standard of care for patients with non-metastatic castration-resistant prostate cancer."

SPARTAN, a Phase 3, randomized, double-blind, placebo-controlled, multicenter study, enrolled 1,207 patients with non-metastatic castration-resistant prostate cancer and was conducted at 332 sites in 26 countries in North America, Europe, Asia-Pacific and Australia. Patients were randomized 2:1 to receive ERLEADA™ in combination with androgen deprivation therapy (ADT) (n=806), or placebo in combination with ADT (n=401).

ERLEADA™ in combination with ADT decreased the risk of metastasis or death by 72 percent compared to placebo in combination with ADT (HR = 0.28; 95% CI, 0.23-0.35; *P*<0.0001).[2] The median MFS was 40.5 months for ERLEADA™ in combination with ADT compared to 16.2 months for placebo in combination with ADT, prolonging MFS by more than two years. MFS benefit was consistently seen across all subgroups of patients.[2]

"Delaying the metastasis of prostate cancer is critical. Once the cancer starts to spread, the patient's overall health, well-being and prognosis change drastically," said Peter Lebowitz, M.D., Ph.D., Global Therapeutic Area Head of Oncology at Janssen Research & Development, LLC. "The ERLEADA™ data presented at ASCO GU demonstrate the important impact this medicine can have for patients with prostate cancer. Janssen is committed to addressing unmet needs for treatment across all stages of disease progression with novel combinations and novel therapeutics."

In addition to improving metastasis free survival, ERLEADA™ in combination with ADT, compared to placebo in combination with ADT, demonstrated clinical improvement across secondary endpoints, with statistically significant improvements in time to metastasis (TTM; median of 40.5 months in the ERLEADA™ arm compared to median of 16.6 months in the placebo arm) and progression-free survival (PFS; median of 40.5 months in the ERLEADA™ arm compared to median of 14.7 months in the placebo arm). Treatment with ERLEADA™ decreased the risk of symptomatic progression by 55 percent compared with placebo (HR=0.45; 95% CI, 0.32-0.63; *P*<0.0001). ERLEADA™ was associated with a 30 percent risk reduction of death compared to placebo at this early interim analysis for overall survival (OS).[2] In exploratory endpoints, ERLEADA™ in combination with ADT, compared to placebo in combination with ADT, also achieved a 94 percent risk reduction in time to PSA progression (HR = 0.06; 95% CI, 0.05-0.08; *P*<0.0001), and a 51 percent risk reduction in second progression-free survival (PFS2). The combination of ERLEADA™ and ADT was tolerable, with maintenance of overall health-related quality of life.

The most common Grade 3/4 treatment-emergent adverse events (TEAEs) for ERLEADA™ in combination with ADT versus placebo in combination with ADT were rash (5.2 percent vs. 0.3 percent), fall (1.7 percent vs. 0.8 percent) and fracture (2.7 percent vs. 0.8 percent). Treatment discontinuation due to adverse events were 11 percent in the ERLEADA™ arm compared to 7 percent in the placebo arm. Rates of serious adverse events (SAEs) were similar in the ERLEADA™ in combination with ADT arm versus placebo in combination with ADT arm (25 percent vs. 23 percent, respectively).

About Non-Metastatic Castration-Resistant Prostate Cancer

Non-metastatic castration-resistant prostate cancer (CRPC) refers to a disease stage when the cancer no longer responds to medical or surgical treatments that lower testosterone, but has not yet been discovered in other parts of the body using a total body bone scan or CT scan.[3] Features include: lack of detectable metastatic disease;[3] rapidly rising prostate-specific antigen while on androgen deprivation therapy (ADT) and serum testosterone level below 50 ng/dL.[4,5] Ninety percent of patients with non-metastatic CRPC will eventually develop bone metastases, which can lead to pain, fractures and spinal cord compression.[6] The relative 5-year survival rate for patients with distant stage prostate cancer is 30 percent.[7] While it is critical to delay the onset of metastasis in patients with non-metastatic CRPC, there are currently no FDA approved treatments.

About ERLEADA™

ERLEADA™ (apalutamide) is an investigational, next-generation[1] oral androgen receptor (AR) inhibitor that blocks the androgen signaling pathway in prostate cancer cells. ERLEADA™ inhibits the growth of cancer cells in three ways: by preventing the binding of androgen to the AR; by stopping the AR from entering the cancer cells; and by preventing the AR from binding to the DNA of the cancer cell.

About the Janssen Pharmaceutical Companies of Johnson & Johnson

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/JanssenGlobal and www.twitter.com/JanssenUS.

Janssen Research & Development, LLC is part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

# # #

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 and the potential benefits and treatment impact of ERLEADA™(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 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] Clegg N., et all. ARN-509: A Novel Antiandrogen for Prostate Cancer Treatment. Amerian Association for Cancer Research. 2012: 72(6):1494-503

[2] Small E., et all. SPARTAN, a phase 3 double-blind, randomized study of apalutamide (APA) vs placebo (PBO) in patients (pts) with nonmetastatic castration-resistant prostate cancer (nmCRPC). Abstract #161.

[3] 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.

[4] 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.

[5] 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. Accessed February 2018.

[6] Saad F, et al. The 2015 CUA0CUOG guidelines for the management of castration-resistant prostate cancer (CRPC). Can Urol Assoc J. 2015;9(3-4):90-96. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4455631/. Accessed February 2018.

[7] American Cancer Society. Cancer Facts & Figures. https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2018/cancer-facts-and-figures-2018.pdf. Accessed February 2018.