Media Inquiries:
Brian Kenney
Phone: 1-215-620-0111

Suzanne Frost
Phone: 1-416-317-0304

Investor Relations:
Christopher DelOrefice
Phone: 1-732-524-2955

Lesley Fishman
Phone: 1-732-524-3922

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

Janssen Announces ERLEADA® (apalutamide) Phase 3 TITAN Study Unblinded as Dual Primary Endpoints Achieved in Clinical Program Evaluating Treatment of Patients with Metastatic Castration-Sensitive Prostate Cancer

Phase 3 Study Unblinded Following Recommendation of Independent Data Monitoring Committee

SPRING HOUSE, PA, January 30, 2019 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today the unblinding of the Phase 3 TITAN study evaluating ERLEADA® (apalutamide) plus androgen deprivation therapy (ADT) in the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC). The decision resulted from an Independent Data Monitoring Committee (IDMC) recommendation coinciding with a pre-planned analysis that showed the dual primary endpoints were both achieved,

significantly improving radiographic progression-free survival (rPFS) and overall survival (OS). Based on these results, the IDMC recommended that patients in the placebo plus ADT group be given the opportunity to cross over to treatment with ERLEADA plus ADT. Patients will continue to be followed for OS and long-term safety as part of the TITAN study.

"The TITAN study was designed to evaluate the efficacy and safety of ERLEADA in combination with androgen deprivation therapy in patients with newly-diagnosed metastatic castration-sensitive prostate cancer, regardless of the extent of their disease," said Margaret Yu, M.D., Vice President, Oncology Clinical Development, Janssen Research & Development, LLC. "We look to continue to build upon our understanding of ERLEADA for patients with metastatic prostate cancer as there remains a significant unmet need for additional treatment options."

Results from the TITAN study will be submitted for presentation at an upcoming medical congress. Applications seeking regulatory approval of ERLEADA supported by data from the Phase 3 TITAN study are planned for 2019.

About Metastatic Castration-Sensitive Prostate Cancer

Metastatic prostate cancer is cancer that has spread to another part of the body.[1] Metastatic castration-sensitive prostate cancer (mCSPC), refers to prostate cancer that still responds to ADT.[1] Patients with newly-diagnosed metastatic disease tend to have a poorer prognosis, resulting in a need for new treatment options.[2,3]

About the TITAN Study

TITAN is a Phase 3 randomized, placebo-controlled, double-blind study in men who were newly diagnosed with metastatic disease, regardless of prognostic risk, volume of disease, prior treatment with docetaxel or treatment of localized disease. More than 1,050 patients with mCSPC were randomized to receive either ERLEADA plus ADT, or placebo plus ADT. Participants were treated until disease progression or the occurrence of unacceptable treatment related toxicity, or end of treatment. The dual primary endpoints of the study are rPFS and OS.[4] Secondary endpoints of the study include time to chemotherapy, time to pain progression, time to chronic opioid use and time to skeletal related event.[4] For additional study information, visit ClinicalTrials.gov.

About ERLEADA

ERLEADA® (apalutamide) is an androgen receptor (AR) inhibitor indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer (nmCRPC). It became the first treatment to receive FDA approval for this disease state on February 14, 2018.[5] The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer include apalutamide as a treatment option for patients with non-metastatic (M0) CRPC with a category 1 recommendation (especially for those with a PSA doubling time ≤10 months)*.[6] Additionally, the American Urological Association (AUA) Guidelines for Castration-Resistant Prostate Cancer (CRPC) were updated to include apalutamide (ERLEADA) with continued ADT as a treatment option that clinicians should offer to patients with asymptomatic nmCRPC. It is included as one of the options clinicians should offer to patients with nmCRPC who are at high-risk for developing metastatic disease (Standard; Evidence Level Grade A)**.[7]

**Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer V.4.2018. © National Comprehensive Cancer Network, Inc. 2018. All rights reserved. Accessed March 12, 2018. To view the most recent and complete version of the NCCN Guidelines®, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use, or application, and disclaims any responsibility for their application or use in any way.*

***Standard: Directive statement that an action should (benefits outweigh risks/burdens) or should not (risks/burdens outweigh benefits) be taken based on Grade A or B evidence.*

***Evidence Level: A designation indicating the certainty of the results as high, moderate, or low (A, B, or C, respectively) based on AUA nomenclature and methodology.*

ERLEADA IMPORTANT SAFETY INFORMATION[5]

CONTRAINDICATIONS

Pregnancy — ERLEADA (apalutamide) can cause fetal harm and potential loss of pregnancy.

WARNINGS AND PRECAUTIONS

Falls and Fractures — In a randomized study (SPARTAN), falls and fractures occurred in 16% and 12% of patients treated with ERLEADA compared to 9% and 7% treated with placebo, respectively. Falls were not associated with loss of consciousness or seizure. Evaluate patients for fracture and fall risk. Monitor and manage patients at risk for fractures according to established treatment guidelines and consider use of bone targeted agents.

Seizure — In a randomized study (SPARTAN), 2 patients (0.2%) treated with ERLEADA experienced a seizure. Permanently discontinue ERLEADA in patients who develop a seizure during treatment. It is unknown whether anti-epileptic medications will prevent seizures with ERLEADA. Advise patients of the risk of developing a seizure while receiving ERLEADA and of engaging in any activity where sudden loss of consciousness could cause harm to themselves or others.

ADVERSE REACTIONS

Adverse Reactions — The most common adverse reactions (≥10%) were fatigue, hypertension, rash, diarrhea, nausea, weight decreased, arthralgia, fall, hot flush, decreased appetite, fracture, and peripheral edema.

Laboratory Abnormalities — All Grades (Grade 3-4)

- Hematology — anemia ERLEADA® 70% (0.4%), placebo 64% (0.5%); leukopenia ERLEADA 47% (0.3%), placebo 29% (0%); lymphopenia ERLEADA 41% (2%), placebo 21% (2%)

- Chemistry — hypercholesterolemia ERLEADA 76% (0.1%), placebo 46% (0%); hyperglycemia ERLEADA® 70% (2%), placebo 59% (1%); hypertriglyceridemia ERLEADA® 67% (2%), placebo 49% (0.8%); hyperkalemia ERLEADA 32% (2%), placebo 22% (0.5%)

Rash — Rash was most commonly described as macular or maculo-papular. Adverse reactions were 24% with ERLEADA® versus 6% with placebo. Grade 3 rashes (defined as covering > 30% body surface area [BSA]) were reported with ERLEADA treatment (5%) versus placebo (0.3%).

The onset of rash occurred at a median of 82 days. Rash resolved in 81% of patients within a median of 60 days (range: 2 to 709 days) from onset of rash. Four percent of patients treated with ERLEADA® received systemic corticosteroids. Rash recurred in approximately half of patients who were re-challenged with ERLEADA.

Hypothyroidism was reported for 8% of patients treated with ERLEADA and 2% of patients treated with placebo based on assessments of thyroid-stimulating hormone (TSH) every 4 months. Elevated TSH occurred in 25% of patients treated with ERLEADA and 7% of patients treated with placebo. The median onset was day 113. There were no Grade 3 or 4 adverse reactions. Thyroid replacement therapy, when clinically indicated, should be initiated or dose-adjusted.

DRUG INTERACTIONS

Effect of Other Drugs on ERLEADA — Co-administration of a strong CYP2C8 or CYP3A4 inhibitor is predicted to increase the steady-state exposure of the active moieties. No initial dose adjustment is necessary; however, reduce the ERLEADA dose based on tolerability *[see Dosage and Administration (2.2)].*

Effect of ERLEADA on Other Drugs — ERLEADA is a strong inducer of CYP3A4 and CYP2C19, and a weak inducer of CYP2C9 in humans. Concomitant use of ERLEADA® with medications that are primarily metabolized by CYP3A4, CYP2C19, or CYP2C9 can result in lower exposure to these medications. Substitution for these medications is recommended when possible or evaluate for loss of activity if medication is continued. Concomitant administration of ERLEADA with medications that are substrates of UDP-glucuronosyl transferase (UGT) can result in decreased exposure. Use caution if substrates of UGT must be co-administered with ERLEADA and evaluate for loss of activity.

P-gp, BCRP or OATP1B1 substrates — Apalutamide is a weak inducer of P-glycoprotein (P- gp), breast cancer resistance protein (BCRP), and organic anion transporting polypeptide 1B1 (OATP1B1) clinically. Concomitant use of ERLEADA with medications that are substrates of P-gp, BCRP, or OATP1B1 can result in lower exposure of these medications. Use caution if substrates of P-gp, BCRP or OATP1B1 must be co-administered with ERLEADA and evaluate for loss of activity if medication is continued.

Please see the full Prescribing Information for ERLEADA®.

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 one of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding the potential benefits and further benefits 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, 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 December 31, 2017, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q 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.

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[1] American Society of Clinical Oncology. Prostate Cancer: Treatment Options. http://www.cancer.net/cancer-types/prostate-cancer/treatment-options. Accessed January 2019.

[2] Cancer.org. Survival rates for prostate cancer. https://www.cancer.org/cancer/prostate-cancer/detection-diagnosis-staging/survival-rates.html. Accessed January 2019.

[3] Fizazi K., et al. Abiraterone plus Prednisone in Metastatic, Castration-Sensitive Prostate Cancer. *New England Journal of Medicine*. June 2017.

[4] ClinicalTrials.gov. A Study of Apalutamide (JNJ-56021927, ARN-509) Plus Androgen Deprivation Therapy (ADT) Versus ADT in Participants With mHSPC (TITAN). Available at: https://clinicaltrials.gov/ct2/show/NCT02489318

[5] ERLEADA Prescribing Information, February 2018.

[6] Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer V.4.2018. © National Comprehensive Cancer Network, Inc. 2018. All rights reserved. Accessed March 12, 2018. To view the most recent and complete version of the NCCN Guidelines®, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use, or application, and disclaims any responsibility for their application or use in any way.

[7] American Urological Association. Castration-Resistant Prostate Cancer Guidelines. http://www.auanet.org/guidelines/castration-resistant-prostate-cancer-(2013-amended-2018). Accessed January 2019.