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Janssen Submits Application to U.S. FDA Seeking Approval of ERLEADA® (apalutamide) for Patients with Metastatic Castration-Sensitive Prostate Cancer

Supplemental New Drug Application Supported by Phase 3 TITAN Study; Submitted Through FDA Real-Time Oncology Review Program

RARITAN, NJ, April 29, 2019 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today the submission of a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) seeking approval of a new indication for ERLEADA® (apalutamide) for the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC). The sNDA is based on findings from the Phase 3 TITAN study, whose dual primary endpoints, overall survival (OS) and radiographic progression-free survival (rPFS), were both achieved. These data will be presented at the upcoming American Society of Clinical Oncology (ASCO) Annual Meeting during an oral abstract session on Friday, May 31st.

The sNDA is being reviewed by the FDA through the Real-Time Oncology Review (RTOR) program, which for certain applications allows the FDA to review data before the applicant

formally submits the complete application. The program aims to explore a more efficient review process to help ensure treatments are available for patients as soon as possible. Selection into the RTOR program does not guarantee or influence approvability of the application.

"This submission marks an important step in providing a potential treatment option for patients with metastatic castration-sensitive prostate cancer, regardless of prior treatment or the extent of their disease," said Craig Tendler, M.D., Vice President, Oncology Clinical Development and Medical Affairs, Janssen Research & Development, LLC. "We look forward to closely collaborating with the FDA through the efficient Real-Time Oncology Review pilot program with the goal of bringing ERLEADA to an earlier population of patients with metastatic prostate cancer as soon as possible."

About the TITAN Study[1]

TITAN (NCT02489318) is a Phase 3 randomized, placebo-controlled, double-blind study in patients with mCSPC regardless of extent of disease, and prior treatment with docetaxel or treatment of localized disease. More than 1,050 patients with mCSPC were randomized to receive either ERLEADA plus androgen deprivation therapy (ADT), or placebo plus ADT. The TITAN study included mCSPC patients with both low and high-volume disease, those who were newly diagnosed or those who have received prior definitive local therapy, or prior treatment with up to six cycles of docetaxel. 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 OS and rPFS. Secondary endpoints include time to chemotherapy, time to pain progression, time to chronic opioid use and time to skeletal related event.[1] 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.[2] 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 for those with a PSA doubling time ≤10 months*.[3] 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)**.[4]

**Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer V.2.2019. © National Comprehensive Cancer Network, Inc. 2018. All rights reserved. Accessed April 23, 2019. 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.*

About Metastatic Castration-Sensitive Prostate Cancer

Metastatic prostate cancer is cancer that has spread to another part of the body.[5] Metastatic castration-sensitive prostate cancer (mCSPC), refers to prostate cancer that still responds to ADT.[5] Patients with mCSPC tend to have a poor prognosis, with a median OS of less than five years, underscoring the need for new treatment options.[6,7,8]

ERLEADA IMPORTANT SAFETY INFORMATION[2]

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 Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

Learn more at www.janssen.com. Follow us at www.twitter.com/JanssenGlobal. Janssen Research & Development, LLC and Janssen Biotech, Inc. are members 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 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 30, 2018, 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. None of 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] 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. Accessed April 2019.

[2] ERLEADA® Prescribing Information, February 2018.

[3] 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.

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

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

[6] American Cancer Society. Survival rates for prostate cancer. https://www.cancer.org/cancer/prostate-cancer/detection-diagnosis-staging/survival-rates.html. Accessed April 2019.

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

[8] Crawford ED, Higano CS, Shore ND, et al. : Treating patients with metastatic castration resistant prostate cancer: A comprehensive review of available therapies. *J Urol* 194:1537-1547, 2015.