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Health-Related Quality of Life Maintained with Addition of ERLEADA® to Androgen Deprivation Therapy for Patients with Non-Metastatic Castration-Resistant Prostate Cancer

Patient-reported outcomes data from the SPARTAN study published in The Lancet Oncology showed no additional treatment-related burden as it relates to quality of life

HORSHAM, PA, September 11, 2018 - The Janssen Pharmaceutical Companies of Johnson & Johnson today announced the publication of new patient-reported outcomes (PRO) data demonstrating that adding ERLEADA® (apalutamide) to androgen-deprivation therapy (ADT) in patients with non-metastatic castration-resistant prostate cancer (nmCRPC) who were at high-risk for development of metastases did not have a significant impact on individuals' overall health-related quality of life (HRQoL). These data from the pivotal SPARTAN study, in which ERLEADA significantly prolonged median metastasis-free survival (MFS), while preserving HRQoL, and delaying the decrease in HRQoL associated with symptomatic progression, were published today in *The Lancet Oncology*.[1]

"Prostate cancer treatment can often result in unwelcomed side effects that can impact or disrupt patients' everyday lives," said Fred Saad, M.D., FRCS, Professor and Chairman of Urology, University of Montreal Hospital Center, and SPARTAN investigator and author of the study. "As clinicians, we want to monitor and measure the impact of new treatments to see if there is an effect on patients' overall health and well-being. The fact that a treatment such as apalutamide can be added to current standard of care, prolonging metastasis-free

survival without significantly impacting HRQoL, is a significant advance for patients with nmCRPC and for clinicians who treat them."

In February 2018, ERLEADA received U.S. Food and Drug Administration approval for the treatment of patients with nmCRPC, making it the first androgen receptor inhibitor approved for patients with this disease state in the U.S. The SPARTAN study was a Phase 3, randomized, double-blind, placebo-controlled multicenter study conducted in 1,207 patients with nmCRPC and a prostate-specific antigen (PSA) doubling time ≤10 months during continuous ADT.[1] Patients were randomized 2:1 to receive ERLEADA in combination with ADT or placebo in combination with ADT.[1] All patients received a concomitant gonadotropin-releasing hormone (GnRH) agonist or had a bilateral orchiectomy. The primary endpoint of this study was MFS.[1]

The Lancet Oncology publication includes prospective data from the treatment phase and the post-progression follow-up phase for the PRO exploratory endpoints as measured by the Functional Assessment of Cancer Therapy–Prostate (FACT-P) and the EuroQol five-dimension, three-level (EQ-5D-3L) questionnaires.[1] The FACT-P PRO questionnaire assessed prostate cancer symptoms, pain-related symptoms and overall HRQoL.[1] The EQ-5D-3L questionnaire evaluated mobility, self-care, usual activities, pain, discomfort, anxiety or depression and health-state.[1]

"Men with non-metastatic castration-resistant prostate cancer are at significant risk for developing metastases and dying from the disease. To date, this patient population has been understudied, and data on health-related quality of life in such men are scarce," said Andree Amelsberg, M.D., Vice President, Oncology Medical Affairs, at Janssen Scientific Affairs, LLC. "Patient-reported outcomes data are gaining importance as healthcare systems place greater emphasis on patient experience with treatment. Amongst men in this patient population, maintaining quality of life is an important endpoint. In this exploratory analysis of the SPARTAN results, we are pleased to see that patients reported they did not experience notable disruptive changes after ERLEADA was added to their standard of care."

About the SPARTAN Study

SPARTAN (NCT01946204) was a Phase 3, randomized, double-blind, placebo-controlled, multicenter study, that evaluated ERLEADA in combination with ADT in men with nmCRPC with a rapidly rising PSA (PSADT≤10 months).[2] The SPARTAN study enrolled 1,207 patients

who were randomized 2:1 to receive either ERLEADA orally at a dose of 240 mg once daily in combination with ADT (n=806) or placebo once daily in combination with ADT (n=401). Study results were announced earlier this year at the 2018 American Society of Clinical Oncology Genitourinary Annual Meeting Cancers Symposium (ASCO GU), and published simultaneously in *The New England Journal of Medicine*.

Warnings and Precautions include seizure, falls and fractures.[2] In the SPARTAN study, the most common adverse reactions (≥10%) were fatigue, hypertension, rash, diarrhea, nausea, weight decreased, arthralgia, fall, hot flush, decreased appetite, fracture and peripheral edema.[2]

About Non-Metastatic Castration-Resistant Prostate Cancer

Non-metastatic castration-resistant prostate cancer (nmCRPC) 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 ADT and serum testosterone level below 50 ng/dL.[4,5] Ninety percent of patients with nmCRPC will eventually develop bone metastases, which can lead to pain, fractures and spinal cord compression.[6] The relative five-year survival rate for patients diagnosed at a distant stage prostate cancer is 30 percent.[7] It is critical to delay the onset of metastasis in patients with nmCRPC.

About ERLEADA®

ERLEADA (apalutamide) is an androgen receptor (AR) inhibitor indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer.[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 (especially for those with a PSA doubling time ≤10 months)*.[8] Additionally, the AUA Guidelines for Castration-Resistant Prostate Cancer (CRPC) were recently updated to include apalutamide (ERLEADA) with continued androgen deprivation as a treatment option for 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)**.[9]

Category 1: Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer V.2.2018. © 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.*

INDICATION

ERLEADA® (apalutamide) is an androgen receptor inhibitor indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer.

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 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 and Janssen Scientific Affairs, LLC are part 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 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, 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] Saad, F, et al. Effect of apalutamide on health-related quality of life in patients with non-metastatic castration-resistant prostate cancer: an analysis of the SPARTAN randomised, placebo-controlled phase 3 trial http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(18)30456-X/fulltext. Accessed September 2018.

[2] ERLEADA Prescribing Information, February 2018.

[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. Accessed September 2018.

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[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 September 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 September 2018.

[8] National Comprehensive Cancer Network. NCCN Clinical Guidelines in Oncology: Prostate Cancer.https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed September 2018.

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