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ERLEADA® (apalutamide) Oral Presentations Demonstrate Importance of Prostate Specific Antigen (PSA) as Key Efficacy Indicator and Show Strong Patient Adherence Rates

Post-hoc analysis shows that ERLEADA® provides rapid, deep and durable PSA declines in advanced prostate cancer, with depth and speed of response correlating to improved overall survival

Real-world data demonstrate that, across racial groups, patients prescribed ERLEADA® for non-metastatic castration-resistant prostate cancer stay on therapy

September 11, 2021 (RARITAN, N.J.) – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced new data demonstrating robust prostate-specific antigen (PSA) response and strong adherence rates in patients with non-metastatic castration-resistant prostate cancer (nmCRPC) treated with ERLEADA® (apalutamide) in the real-world clinical setting. The strong PSA response was also seen in a separate post-hoc analysis that showed a correlation between rapid and deep PSA response and prolonged survival in both metastatic castration-sensitive prostate cancer (mCSPC) and nmCRPC. The post-hoc analysis also supports the use of PSA as a predictive biomarker in the treatment of patients with advanced prostate cancer. These findings were presented during two podium sessions at the virtual American Urological Association Annual Meeting (AUA 2021), September 10-13.

The post-hoc analysis (Abstract #PD34-11) of the Phase 3 TITAN and SPARTAN studies examined PSA kinetics in 2,259 patients with either mCSPC (TITAN) or nmCRPC (SPARTAN). Results showed that patients with advanced prostate cancer, whether mCSPC or nmCRPC, treated with ERLEADA® plus androgen deprivation therapy (ADT) had rapid, deep and durable PSA declines as early as three months and continuing beyond a year after initiating ERLEADA® therapy.[1] In mCSPC (TITAN), the percentage of patients with a PSA decline of ≥50 percent or ≥90 percent or with an undetectable PSA (<0.2ng/mL) was approximately three times higher for patients treated with ERLEADA® plus ADT, compared to patients treated with ADT alone.[1] In nmCRPC (SPARTAN), no PSA decline was observed in patients treated with ADT alone, as may be expected, but the addition of ERLEADA® showed robust PSA decline, including undetectable levels in a significant proportion of patients, similar to TITAN.[1]

In both studies, those patients who achieved a deeper PSA decline (defined as ≥90 percent from baseline and/or a PSA nadir of ≤0.2 ng/mL) also showed a rapid PSA decline (<3 months across both studies); a faster and deeper PSA decline was correlated with longer overall survival.[1] Further, median time to deep PSA decline appeared to be more rapid for ERLEADA® plus ADT (1.9 months for TITAN, 2.8 months for SPARTAN) than has been previously reported for other therapies.[2]

"The sooner that urologists and oncologists have an indicator that a patient is benefitting from a therapy, the better able they are to provide the best care," said Tracy McGowan, M.D., Therapeutic Head, Prostate Cancer, U.S. Medical Affairs, Janssen Biotech, Inc. "As reported in this post-hoc analysis, PSA is an important early predictive indicator in patients with either mCSPC or nmCRPC, and depth and speed of PSA decline were significantly improved with apalutamide treatment."

In a separate presentation (Abstract #PD05-08), a U.S. real-world study of 193 patients with nmCRPC treated with ERLEADA® plus ADT for an average of approximately one year found that the majority of patients demonstrated high treatment adherence, with >90 percent of patients adhering to therapy in both Black and non-Black subgroups (90.1 percent and 94.5 percent, respectively).[3]

Moreover, the majority (83.5 percent) of the overall population – regardless of race – achieved a 50 percent reduction in PSA (PSA50 response) in the first six months and 86

percent reduction at 12 months after initiating ERLEADA®.[3] These results were consistent with PSA responses reported from the Phase 3 results of the SPARTAN trial, which showed that 90 percent of patients achieved ≥50 percent reduction in PSA by three months, and maintained that response 12 months after initiating ERLEADA.[4]

"Outside of a clinical trial setting, healthcare professionals are focused on ensuring a therapy can benefit patients treated in the real world. To have both high adherence rates and robust PSA reductions is very encouraging," said Benjamin Lowentritt, M.D., Director Prostate Cancer Care Program, Chesapeake Urology, and Immediate Past President, AUA, Mid-Atlantic Region and lead study investigator.* "These findings support the use of apalutamide in delaying disease progression and metastasis in patients with nmCRPC across various demographics."

To date, published results on ERLEADA® include data from more than 2,000 patients across three Phase 3 clinical studies. ERLEADA® has shown a statistically significant improvement in overall survival with a consistent safety profile, while maintaining health-related quality of life in both approved indications of mCSPC and nmCRPC.[4] ERLEADA® is currently approved in more than 74 countries.

About ERLEADA®

ERLEADA® is an androgen receptor inhibitor indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer (nmCRPC) and for the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC).[4] ERLEADA® received U.S. Food and Drug Administration (FDA) approval for nmCRPC on February 14, 2018 and was approved for mCSPC on September 17, 2019.[4] To date, more than 40,000 patients worldwide have been treated with ERLEADA®. ERLEADA® is taken orally, once daily, with or without food.[4] The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer include apalutamide (ERLEADA®) with continued androgen deprivation therapy**† as a Category 1 Preferred treatment option for patients with non-metastatic (M0) castration-resistant prostate cancer and a PSADT ≤10 months.[5] The NCCN Clinical Practice Guidelines® also include apalutamide (ERLEADA®) with androgen deprivation**† as a Category 1 Preferred treatment option for patients with metastatic (M1) castration-naive prostate cancer.‡[5] The American Urological Association (AUA) Guidelines for Castration-Resistant Prostate Cancer (CRPC) recommend clinicians offer apalutamide (ERLEADA®) with continued androgen deprivation therapy (ADT) as one of the treatment options for patients

with nmCRPC at high risk for developing metastatic disease (Standard; Evidence Level Grade A)***.[6] ERLEADA® is being further studied in two ongoing Phase 3 clinical trials.

For more information about ERLEADA®, visit www.ERLEADA.com.

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***Orchiectomy, LHRH agonist, or LHRH antagonist*

†Use of an LHRH agonist plus a first-generation antiandrogen is an option for patients receiving ADT alone, but is not an option for patients receiving apalutamide.

‡The term "castration-naive" is used to define patients who are not on ADT at the time of progression. The NCCN Prostate Cancer Panel uses the term "castration-naive" even when patients have had neoadjuvant, concurrent, or adjuvant ADT as part of radiation therapy provided they have recovered testicular function.

****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[4]
WARNINGS AND PRECAUTIONS

Cerebrovascular and Ischemic Cardiovascular Events — In a randomized study (SPARTAN) of patients with nmCRPC, ischemic cardiovascular events occurred in 4% of patients treated with ERLEADA® and 3% of patients treated with placebo. In a randomized study (TITAN) in patients with mCSPC, ischemic cardiovascular events occurred in 4% of patients treated with ERLEADA® and 2% of patients treated with placebo. Across the SPARTAN and TITAN studies, 5 patients (0.5%) treated with ERLEADA® and 2 patients (0.2%) treated with placebo died from an ischemic cardiovascular event. Patients with history of unstable angina, myocardial infarction, congestive heart failure, stroke, or transient ischemic attack

within 6 months of randomization were excluded from the SPARTAN and TITAN studies.

In the SPARTAN study, cerebrovascular events occurred in 4.7% of patients treated with ERLEADA® and 0.8% of patients treated with placebo. In the TITAN study, cerebrovascular events occurred in 1.9% of patients treated with ERLEADA® and 2.1% of patients treated with placebo. Across the SPARTAN and TITAN studies, 3 patients (0.2%) treated with ERLEADA®, and 2 patients (0.2%) treated with placebo died from a cerebrovascular event.

Cerebrovascular and ischemic cardiovascular events, including events leading to death, occurred in patients receiving ERLEADA®. Monitor for signs and symptoms of ischemic heart disease and cerebrovascular disorders. Optimize management of cardiovascular risk factors, such as hypertension, diabetes, or dyslipidemia. Consider discontinuation of ERLEADA® for Grade 3 and 4 events.

Fractures — In a randomized study (SPARTAN) of patients with nmCRPC, fractures occurred in 12% of patients treated with ERLEADA® and in 7% of patients treated with placebo. In a randomized study (TITAN) of patients with mCSPC, fractures occurred in 9% of patients treated with ERLEADA® and in 6% of patients treated with placebo. Evaluate patients for fracture risk. Monitor and manage patients at risk for fractures according to established treatment guidelines and consider use of bone-targeted agents.

Falls — In a randomized study (SPARTAN), falls occurred in 16% of patients treated with ERLEADA® compared with 9% of patients treated with placebo. Falls were not associated with loss of consciousness or seizure. Falls occurred in patients receiving ERLEADA® with increased frequency in the elderly. Evaluate patients for fall risk.

Seizure — In 2 randomized studies (SPARTAN and TITAN), 5 patients (0.4%) treated with ERLEADA® and 1 patient treated with placebo (0.1%) 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.

Embryo-Fetal Toxicity — The safety and efficacy of ERLEADA® have not been established in females. Based on its mechanism of action, ERLEADA® can cause fetal harm and loss of

pregnancy when administered to a pregnant female. Advise males with female partners of reproductive potential to use effective contraception during treatment and for 3 months after the last dose of ERLEADA® *[see Use in Specific Populations (8.1, 8.3)]*.

ADVERSE REACTIONS

Adverse Reactions — The most common adverse reactions (≥10%) that occurred more frequently in the ERLEADA®-treated patients (≥ 2% over placebo) from the randomized placebo-controlled clinical trials (TITAN and SPARTAN) were fatigue, arthralgia, rash, decreased appetite, fall, weight decreased, hypertension, hot flush, diarrhea and fracture.

Laboratory Abnormalities — All Grades (Grade 3-4)

- Hematology — In the TITAN study: white blood cell decreased ERLEADA® 27% (0.4%), placebo 19% (0.6%). In the SPARTAN study: 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 — In the TITAN study: hypertriglyceridemia ERLEADA® 17% (3%), placebo 12% (2%). In the SPARTAN study: 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 — In 2 randomized studies, rash was most commonly described as macular or maculopapular. Adverse reactions of rash were 26% with ERLEADA® vs 8% with placebo. Grade 3 rashes (defined as covering >30% body surface area [BSA]) were reported with ERLEADA® treatment (6%) vs placebo (0.5%).

The onset of rash occurred at a median of 83 days. Rash resolved in 78% of patients within a median of 78 days from onset of rash. Rash was commonly managed with oral antihistamines, topical corticosteroids, and 19% of patients received systemic corticosteroids. Dose reduction or dose interruption occurred in 14% and 28% of patients, respectively. Of the patients who had dose interruption, 59% experienced recurrence of rash upon reintroduction of ERLEADA®.

Hypothyroidism — In 2 randomized studies (SPARTAN and TITAN), 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 at the first scheduled assessment. 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

CYP3A4, CYP2C9, CYP2C19, and UGT Substrates — 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 @JanssenUS and @JanssenGlobal. Janssen Research & Development, LLC and Janssen Biotech, Inc. are part the Janssen Pharmaceutical Companies of Johnson & Johnson.

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*Dr. Lowentritt has served as a consultant to Janssen; he has not been paid for any media work.

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, Janssen Biotech, Inc., or 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 3, 2021, 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] Chi et al. Prostate-Specific Antigen Kinetics in Patients With Advanced Prostate Cancer Treated With Apalutamide: Results From the TITAN and SPARTAN Studies. AUA 2021.
[2] Shore et al. Impact of Baseline Disease Volume And Prior Docetaxel Therapy on Prostate-Specific Antigen-Related Outcomes in Patients With Metastatic Hormone-Sensitive Prostate Cancer Treated With Enzalutamide Plus Androgen Deprivation Therapy. *Journal of Urology*. 2020. 403 (4S): e249-e250.
[3] Lowentritt et al. Real-World Effectiveness and Treatment Adherence of Apalutamide in Non-Metastatic Castration-Resistant Prostate Cancer Patients. AUA 2021.
[4] ERLEADA® U.S. Prescribing Information, July 2021.
[5] NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer V.3.2020. National Comprehensive Cancer Network, Inc. 2020. All rights reserved. Accessed August 2021.
[6] American Urological Association. Castration-Resistant Prostate Cancer Guidelines. http://www.auanet.org/guidelines/castration-resistant-prostate-cancer-(2013-amended-2018). Accessed August 2021.