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Striving to Deliver Better Outcomes: Janssen to Showcase Commitment to Advancing Science for Genitourinary Cancers at AUA 2021

Compelled to advance innovation for patients and the urology community, oral presentations highlight real-world effectiveness of and patient adherence to ERLEADA® (apalutamide), plus PSA response from Phase 3 TITAN and SPARTAN studies in patients with advanced prostate cancer

August 31, 2021 (RARITAN, N.J.) – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today multiple company-sponsored presentations in prostate and bladder cancers will be highlighted at the virtual 2021 American Urological Association Annual Meeting (AUA 2021), September 10-13.

"Janssen maintains a strong commitment to advancing innovation and new therapeutic options for patients with genitourinary malignancies. As the treatment of genitourinary cancers becomes more complex, we continue to work with urologists and their teams to improve outcomes for patients across the continuum of disease," said Craig Tendler, M.D., Vice President, Late Development and Global Medical Affairs, Janssen Research & Development, LLC. "We look forward to sharing the latest results from across our pipeline and portfolio at the upcoming AUA meeting and remain focused on accelerating science that unlocks new opportunities along the care pathway, from diagnosis to treatment of advanced disease."

Janssen will share four data presentations highlighting clinical advances for two therapies from our solid tumor portfolio.

ERLEADA® studies to be presented at AUA include:

- **Real-World Effectiveness and Treatment Adherence in Non-Metastatic Castration-Resistant Prostate Cancer (nmCRPC) Patients (oral presentation)**: Real-world evidence from 63 urology practices across the U.S. detailing prostate-specific antigen (PSA) outcomes and treatment adherence among patients with nmCRPC treated with ERLEADA®, with stratification by race (Abstract #PD05-08)
- **Prostate-Specific Antigen Kinetics in Patients from TITAN and SPARTAN (oral presentation)**: Post-hoc analysis of PSA kinetics in 1,331 patients treated with ERLEADA® from both the TITAN and SPARTAN trials (Abstract #PD34-11)
- **Sites and Burden of Metastases and Long-Term Outcomes in TITAN Patients (moderated poster session)**: Assessment of relationships between the number and location of metastases and oncological outcomes in 1,052 patients with metastatic castration-sensitive prostate cancer (mCSPC) enrolled in the TITAN trial (Abstract #MP24-08)

Additionally, Janssen will present an update on the Phase 3 SunRISe-2 trial evaluating an investigational intravesical drug delivery system, TAR-200, in combination with the programmed cell death receptor-1 (PD-1) inhibitor cetrelimab in muscle-invasive urothelial carcinoma (Abstract # MP13-17).[1]

"As part of our commitment to help patients live longer and better lives, Janssen looks forward to expanding the focus from our legacy in prostate cancer to include other genitourinary cancers," said Serge Messerlian, President, Oncology, Janssen Biotech, Inc. "We're collaborating with diverse urology stakeholders to understand and meet the challenges along the path to better care, leveraging clinical and operational excellence to strengthen our allyship with the entire urology community."

Further details about these data and the ways Janssen is working to shape the future of urologic care will be made available throughout AUA 2021 via the Janssen AUA Virtual Newsroom.

Abstracts to be presented at the meeting include:

Abstract No.	Title	Date/Time
ERLEADA® (apalutamide)		
	Podium Presentations	
Abstract # PD05-08	Real-World Effectiveness and Treatment Adherence of Apalutamide in Non-Metastatic Castration-Resistant Prostate Cancer Patients	Friday, September 10 8:10 AM – 8:20 AM PST
Abstract # PD34-11	Prostate-Specific Antigen Kinetics in Patients with Advanced Prostate Cancer Treated with Apalutamide: Results from the TITAN and SPARTAN Studies	Saturday, September 11 5:10 PM – 5:20 PM PST
	Moderated Poster	
Abstract # MP24-08	Relationships of Sites and Burden of Metastases with Long-Term Outcomes and Molecular Subtypes in TITAN	Saturday, September 11 8:45 AM – 10:00 AM PST
TAR-200		
	Poster Presentation	
Abstract # MP13-17	SunRISe-2: A Phase 3, Multicenter, Randomized Study Evaluating the Efficacy of TAR-200 in Combination with Cetrelimab Versus Concurrent Chemoradiotherapy in Participants with Muscle-Invasive Urothelial Carcinoma of the Bladder	Friday, September 10 2:45 PM – 4:00 PM PST

About ERLEADA®

ERLEADA® (apalutamide) 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).[2] ERLEADA® received U.S. FDA approval for nmCRPC in February 2018, and was approved for mCSPC in September 2019.[2] To date, more than 40,000 patients worldwide have been treated with ERLEADA®.

For more information, visit www.ERLEADA.com.

About TAR-200

TAR-200 is an investigational drug delivery system, enabling controlled release of gemcitabine into the bladder, increasing dwell time and local drug exposure. The safety and

efficacy of TAR-200 is being evaluated in Phase 3 studies in patients with muscle-invasive bladder cancer (MIBC).

About Cetrelimab

Cetrelimab is an investigational programmed cell death receptor-1 (PD-1) monoclonal antibody being studied to treat MIBC, prostate cancer and multiple myeloma as a combination treatment.

ERLEADA® IMPORTANT SAFETY INFORMATION[2]

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 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), TAR-200 and cetrelimab. 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] Williams et al. SunRISe-2: A Phase 3, Multicenter, Randomized Study Evaluating the Efficacy of TAR-200 in Combination With Cetrelimab Versus Concurrent Chemoradiotherapy in Participants With Muscle-Invasive Urothelial Carcinoma of the Bladder. AUA 2021.
[2] ERLEADA® U.S. Prescribing Information, July 2020.