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Media contact:
Oncology Media Relations
Oncology_media_relations@its.jnj.com

Investor contact:
Lauren Johnson
investor-relations@its.jnj.com

U.S. medical inquiries:
+1 800 526-7736

For Immediate Release

Real-world head-to-head analysis shows 51% reduction in risk of death for patients with metastatic castration-sensitive prostate cancer treated with ERLEADA® (apalutamide) versus darolutamide without docetaxel through 24 months

First ever head-to-head analysis compares overall survival outcomes of ERLEADA® versus darolutamide

Retrospective study reinforces real-world efficacy of ERLEADA® for patients with mCSPC

HORSHAM, PA, February 2, 2026 – Johnson & Johnson today announced new real world head-to-head evidence demonstrating that patients with metastatic castration-sensitive prostate cancer (mCSPC) initiating ERLEADA® without docetaxel experienced a statistically significant 51 percent reduction in the risk of death compared to those who initiated on darolutamide without docetaxel through 24-months of follow-up (hazard ratio [HR] 0.49; 95% confidence interval [CI], 0.30–0.83; *P*=0.007). These findings reflecting patients treated in routine clinical practice were presented at the 36th Annual International Prostate Cancer Update on February 2, where it was selected as a top abstract (Abstract #6).

Designed to meet rigorous FDA guidance and robust methodological framework on real-world evidence, this study included a pre-specified protocol, pre-specified primary endpoint of overall survival (OS), power calculation, and propensity score matching through inverse probability of treatment weighting (IPTW).[1,2,3] Together, these methodological safeguards deliver robust, reproducible insights that inform real-world treatment decisions. The retrospective study identified mCSPC patients who initiated ERLEADA® or darolutamide without docetaxel between August 2022 and June 2025. There were 1,460 ERLEADA® patients and 287 darolutamide initiators who met study criteria.

“These real-world data show the survival benefit of apalutamide versus darolutamide in patients with mCSPC without the concurrent use of docetaxel. The results are consistent with other datasets showing similar overall survival benefit versus other commonly used agents,” said Mehmet Bilen, M.D. Director, Genitourinary Medical Oncology Program, Winship Cancer Institute of Emory University.* “This real-world analysis utilized large contemporary datasets using rigorous methodology to support clinical decision-making in the absence of prospective head-to-head studies that are likely impractical to conduct.”

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As reported previously, ERLEADA® plus androgen deprivation therapy (ADT) treatment shows rapid and deep prostate-specific antigen (PSA) decline that was associated with prolonged OS.[4,5] These real-world OS data build upon findings from the Phase 3 multinational, double-blinded, placebo-controlled TITAN trial, which evaluated mCSPC patients (n=1052) randomized (1:1) receiving either ERLEADA® 240 mg once daily (n=525) or placebo once daily (n=527).[4]

“Real-world comparisons can provide critical information to support patient care when conducted in a rigorous and methodologically sound manner,” said Mahadi Baig, M.D., M.H.C.M., Vice President, U.S. Medical Affairs, Johnson & Johnson Innovative Medicine. “We have now seen in repeated real-world examinations the overall survival benefit of apalutamide versus other agents and this head-to-head analysis supports apalutamide being a key standard of care treatment for patients with mCSPC.”

TITAN demonstrated a statistically significant OS benefit for mCSPC patients treated with ERLEADA® plus ADT compared to ADT alone at the primary analysis after a median 22.7 months of follow-up (HR 0.67; 95% CI, 0.51-0.89; *P*=0.005) and at the final analysis after a median 44 months of follow-up (HR 0.65; 95% CI, 0.53-0.79; *P*<0.0001).[4,5] The proportion of patients alive at 24 months (92.1 percent) observed in the ERLEADA® cohort in this real-world analysis is generally consistent with that reported in TITAN (82.4 percent). All patients in the TITAN trial received a concomitant gonadotropin-releasing hormone agonist (GnRH) analog or had a prior bilateral orchiectomy. The dual primary endpoints were OS and radiographic progression-free survival (rPFS).

About the Study

These real-world findings adhere to the rigorous standards set by the U.S. FDA, including providing comparative effectiveness evidence from large, contemporary U.S. datasets used in routine clinical practice, peer-reviewed methods, and strict study monitoring. Complementing randomized controlled trials, real-world evidence can help inform clinical decisions, including comparative data into treatments, by collecting a plethora of data from a diverse range of patients in the real-world setting.

In this real-world analysis, both ERLEADA® and darolutamide were administered without docetaxel. Study investigators applied propensity score matching (PSM) to match the apalutamide and darolutamide groups through adjusting for baseline differences in measured patient characteristics. PSM is employed in observational studies to support fair comparison of outcomes.

Some limitations of this study include potential miscoding or missing information in the data sources; however, the data sources used in this study were deemed fit for purpose to identify the patient population correctly and to assess survival. IPTW, a propensity score matching statistical method, was employed to balance baseline characteristics between treatment groups, removing bias from measured confounders and replicating the conditions of a randomized clinical trial.

About Prostate Cancer

Approximately 330,000 people are diagnosed with prostate cancer each year in the U.S.[6] Up to 40 percent of patients will be classified as high-risk.[7] Despite advancements in treatment, disease recurrence remains substantial; up to 50 percent of patients within ten years of surgery experience recurrence and carry a significant risk of disease progression and death.[7] It’s estimated that more than 36,000 men will succumb to prostate cancer in 2026, which reinforces the importance of choosing the best possible therapy early for patients with advanced prostate cancer.[6]

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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). ERLEADA® received U.S. Food and Administration (FDA) approval for nmCRPC in February 2018 and received U.S. FDA approval for mCSPC in September 2019. ERLEADA® is the first and only next-generation androgen receptor inhibitor offering a once-daily, single-tablet treatment option for patients. To date, more than 325,000 patients worldwide have been treated with ERLEADA®. Additional studies are ongoing in the evaluation of ERLEADA® for the treatment of localized high-risk or locally advanced prostate cancer including, the Phase 3 ATLAS (NCT02531516) and PROTEUS (NCT03767244) studies.

For more information, visit www.ERLEADA.com.

ERLEADA® IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Cerebrovascular and Ischemic Cardiovascular Events — In a randomized study (SPARTAN) of patients with nmCRPC, ischemic cardiovascular events occurred in 3.7% of patients treated with ERLEADA® and 2% of patients treated with placebo. In a randomized study (TITAN) in patients with mCSPC, ischemic cardiovascular events occurred in 4.4% of patients treated with ERLEADA® and 1.5% of patients treated with placebo. Across the SPARTAN and TITAN studies, 4 patients (0.3%) 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 2.5% of patients treated with ERLEADA® and 1% 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 two 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.

Severe Cutaneous Adverse Reactions — Fatal and life-threatening cases of severe cutaneous adverse reactions (SCARs), including Stevens-Johnson syndrome/toxic epidermal necrolysis (SJS/TEN), and drug reaction with eosinophilia and systemic symptoms (DRESS) occurred in patients receiving ERLEADA®.

Monitor patients for the development of SCARs. Advise patients of the signs and symptoms of SCARs (e.g., a prodrome of fever, flu-like symptoms, mucosal lesions, progressive skin rash, or lymphadenopathy). If a SCAR is suspected, interrupt ERLEADA® until the etiology of the reaction has been determined. Consultation with a dermatologist is recommended. If a SCAR is confirmed, or for other Grade 4 skin reactions, permanently discontinue ERLEADA® *[see Dosage and Administration (2.2)].*

Interstitial Lung Disease (ILD)/Pneumonitis — Fatal and life-threatening interstitial lung disease (ILD) or pneumonitis can occur in patients treated with ERLEADA®.

Post-marketing cases of ILD/pneumonitis, including fatal cases, occurred in patients treated with ERLEADA®. Across clinical trials (TITAN and SPARTAN, n=1327), 0.8% of patients treated with ERLEADA® experienced ILD/pneumonitis, including 0.2% who experienced Grade 3 events *[see Adverse Reactions (6.1, 6.2)].*

Monitor patients for new or worsening symptoms indicative of ILD/pneumonitis (e.g., dyspnea, cough, fever). Immediately withhold ERLEADA® if ILD/pneumonitis is suspected. Permanently discontinue ERLEADA® in patients with severe ILD/pneumonitis or if no other potential causes of ILD/pneumonitis are identified *[see Dosage and Administration (2.2)]*.

Embryo-Fetal Toxicity — The safety and efficacy of ERLEADA® have not been established in females. Based on findings from animals and 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

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% (1.8%), placebo 21% (1.6%)

- **Chemistry** — In the TITAN study: hypertriglyceridemia ERLEADA® 17% (2.5%), placebo 12% (2.3%). In the SPARTAN study: hypercholesterolemia ERLEADA® 76% (0.1%), placebo 46% (0%); hyperglycemia ERLEADA® 70% (2%), placebo 59% (1.0%); hypertriglyceridemia ERLEADA® 67% (1.6%), placebo 49% (0.8%); hyperkalemia ERLEADA® 32% (1.9%), placebo 22% (0.5%)

Rash — In 2 randomized studies (SPARTAN and TITAN), 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 1.5% 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 Johnson & Johnson

At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow, and profoundly impact health for humanity. Learn more at https://www.jnj.com/ or at www.innovativemedicine.jnj.com. Janssen Research & Development, LLC and Janssen Biotech, Inc. are Johnson & Johnson companies.

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 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, 2023, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other 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. Johnson & Johnson does not undertake to update any forward-looking statement as a result of new information or future events or developments.

** Dr. Bilen has provided consulting, advisory, and speaking services to Johnson & Johnson; he has not been paid for any media work.*

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