News Release

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Janssen Data at ASCO GU Demonstrate Longstanding Leadership in Prostate Cancer and Commitment to Advancing Potential New Therapeutic Options for Genitourinary Cancers

Initial results from Phase 3 MAGNITUDE study of niraparib in combination with abiraterone acetate plus prednisone as a first-line therapy in patients with metastatic castration-resistant prostate cancer featured as an oral presentation

New data for ERLEADA® (apalutamide) build on more than a decade of experience in prostate cancer; updated clinical trial information for novel drug delivery system TAR-200 plus cetrelimab in early-stage bladder cancer to be presented

Raritan, NJ, Feb. 1, 2022 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that 17 presentations will be featured at the 2022 American Society of Clinical Oncology Genitourinary (ASCO GU) Cancers Symposium, taking place in San Francisco and virtually from February 17-19. Building on its long-term leadership in prostate cancer, Janssen is committed to advancing innovative treatments and transforming patient experiences, while focusing on research that may drive better outcomes for people across the genitourinary cancer spectrum. Data to be presented include Phase 3 results for the selective poly-ADP ribose polymerase (PARP) inhibitor niraparib in combination with abiraterone acetate plus prednisone in prostate cancer, and updated clinical trial information

on the Phase 2b study of TAR-200, a novel drug delivery system, in combination with cetrelimab in early-stage bladder cancer. Janssen will also present new analyses for the androgen receptor inhibitor ERLEADA® (apalutamide).

"This year's ASCO GU annual meeting commemorates nearly a decade of Janssen generating outcomes demonstrating the utility of ERLEADA as a transformational therapy in advanced prostate cancer," said Luca Dezzani, M.D., U.S. Vice President, Medical Affairs, Solid Tumor, Janssen Scientific Affairs, LLC. "We continue to deepen our understanding of how our medicines are being used in real-world settings, as we strive to optimize treatment and care delivery to help patients achieve the best possible outcomes."

"Despite the advancements Janssen has made in delivering innovative medicines for the treatment of genitourinary cancers, we recognize the continued unmet needs that persist for patients and physicians," said Kiran Patel M.D., Vice President, Clinical Development, Solid Tumors, Janssen Research & Development, LLC. "At this year's ASCO GU meeting, we look forward to presenting new data from our portfolio and pipeline, highlighting our commitment to improving patient outcomes, the benefits of our approved treatments and the possibilities for new potential therapeutic options."

Further details about these data and the science Janssen is advancing will be made available throughout ASCO GU via the Janssen Oncology Virtual Newsroom. Key highlights include:

Niraparib late-breaking data:

- First results from the Phase 3 MAGNITUDE study of niraparib in combination with abiraterone acetate plus prednisone as a first-line therapy in patients with metastatic castration-resistant prostate cancer (mCRPC) with and without homologous recombination repair (HRR) gene alterations (Abstract #12)

ERLEADA® data:

- Association between patient-reported outcomes and changes in prostate-specific antigen (PSA) in patients with advanced prostate cancer treated with ERLEADA® in the SPARTAN and TITAN studies
- Real-world Comparative Evidence: Attainment of early, deep PSA response in metastatic castration-sensitive prostate cancer (mCSPC): A comparison of patients initiated on ERLEADA® and enzalutamide

TAR-200 and cetrelimab update:

- Clinical Trial in Progress: SunRISe-1: Phase 2b study of TAR-200 plus cetrelimab, TAR-200 alone, or cetrelimab alone in participants with high-risk non-muscle-invasive bladder cancer unresponsive to Bacillus Calmette-Guerin who are ineligible for or elected not to undergo radical cystectomy

About Niraparib

Niraparib is an orally administered, poly-ADP ribose polymerase (PARP) inhibitor that is currently being studied by Janssen for the treatment of patients with prostate cancer. Ongoing studies include the Phase 3 AMPLITUDE study evaluating niraparib in combination with abiraterone acetate plus prednisone in a biomarker-selected patient population with mCSPC; the Phase 3 MAGNITUDE study evaluating niraparib in combination with abiraterone acetate plus prednisone as a first-line treatment option compared to abiraterone acetate and prednisone plus placebo in adults with mCRPC; and QUEST, a Phase 1b/2 study of niraparib combination therapies for the treatment of mCRPC.

In April 2016, Janssen Biotech, Inc. entered a worldwide (except Japan) collaboration and license agreement with TESARO, Inc. (acquired by GSK in 2018), for exclusive rights to niraparib in prostate cancer. In the U.S., niraparib is indicated for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy; for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy; for the treatment of adult patients with advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with three or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either: a deleterious or suspected deleterious BRCA mutation, or genomic instability and who have progressed more than six months after response to the last platinum-based chemotherapy. Niraparib is currently marketed by GSK as ZEJULA®.[1]

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 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 50,000 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 2 and Phase 3 studies in patients with muscle-invasive bladder cancer (MIBC) and non-muscle invasive bladder cancer (NMIBC).

About Cetrelimab

Cetrelimab is an investigational programmed cell death receptor-1 (PD-1) monoclonal antibody being studied to treat bladder cancer, prostate cancer and multiple myeloma as a combination treatment. Cetrelimab is also being evaluated in multiple combination regimens across the Janssen oncology portfolio.

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.

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 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 niraparib, 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] ZEJULA® U.S. Prescribing Information, May 2020.
[2] ERLEADA® U.S. Prescribing Information, November 2021.