News Release

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Janssen Data at ASCO GU Support Ambition to Transform Treatment of Prostate and Bladder Cancer Through Precision Medicine and Early Intervention

Updated data from the Phase 3 MAGNITUDE study of niraparib in combination with abiraterone acetate plus prednisone in patients with metastatic castration-resistant prostate cancer will be featured

RARITAN, N.J., February 13, 2023 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced plans to present more than 20 abstracts featuring seven oncology therapies from its robust portfolio and pipeline at the annual American Society of Clinical Oncology (ASCO) Genitourinary (GU) Cancers Symposium, taking place in San Francisco on February 16-18. Building on more than a decade of leadership in the development of medicines for people diagnosed with GU cancers, Janssen will present data demonstrating its ambition to advance patient-centered treatment through precision medicine, real-world evidence and innovative development approaches across all stages of prostate and bladder cancer.

"At Janssen, we are focused on early intervention in prostate and bladder cancer and optimizing outcomes through treatment approaches based on the genetic profiles of tumors," said Kiran Patel, M.D., Vice President, Clinical Development, Solid Tumors, Janssen Research

& Development, LLC. "Data featured at this year's ASCO GU reflect the cutting-edge therapies in our portfolio and pipeline and illustrate how Janssen's science is advancing our vision to eliminate cancer."

"Despite advances in treatment over the past decade, we continue to see unmet needs across genitourinary cancers, especially for tumors with certain genetic mutations," said Luca Dezzani, M.D., U.S. Vice President, Medical Affairs, Solid Tumor, Janssen Scientific Affairs, LLC. "Presentations at this year's ASCO GU underscore our continuing commitment to addressing the needs of patients living with prostate and bladder cancer at all stages of their disease."

Further information about these data and efforts across Janssen to advance the science of prostate and bladder cancer will be made available throughout ASCO GU via the Janssen Oncology Virtual Newsroom.

Key highlights from Janssen-sponsored studies to be presented at ASCO GU include:

Updated Data from the Phase 3 MAGNITUDE Study of Niraparib in Combination with Abiraterone Acetate Plus Prednisone (AAP) for the Treatment of Patients with BRCA-Positive Metastatic Castration-Resistant Prostate Cancer (mCRPC)

- **Rapid Oral Presentation**: A presentation will highlight data from the second interim analysis of the Phase 3 MAGNITUDE study evaluating niraparib in combination with AAP for the treatment of patients with mCRPC with specific homologous recombination repair (HRR) gene alterations, in particular BRCA mutations (Abstract #170).[1]
- **Poster Presentation**: An additional analysis from MAGNITUDE will review the impact of run-in treatment with AAP on the safety and efficacy of niraparib in combination with AAP to determine if the combination improved outcomes in patients with HRR genetic alterations, in particular BRCA mutations (Abstract #172).[2]

Latest ERLEADA® (apalutamide) Data Includes Results from the Phase 3 PRESTO Study in High-Risk Biochemically Relapsed Prostate Cancer, a Post-Hoc Analysis from the Phase 3 SPARTAN Study Evaluating Treatment Sequencing in People with Advanced Disease and Multiple Real-World Evidence Presentations

- **Poster Presentation:** New data from the collaborative Phase 3 PRESTO study will evaluate baseline factors associated with improved prostate-specific antigen (PSA)

progression-free survival (PFS) when intensifying treatment beyond androgen deprivation therapy (ADT) with the addition of ERLEADA®, with or without AAP in patients with high-risk biochemically relapsed prostate cancer (Abstract #208).[3]

- **Poster Presentation:** A post-hoc analysis from the Phase 3 SPARTAN study will report the efficacy of subsequent therapies for mCRPC in patients with non-metastatic castration-resistant prostate cancer (nmCRPC) treated with ERLEADA® (Abstract #157).[4]
- **Poster Presentations:** Multiple real-world evidence data studies will evaluate the benefit of ERLEADA® in patients across the prostate cancer spectrum including:
    - Real-world evidence data in patients with nmCRPC treated with ERLEADA® assessed for PSA response and metastasis-free survival (MFS) (Abstract #69).[5]
    - A study describing time-to-castration resistance based on real-world evidence data for patients with metastatic castration-sensitive prostate cancer (mCSPC) who were treated with ERLEADA®, abiraterone acetate or enzalutamide (Abstract #65).[6]
    - A retrospective study will examine real-world evidence data in patients with high-risk localized or locally advanced prostate cancer treated with external beam radiation therapy (Abstract # 330).[7]

Data from the Phase 1 TAR-200-102 Study Evaluating Safety and Efficacy of TAR-200, Real-World Evidence Data Evaluating Treatment Patterns and Adherence to Standard of Care in Patients with Non-Muscle Invasive Bladder Cancer (NMIBC), and a Trial-In-Progress Update from SunRISe-4 in Some Patients with Muscle-Invasive Bladder Cancer (MIBC)

- **Poster Presentation:** New findings from the Phase 1 TAR-200-102 study will assess the safety and tolerability of TAR-200, a novel intravesical drug delivery system designed to provide a continuous, slow release of gemcitabine within the bladder, in patients with intermediate-risk NMIBC (Abstract #505).[8]
- **Poster Presentation:** Real-world treatment patterns and adherence to Bacillus Calmette-Guerin (BCG) in the context of guideline recommendations for patients with NMIBC will help to emphasize the need for additional available treatment options that are safe, effective and tolerable (Abstract #470).[9]
- **Poster Presentation**: Researchers will share a trial-in-progress update from the SunRISe-4 study of TAR-200 in combination with cetrelimab, an investigational programmed cell death receptor-1 (PD-1) monoclonal antibody, or cetrelimab alone in

patients with MIBC who are ineligible or refuse neoadjuvant platinum-based chemotherapy (Abstract #TPS584).[10]

Data from the Phase 2 THOR-2 Study Evaluating the Safety and Efficacy of BALVERSA® (erdafitinib) in High-Risk NMIBC and Intermediate-Risk NMIBC; TAR-210 Trial-in-Progress Update

- **Poster Presentation:** Cohort 2 will assess patients with BCG-unresponsive high-risk NMIBC carcinoma in situ (CIS) with fibroblast growth factor receptor (FGFR) 3/2 genetic alterations. (Abstract #503).[11]
- **Poster Presentation:** Cohort 3 will assess patients with intermediate-risk NMIBC and residual marker lesions with FGFR 3/2 genetic alterations. (Abstract #504).[12]
- **Poster Presentation:** A trial-in-progress update from the open-label, multicenter Phase 1 TAR-210 study (Erdafitinib Intravesical Delivery System) will evaluate the safety and efficacy of TAR-210 in patients with NMIBC and MIBC harboring select FGFR genetic alterations (Abstract #TPS583).[13]

About Niraparib

Niraparib is an orally administered, highly selective poly (ADP-ribose) polymerase (PARP) inhibitor that is currently being studied by Janssen for the treatment of patients with prostate cancer.

Additional ongoing studies include the Phase 3 AMPLITUDE study evaluating the combination of niraparib and AAP in a biomarker-selected patient population with metastatic castration-sensitive prostate cancer (mCSPC).[14]

In April 2016, Janssen Biotech, Inc. entered a worldwide (except Japan) collaboration and license agreement with TESARO, Inc. (acquired by GlaxoSmithKline [GSK] in 2019) for exclusive rights to niraparib in prostate cancer. Niraparib is currently marketed by GSK as ZEJULA®.[15]

About Abiraterone Acetate

Abiraterone acetate is an orally administered androgen biosynthesis inhibitor. In the United States, abiraterone acetate is indicated with prednisone for the treatment of mCRPC and high-risk mCSPC.[16]

About ERLEADA®

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

for the treatment of patients with mCSPC.[17] 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.[17] To date, more than 100,000 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 are 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, melanoma and multiple myeloma as part of a combination treatment. Cetrelimab is also being evaluated in multiple other combination regimens across the Janssen Oncology portfolio.

About BALVERSA®

BALVERSA® (erdafitinib) is a once-daily, oral FGFR kinase inhibitor for the treatment of adults with locally advanced or metastatic urothelial carcinoma (mUC) that has susceptible FGFR3 or FGFR2 genetic alterations and has progressed during or following at least one line of platinum-containing chemotherapy, including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy and received U.S. FDA approval in April 2019.[18] Patients are selected for therapy based on an FDA-approved companion diagnostic for BALVERSA®. This indication is approved under accelerated approval based on tumor response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.[18,19] BALVERSA® is the only approved treatment option for patients with FGFR-mutated mUC.

In 2008, Janssen Pharmaceutica NV entered into an exclusive worldwide license and collaboration agreement with Astex Pharmaceuticals to develop and commercialize BALVERSA®.

For more information, visit www.BALVERSA.com.

About TAR-210

TAR-210 is an intravesical drug delivery system designed to provide local, continuous release of erdafitinib within the bladder. The safety and efficacy of TAR-210 is being evaluated in a Phase 1 study in patients with muscle-invasive bladder cancer (MIBC) and non-muscle invasive bladder cancer (NMIBC).

ERLEADA® IMPORTANT Safety Information[17]
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)].

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®.

BALVERSA® IMPORTANT SAFETY INFORMATION[18]

WARNINGS AND PRECAUTIONS

Ocular Disorders – BALVERSA® can cause ocular disorders, including central serous retinopathy/retinal pigment epithelial detachment (CSR/RPED) resulting in visual field defect.

CSR/RPED was reported in 25% of patients treated with BALVERSA®, with a median time to first onset of 50 days. Grade 3 CSR/RPED, involving central field of vision, was reported in 3% of patients. CSR/RPED resolved in 13% of patients and was ongoing in 13% of patients at the study cutoff. CSR/RPED led to dose interruptions and reductions in 9% and 14% of patients, respectively, and 3% of patients discontinued BALVERSA®. Dry eye symptoms occurred in 28% of patients during treatment with BALVERSA® and were Grade 3 in 6% of patients. All patients should receive dry eye prophylaxis with ocular demulcents as needed.

Perform monthly ophthalmological examinations during the first 4 months of treatment and every 3 months afterwards, and urgently at any time for visual symptoms. Ophthalmological examination should include assessment of visual acuity, slit lamp examination, fundoscopy, and optical coherence tomography. Withhold BALVERSA® when CSR occurs and permanently

discontinue if it does not resolve within 4 weeks or if Grade 4 in severity. For ocular adverse reactions, follow the dose modification guidelines *[see Dosage and Administration (2.3)]*.

Hyperphosphatemia and Soft Tissue Mineralization – BALVERSA® can cause hyperphosphatemia leading to soft tissue mineralization, cutaneous calcinosis, non-uremic calciphylaxis and vascular calcification. Increases in phosphate levels are a pharmacodynamic effect of BALVERSA® *[see Pharmacodynamics (12.2)].* Hyperphosphatemia was reported as adverse reaction in 76% of patients treated with BALVERSA®. The median onset time for any grade event of hyperphosphatemia was 20 days (range: 8–116) after initiating BALVERSA®. Thirty-two percent of patients received phosphate binders during treatment with BALVERSA®. Cutaneous calcinosis, non-uremic calciphylaxis and vascular calcification have been observed in 0.3% of patients treated with BALVERSA®.

Monitor for hyperphosphatemia throughout treatment. In all patients, restrict phosphate intake to 600-800 mg daily. If serum phosphate is above 7.0 mg/dL, consider adding an oral phosphate binder until serum phosphate level returns to <5.5 mg/dL. Withhold, dose reduce, or permanently discontinue BALVERSA® based on duration and severity of hyperphosphatemia *[see Dosage and Administration (2.3), Table 2: Dose Modifications for Adverse Reactions].*

Embryo-fetal Toxicity –Based on the mechanism of action and findings in animal reproduction studies, BALVERSA® can cause fetal harm when administered to a pregnant woman. In a rat embryo-fetal toxicity study, erdafitinib was embryotoxic and teratogenic at exposures less than the human exposures at all doses studied. Advise pregnant women of the potential risk to the fetus. Advise female patients of reproductive potential to use effective contraception during treatment with BALVERSA® and for one month after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with BALVERSA® and for one month after the last dose [see Use in Specific Populations (8.1, 8.3) and Clinical Pharmacology (12.1)].

Most common adverse reactions including laboratory abnormalities ≥20%:
Phosphate increased (76%), stomatitis (56%), fatigue (54%), creatinine increased (52%), diarrhea (47%), dry mouth (45%), nail disorder (45%), alanine aminotransferase increased (41%), alkaline phosphatase increased (41%), sodium decreased (40%), decreased appetite (38%), albumin decreased (37%), dysgeusia (37%), hemoglobin decreased (35%), dry skin (34%), aspartate aminotransferase increased (30%), magnesium decreased (30%), dry eye

(28%), alopecia (26%), palmar-plantar erythrodysesthesia syndrome (26%), constipation (28%), phosphate decreased (24%), abdominal pain (23%), calcium increased (22%), nausea (21%), and musculoskeletal pain (20%). The most common Grade 3 or greater adverse reactions (>1%) were stomatitis (9%), nail dystrophy*, palmar-plantar erythrodysesthesia syndrome (6%), paronychia (3%), nail disorder (10%), keratitis†, and hyperphosphatemia (1%).

*Included within onycholysis. †Included within dry eye.

- An adverse reaction with a fatal outcome in 1% of patients was acute myocardial infarction.
- Serious adverse reactions occurred in 41% of patients, including eye disorders (10%).
- Permanent discontinuation due to an adverse reaction occurred in 13% of patients. The most frequent reasons for permanent discontinuation included eye disorders (6%).
- Dosage interruptions occurred in 68% of patients. The most frequent adverse reactions requiring dosage interruption included hyperphosphatemia (24%), stomatitis (17%), eye disorders (17%), and palmar-plantar erythrodysesthesia syndrome (8%).
- Dose reductions occurred in 53% of patients. The most frequent adverse reactions for dose reductions included eye disorders (23%), stomatitis (15%), hyperphosphatemia (7%), palmar-plantar erythrodysesthesia syndrome (7%), paronychia (7%), and nail dystrophy (6%).

Drug Interactions

- Moderate CYP2C9 or strong CYP3A4 Inhibitors: Consider alternative agents or monitor closely for adverse reactions. (7.1)
- Strong CYP2C9 or CYP3A4 inducers: Avoid concomitant use with BALVERSA®. (7.1)
- Moderate CYP2C9 or CYP3A4 inducers: Increase BALVERSA® dose up to 9 mg. (7.1)
- Serum phosphate level-altering agents: Avoid concomitant use with agents that can alter serum phosphate levels before the initial dose modification period. (2.3, 7.1)
- CYP3A4 substrates: Avoid concomitant use with sensitive CYP3A4 substrates with narrow therapeutic indices. (7.2)
- OCT2 substrates: Consider alternative agents or consider reducing the dose of OCT2 substrates based on tolerability. (7.2)
- P-gp substrates: Separate BALVERSA® administration by at least 6 hours before or after administration of P-gp substrates with narrow therapeutic indices. (7.2)

Use in Specific Populations

Lactation – Because of the potential for serious adverse reactions from erdafitinib in a breastfed child, advise lactating women not to breastfeed during treatment with BALVERSA® and for one month following the last dose.

Please see the full Prescribing Information for BALVERSA®.

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 & Retina; 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.

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 niraparib, abiraterone acetate + prednisone, ERLEADA® (apalutamide), TAR-200, cetrelimab, BALVERSA® (erdafitinib) and TAR-210. 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, 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 2, 2022, 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. 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] Efstathiou, E e at. Niraparib (NIRA) with abiraterone acetate and prednisone (AAP) in patients (pts) with metastatic castration-resistant prostate cancer (mCRPC) and homologous recombination repair (HRR) gene alterations: second interim analysis (IA2) of MAGNITUDE. ASCO GU 2023.
[2] Castro, E et al. Impact of run-in treatment with abiraterone acetate and prednisone (AAP) in the MAGNITUDE study of niraparib (NIRA) and AAP in patients (pts) with metastatic castration-resistant prostate cancer (mCRPC) and homologous recombination repair (HRR) gene alterations. ASCO GU 2023.
[3] Aggarwal, R et al. Baseline Characteristic Associated with PSA Progression-Free Survival in Patients (pts) with High-Risk Biochemically Relapsed Prostate Cancer: Results from the Phase 3 PRESTO study (AFT-19). ASCO 2023.
[4] Oudard, S et al. Efficacy of subsequent treatments in patients who progressed to mCRPC following treatment with apalutamide for nonmetastatic castration-resistant prostate cancer (nmCRPC): a post hoc analysis of the SPARTAN phase III trial. ASCO GU 2023.
[5] Lowentritt, B et al. Real-world prostate-specific antigen (PSA) response and disease progression among patients with non-metastatic castration-resistant prostate cancer (nmCRPC) initiated on apalutamide (APA). ASCO GU 2023.
[6] Lowentritt, B et al. Real-world time-to-castration resistance (CR) among patients (pts) with metastatic castration-sensitive prostate cancer (mCSPC) initiating apalutamide (APA), enzalutamide (ENZ), or abiraterone acetate (ABI) from an oncology database. ASCO GU 2023.
[7] Karsh, L et al. Real-World Clinical Outcomes of Patients with Localized Prostate Cancer (LPC) Treated with External Beam Radiation Therapy (EBRT). ASCO GU 2023.
[8] Hans van Valenberg, T et al. Safety, tolerability, and preliminary efficacy of TAR-200 in intermediate risk non-muscle invasive bladder cancer patients: a phase 1 study. ASCO GU 2023.
[9] Gaylis, F et al. Study of real-world treatment patterns and adherence to Bacillus Calmette-Guerin (BCG) in the context of guideline recommendations for patients with high-risk non-muscle invasive bladder cancer (NMIBC). ASCO GU 2023.
[10] Psutka, S et al. SunRISe-4: Tar-200 plus cetrelimab or cetrelimab alone as neoadjuvant therapy in patients with muscle-invasive bladder cancer (MIBC) who are ineligible for or refuse neoadjuvant platinum-based chemotherapy. ASCO GU 2023.
[11] Catto, J et al. Phase 2 study of the efficacy and safety of erdafitinib in patients (pts) with Bacilius Calmette-Guerin (BCG)-unresponsive, high-risk non-muscle invasive bladder cancer (HR-NMIBC) with *FGFR3/2* alterations (alt) in THOR-2: cohort 2 interim analysis results. ASCO GU 2023.
[12] Daneshmand, S et al. Phase 2 study of the efficacy and safety of erdafitinib in patients with intermediate-risk non-muscle invasive bladder cancer (IR-NMIBC) with *FGFR3/2* alterations (alt) in THOR-2: cohort 3 interim analysis results. ASCO GU 2023.
[13] Vilaseca, A et al. Safety and efficacy of the erdafitinib (erda) intravesical delivery system, TAR-210, in patients (pts) with non-muscle invasive bladder cancer (NMBIC) or muscle-invasive bladder cancer (MIBC) harboring select *FGFR* mutations or fusions: phase 1 first-in-human study. ASCO GU 2023.
[14] Clinical Trials.Gov. A Study of Niraparib in Combination With Abiraterone Acetate and Prednisone Versus Abiraterone Acetate and Prednisone for the Treatment of Participants With Deleterious Germline or Somatic Homologous Recombination Repair (HRR) Gene-Mutated Metastatic Castration Sensitive Prostate Cancer

(mCSPC) (AMPLITUDE). Available at: https://clinicaltrials.gov/ct2/show/NCT04497844. Last accessed February 2023.
[15] ZEJULA® U.S. Prescribing Information, September 2022.
[16] ZYTIGA® U.S. Prescribing Information, August 2021.
[17] ERLEADA® U.S. Prescribing Information, November 2021.
[18] BALVERSA® U.S. Prescribing Information, April 2019.
[19] U.S. Food & Drug Administration. FDA grants accelerated approval to erdafitinib for metastatic urothelial carcinoma. Available at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-erdafitinib-metastatic-urothelial-carcinoma. Accessed February 2023.