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Janssen to Highlight Robust Solid Tumor Portfolio and Pipeline at 2021 ASCO GU

Multiple data presentations to show long-term benefit and consistency of ERLEADA® (apalutamide) in advanced prostate cancer; oral presentations to highlight Phase 3 ACIS, TITAN and SPARTAN study results

February 2, 2021 (RARITAN, N.J.) – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today it will highlight the depth of its solid tumor portfolio at the American Society of Clinical Oncology Genitourinary (ASCO GU) Cancers Symposium with 12 data presentations, including three company-sponsored oral presentations from the ERLEADA® (apalutamide) clinical development program. The virtual meeting will take place February 11-13, 2021.

"We are committed to the development of innovative therapies for patients with genitourinary cancers for whom there remains a high unmet need," said Craig Tendler, M.D., Vice President, Clinical Development and Global Medical Affairs, Janssen Research & Development, LLC. "This year, we look forward to presenting data from our robust prostate cancer development program, including analyses of the Phase 3 ACIS and TITAN studies, which underscore the clinical value of our portfolio for patients today and set the stage for the next generation of therapies in our pipeline."

New Analyses for ERLEADA® Highlight Breadth of Ongoing Clinical Development Program

Data from three Phase 3 registrational clinical trials will be featured in oral presentations:

- **ACIS**: Analysis evaluating ERLEADA® (apalutamide) in combination with ZYTIGA® (abiraterone acetate) plus prednisone versus abiraterone acetate plus prednisone in patients with chemo-naïve metastatic castration-resistant prostate cancer (Abstract #9)
- **TITAN**: Final analysis with close to four years of follow-up data evaluating ERLEADA® versus placebo on overall survival (OS) and other endpoints in patients with metastatic castration-sensitive prostate cancer (mCSPC) receiving hormone therapy (Abstract #11)
- **SPARTAN**: Post-hoc analysis data from a biomarker cohort study identifying the molecular signatures associated with long-term response to ERLEADA® (Abstract #8)

Combined, the ERLEADA® presentations include data from more than 2,000 patients across multiple studies. ERLEADA® has shown a statistically significant improvement in OS in its approved indications of metastatic castration-sensitive prostate cancer (TITAN) and non-metastatic castration-resistant prostate cancer (SPARTAN).[1] Both TITAN and SPARTAN trials confirm the safety profile of ERLEADA®, with over four years of patient follow-up demonstrating exposure-adjusted rates of Grade 3 and 4 adverse events for ERLEADA® that are comparable to androgen deprivation therapy alone.

Further details about these data and the science that Janssen is advancing for patients with genitourinary cancers will be made available throughout ASCO GU via the Janssen Oncology Virtual Newsroom.

Abstracts to be presented at the meeting include:

Abstract No.	**Title**	**Date/Time**
ERLEADA® (apalutamide)		
Oral Presentations		
Abstract #8	Molecular Determinants Associated with Long-Term Response to Apalutamide in Non-Metastatic Castration-Resistant Prostate Cancer	Thursday, February 11 12:45 PM – 2:00 PM EST
Abstract #9	Results from ACIS, a Randomized, Placebo-Controlled Double-Blind Phase 3 Study of Apalutamide and Abiraterone Acetate Plus	Thursday, February 11

	Prednisone Versus Abiraterone in Patients with Chemo-Naive Castration-Resistant Prostate Cancer	12:45 PM – 2:00 PM EST
Abstract #11	Final Analysis Results From TITAN: A Phase 3 Study of Apalutamide vs Placebo in Patients with Metastatic Castration-Sensitive Prostate Cancer Receiving Androgen Deprivation Therapy	Thursday, February 11 3:30 PM – 4:15 PM EST
Poster Presentations		
Abstract #44	Medication Adherence Among Prostate Cancer Patients Using Advanced Oral Therapies	Poster Session: Prostate Cancer – Advanced Disease, available on-demand throughout the meeting
Abstract #64	Health-Related Quality of Life Analysis from a Randomized Phase 2 Trial of Androgen Signaling Inhibitors with or without Androgen Deprivation Therapy for Castration-Sensitive Prostate Cancer: LACOG0415	Poster Session: Prostate Cancer – Advanced Disease, available on-demand throughout the meeting
Abstract #83	Outcomes in Men with Metastatic Castrate-Resistant Prostate Cancer Treated with Early Platinum-Based Chemotherapy Following an Unsatisfactory Response to Androgen Receptor Inhibition as Part of the Phase 2 Dynamic Allocation Modular Sequential (DynAMo) Trial	Poster Session: Prostate Cancer – Advanced Disease, available on-demand throughout the meeting
Abstract #90	Interim Analysis of STARTAR: A Phase 2 Salvage Trial of Androgen Receptor Inhibition with Androgen Deprivation Therapy and Apalutamide with Radiation Therapy Followed by Docetaxel in Men with PSA Recurrent Prostate Cancer After Radical Prostatectomy	Poster Session: Prostate Cancer – Advanced Disease, available on-demand throughout the meeting
BALVERSA® (erdafitinib)		
Poster Presentation		
Abstract #426	Management of Fibroblast Growth Factor Receptor Inhibitor Treatment-Emergent Adverse Events of Interest in Patients with Locally Advanced or Metastatic Urothelial Carcinoma	Poster Session: Urothelial Carcinoma, available on-demand throughout the meeting
Niraparib		
Poster Presentation		
Abstract #TPS176	AMPLITUDE: A Study of Niraparib in Combination with Abiraterone Acetate Plus Prednisone (AAP) Versus AAP for the Treatment of Patients with Deleterious Germline or Somatic Homologous Recombination Repair Gene-Altered Metastatic Castration-Sensitive Prostate Cancer	Trials in Progress Poster Session: Advanced Prostate Cancer, available on-demand throughout the meeting

Other

Poster Presentations		
Abstract #47	Real-World Utilization of Docetaxel Among Men with De Novo Metastatic Castration-Sensitive Prostate Cancer: A Population-Based Study in Men Aged 66 or Older	Poster Session: Prostate Cancer – Advanced Disease, available on-demand throughout the meeting
Abstract #50	Geographic Variation in Systemic Therapy in Men Age 66 Years and Older With De Novo Metastatic Castration Sensitive Prostate Cancer: A Population-Based Study in a Single Payer Health-System	Poster Session: Prostate Cancer – Advanced Disease, available on-demand throughout the meeting
Abstract #149	Prognostic Association Between Common Laboratory Tests and Overall Survival in Men with De Novo Metastatic Castration-Sensitive Prostate Cancer: A Population-Based Study	Poster Session: Prostate Cancer – Advanced Disease, available on-demand throughout the meeting

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).[1] ERLEADA® received U.S. FDA approval for nmCRPC in February 2018, and was approved for mCSPC in September 2019.[3] To date, more than 25,000 patients worldwide have been treated with ERLEADA®.

For more information, visit www.ERLEADA.com.

About ZYTIGA®

ZYTIGA® (abiraterone acetate) in combination with prednisone is indicated for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC), first approved by the U.S. FDA on April 28, 2011.[2] Additionally, ZYTIGA® was approved for the treatment of high-risk metastatic castration-sensitive prostate cancer (mCSPC) by the U.S. FDA on February 8, 2018. Since its first approval in the U.S. in 2011, ZYTIGA® has been approved in combination with prednisone or prednisolone, in more than 100 countries. More than 700,000 patients worldwide have been prescribed ZYTIGA®.

About BALVERSA®

BALVERSA® (erdafitinib) is a kinase inhibitor indicated for the treatment of adults with locally advanced or metastatic urothelial carcinoma (UC) that has susceptible fibroblast growth factor receptor (FGFR)3 or FGFR2 genetic alterations and progressed during or following at least one line of prior platinum-containing chemotherapy, including within 12

months of neoadjuvant or adjuvant platinum-containing chemotherapy. Patients are selected for therapy based on a FDA-approved companion diagnostic for BALVERSA®.[3] In 2008, Janssen 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 Niraparib

Niraparib is an orally administered, selective 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 in adults with mCRPC; and QUEST, a Phase 1b/2 study of niraparib combination therapies for the treatment of mCRPC.

In April 2016, Janssen 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®.[4]

ERLEADA® IMPORTANT SAFETY INFORMATION[1]

WARNINGS AND PRECAUTIONS

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, 6 patients (0.5%) treated with ERLEADA® and 2 patients (0.2%) treated with placebo died from an ischemic cardiovascular event. Patients with current evidence of unstable angina, myocardial infarction, or congestive heart failure within 6 months of randomization were excluded from the SPARTAN and TITAN studies.

Ischemic cardiovascular events, including events leading to death, occurred in patients receiving ERLEADA®. Monitor for signs and symptoms of ischemic heart disease. 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, 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 — 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®.

ZYTIGA® IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS

Hypokalemia, Fluid Retention, and Cardiovascular Adverse Reactions due to Mineralocorticoid Excess - ZYTIGA® may cause hypertension, hypokalemia, and fluid retention as a consequence of increased mineralocorticoid levels resulting from CYP17 inhibition *[see Clinical Pharmacology (12.1)]*. Monitor patients for hypertension, hypokalemia, and fluid retention at least once a month. Control hypertension and correct hypokalemia before and during treatment.

Closely monitor patients whose underlying medical conditions might be compromised by increases in blood pressure, hypokalemia, or fluid retention, such as those with heart failure, recent myocardial infarction, cardiovascular disease, or ventricular arrhythmia. In

postmarketing experience, QT prolongation, and torsades de pointes have been observed in patients who develop hypokalemia while taking ZYTIGA®. The safety of ZYTIGA® in patients with left ventricular ejection fraction <50% or New York Heart Association (NYHA) Class III or IV heart failure (in COU-AA-301) or NYHA Class II to IV heart failure (in COU-AA-302 and LATITUDE) has not been established because these patients were excluded from these randomized clinical trials *[see Clinical Studies (14)]*.

Adrenocortical Insufficiency - Adrenocortical insufficiency was reported in patients receiving ZYTIGA® in combination with prednisone, after an interruption of daily steroids and/or with concurrent infection or stress. Monitor patients for symptoms and signs of adrenocortical insufficiency if prednisone is stopped or withdrawn, if the prednisone dose is reduced, or if the patient experiences unusual stress. Symptoms and signs of adrenocortical insufficiency may be masked by adverse reactions associated with mineralocorticoid excess seen in patients treated with ZYTIGA®. Perform appropriate tests, if clinically indicated, to confirm adrenocortical insufficiency. Increased dosages of corticosteroids may be used before, during, and after stressful situations *[see Warnings and Precautions (5.1)].*

Hepatotoxicity - In postmarketing experience, there have been ZYTIGA®-associated severe hepatic toxicities, including fulminant hepatitis, acute liver failure, and deaths. Measure serum transaminases (ALT and AST) and bilirubin levels prior to starting treatment with ZYTIGA®, every two weeks for the first three months of treatment, and monthly thereafter. In patients with baseline moderate hepatic impairment receiving a reduced ZYTIGA® dose of 250 mg, measure ALT, AST, and bilirubin prior to the start of treatment, every week for the first month, every two weeks for the following two months of treatment, and monthly thereafter. Promptly measure serum total bilirubin, AST, and ALT if clinical symptoms or signs suggestive of hepatotoxicity develop. Elevations of AST, ALT, or bilirubin from the patient's baseline should prompt more frequent monitoring. If at any time AST or ALT rise above five times the upper limit of normal (ULN) or the bilirubin rises above three times the ULN, interrupt ZYTIGA® treatment and closely monitor liver function. Re-treatment with ZYTIGA® at a reduced dose level may take place only after return of liver function tests to the patient's baseline or to AST and ALT less than or equal to 2.5X ULN and total bilirubin less than or equal to 1.5X ULN *[see Dosage and Administration (2.4)].*

Permanently discontinue ZYTIGA® for patients who develop a concurrent elevation of ALT greater than 3X ULN and total bilirubin greater than 2X ULN in the absence of biliary obstruction or other causes responsible for the concurrent elevation.

The safety of ZYTIGA® re-treatment of patients who develop AST or ALT greater than or equal to 20X ULN and/or bilirubin greater than or equal to 10X ULN is unknown.

Increased Fractures and Mortality in Combination with Radium Ra 223 Dichloride - ZYTIGA® plus prednisone/prednisolone is not recommended for use in combination with radium Ra 223 dichloride outside of clinical trials. Increased incidences of fractures (28.6% vs 11.4%) and deaths (38.5% vs 35.5%) have been observed in patients who received ZYTIGA® plus prednisone/prednisolone in combination with radium Ra 223 dichloride compared to patients who received placebo in combination with ZYTIGA® plus prednisone/prednisolone *[see Warnings and Precautions (5.4)]*.

Embryo-Fetal Toxicity - The safety and efficacy of ZYTIGA® have not been established in females. Based on animal reproductive studies and mechanism of action, ZYTIGA® 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 with ZYTIGA® and for 3 weeks after the last dose of ZYTIGA® *[see Use in Specific Populations (8.1, 8.3)]*. ZYTIGA® should not be handled by females who are or may become pregnant *[see How Supplied/Storage and Handling (16)]*.

ADVERSE REACTIONS

Adverse Reactions - The most common adverse reactions (≥10%) are fatigue, arthralgia, hypertension, nausea, edema, hypokalemia, hot flush, diarrhea, vomiting, upper respiratory tract infection, cough, and headache.

The most common laboratory abnormalities (>20%) are anemia, elevated alkaline phosphatase, hypertriglyceridemia, lymphopenia, hypercholesterolemia, hyperglycemia, and hypokalemia.

Drug Interactions - Based on *in vitro* data, ZYTIGA® is a substrate of CYP3A4. In a drug interaction trial, co-administration of rifampin, a strong CYP3A4 inducer, decreased exposure of abiraterone by 55%. Avoid concomitant strong CYP3A4 inducers during ZYTIGA® treatment. If a strong CYP3A4 inducer must be co-administered, increase the ZYTIGA® dosing frequency only during the co-administration period *[see Dosage and Administration (2.3)].* In a dedicated drug interaction trial, co-administration of ketoconazole, a strong inhibitor of CYP3A4, had no clinically meaningful effect on the pharmacokinetics of abiraterone.

ZYTIGA® is an inhibitor of the hepatic drug-metabolizing enzymes CYP2D6 and CYP2C8. Avoid co-administration with CYP2D6 substrates with a narrow therapeutic index. If alternative treatments cannot be used, consider a dose reduction of the CYP2D6 substrate drug. In a CYP2C8 drug interaction trial in healthy subjects, the AUC of pioglitazone, a CYP2C8 substrate, was increased by 46% when administered with a single dose of ZYTIGA®. Patients should be monitored closely for signs of toxicity related to a CYP2C8 substrate with a narrow therapeutic index if used concomitantly with ZYTIGA®.

Use in Specific Populations -

- Females and Males of Reproductive Potential: Advise males with female partners of reproductive potential to use effective contraception.
- Do not use ZYTIGA® in patients with baseline severe hepatic impairment (Child-Pugh Class C).

Please read the full Prescribing Information and Patient Information for ZYTIGA®.

BALVERSA® IMPORTANT SAFETY INFORMATION

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 – 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®. Monitor for hyperphosphatemia and follow the dose modification guidelines when required *[see Dosage and Administration (2.2, 2.3)]*.

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%), onycholysis (41%), 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*, keratitis†, onycholysis* (10%), and hyperphosphatemia.

*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, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology and Pulmonary Hypertension.

Learn more at www.janssen.com. Follow us at www.twitter.com/JanssenGlobal and www.twitter.com/JanssenUS. 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), ZYTIGA® (abiraterone acetate), BALVERSA® (erdafitinib) and niraparib. 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 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 December 29, 2019, 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] ERLEADA® U.S. Prescribing Information, November 2020.
[2] ZYTIGA® U.S. Prescribing Information, October 2020.
[3] BALVERSA® U.S. Prescribing Information, April 2020.
[4] ZEJULA® U.S. Prescribing Information, April 2020.