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Janssen to Highlight Depth of Prostate Cancer and Solid Tumor Portfolios with Multiple Data Presentations at ESMO 2019

- *Second interim analysis from the Phase 3 SPARTAN study reporting updated overall survival results in patients with non-metastatic castration-resistant prostate cancer treated with ERLEADA® (apalutamide)*
- *Patient-reported outcomes from the Phase 3 TITAN study evaluating ERLEADA® in patients with metastatic castration-sensitive prostate cancer*
- *Interim analysis from the Phase 2 GALAHAD study evaluating niraparib in the treatment of patients with metastatic castration-resistant prostate cancer and biallelic DNA-repair gene defects, featured as late-breaking abstract*

RARITAN, N.J., September 17, 2019 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today multiple data presentations from its prostate cancer and solid tumor portfolios will be featured at the European Society for Medical Oncology (ESMO) Annual Congress 2019, taking place September 27 to October 1 in Barcelona, Spain. Among Janssen's 12 accepted abstracts are an oral presentation reporting updated overall survival results from the ERLEADA® (apalutamide) Phase 3 SPARTAN study in patients with non-metastatic castration-resistant prostate cancer (nmCRPC); patient-reported outcomes from the ERLEADA® Phase 3 TITAN study in patients with metastatic castration-sensitive prostate cancer (mCSPC), demonstrating preservation of overall health-related quality of life; and a late-breaking interim

analysis from the Phase 2 GALAHAD study evaluating niraparib in the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC) and biallelic DNA-repair gene defects (DRD).

"Janssen is focused on addressing areas of unmet need in both prostate cancer and solid tumors, and this year's ESMO Annual Congress provides an opportunity to share these important study results for both approved and investigational therapies," said Mark Wildgust, Ph.D., Vice President, Global Medical Affairs, Oncology, Janssen Research & Development, LLC. "In particular, we look forward to presenting new data for ERLEADA® and niraparib, which reinforce our continued commitment to improve outcomes for patients diagnosed with prostate cancer across the disease spectrum."

Company-sponsored abstracts to be presented at the meeting include:

Abstract No.	**Title**	**Date/Time**
ERLEADA® (apalutamide)		
	Oral Presentation	
Abstract #843O	Apalutamide and Overall Survival in Patients with Nonmetastatic Castration-Resistant Prostate Cancer (nmCRPC): Updated Results from the Phase 3 SPARTAN Study	Friday, September 27 2:39 PM - 2:51 PM CET
	Poster Presentations	
Abstract #851PD	Patient-Reported Outcomes (PROs) From TITAN: A Phase 3, Randomized, Double-Blind Study of Apalutamide Versus Placebo Added to Androgen Deprivation Therapy in Patients with Metastatic Castration-Sensitive Prostate Cancer (mCSPC)	Monday, September 30 12:00 PM CET
Abstract #883P	Androgen Receptor Aberrations in Patients with Metastatic Castration-Sensitive Prostate Cancer (mCSPC) Treated with Apalutamide Plus Androgen Deprivation Therapy in TITAN	Monday, September 30 12:00 PM CET
Abstract #900TiP	A Phase 2 randomized, open-label study comparing salvage radiotherapy in combination with 6 months of androgen-deprivation therapy with LHRH agonist or antagonist versus anti-androgen therapy with apalutamide in patients with biochemical progression after radical prostatectomy	Monday, September 30 12:00 PM CET
Niraparib		
	Poster Presentations	
Abstract #LBA50	Pre-specified interim analysis of GALAHAD: A Phase 2 study of niraparib in patients with metastatic castration-resistant prostate cancer (mCRPC) and biallelic DNA-repair gene defects	Sunday, September 29 8:30 AM CET
Abstract #897TiP	A Phase 3 randomized, placebo-controlled, double-blind study of niraparib plus abiraterone acetate and prednisone versus abiraterone acetate	Monday, September 30 12:00 PM CET

	and prednisone in patients with metastatic prostate cancer (NCT03748641)	
Abstract #1412P	Analytical performance of the Resolution-HRD plasma assay used to identify mCRPC patients with biallelic disruption of DNA repair genes for treatment with niraparib	Monday, September 30 12:00 PM CET
ZYTIGA® (abiraterone acetate)		
Poster Presentation		
Abstract #95P	Evaluation of markers associated with efficacy of abiraterone acetate plus prednisone in patients with castration-sensitive prostate cancer (mCSPC) from the LATITUDE study	Monday, September 30 12:00 PM CET
BALVERSA™ (erdafitinib)		
Poster Presentations		
Abstract #925P	Analysis of response to prior therapies and therapies after treatment with erdafitinib in fibroblast growth factor receptor (FGFR)-positive patients with metastatic urothelial carcinoma	Monday, September 30 12:00 PM CET
Abstract #926P	Erdafitinib versus available therapies in advanced urothelial cancer: A matching adjusted indirect comparison	Monday, September 30 12:00 PM CET
Abstract #932P	Hyperphosphatemia due to Erdafitinib (a Pan-FGFR Inhibitor) and Antitumor Activity Among Patients with Advanced Urothelial Carcinoma	Monday, September 30 12:00 PM CET
Solid Tumor Portfolio		
Poster Presentation		
Abstract #488P	Correlation of Progression Free Survival-2 and Overall Survival in Solid Tumors	Saturday, September 28 2:00 PM CET

About ERLEADA® (apalutamide)

ERLEADA® (apalutamide) is an androgen receptor (AR) inhibitor indicated for the treatment of patients with nmCRPC.[1] It became the first treatment to receive FDA approval for nmCRPC on February 14, 2018.[1] ERLEADA® was also approved for the treatment of nmCRPC by the European Commission on January 12, 2019. ERLEADA® is being studied in five Phase 3 registrational clinical trials. The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer include apalutamide as a treatment option for patients with non-metastatic (M0) CRPC with a category 1 recommendation for those with a PSA doubling time ≤10 months*.[2] Similarly, the American Urological Association (AUA) Guidelines for Castration-Resistant Prostate Cancer (CRPC) recommend clinicians offer apalutamide (ERLEADA®) with continued androgen deprivation therapy (ADT) as one of the treatment options for patients with nmCRPC at high risk for developing metastatic disease. (Standard; Evidence Level Grade A)**.[3] ERLEADA® is taken orally, once daily, with or without food.[1]

**Referenced from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer V.4.2019. © National Comprehensive Cancer Network, Inc. 2019. All rights reserved. Accessed September 5, 2019. To view the most recent and complete version of the*

NCCN Guidelines®, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use, or application, and disclaims any responsibility for their application or use in any way

***Standard: Directive statement that an action should (benefits outweigh risks/burdens) or should not (risks/burdens outweigh benefits) be taken based on Grade A or B evidence.*

***Evidence Level: A designation indicating the certainty of the results as high, moderate, or low (A, B, or C, respectively) based on AUA nomenclature and methodology.*

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. In April 2016, Janssen entered a worldwide (except Japan) collaboration and license agreement with TESARO, Inc., for exclusive rights to niraparib in prostate cancer. In the U.S., niraparib is indicated 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.[4] Niraparib is currently marketed as ZEJULA® by TESARO, an oncology-focused business within GSK, devoted to providing transformative therapies to people facing cancer. Please refer to the full Prescribing Information available at https://www.zejula.com/prescribing-information.

About ZYTIGA® (abiraterone acetate)

ZYTIGA® (abiraterone acetate) in combination with prednisone is indicated for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC), approved by the U.S. FDA on April 28, 2011 and by the European Commission on September 7, 2011. Additionally, ZYTIGA® was approved for the treatment of high-risk metastatic castration-sensitive prostate cancer (mCSPC) by the European Commission on November 20, 2017 and 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 500,000 patients worldwide have been prescribed ZYTIGA®.

About BALVERSA™ (erdafitinib)

BALVERSA™ (erdafitinib) is a once-daily, oral fibroblast growth factor receptor (FGFR) kinase inhibitor indicated for the treatment of adults with locally advanced or metastatic urothelial carcinoma (mUC) that has susceptible FGFR3 or FGFR2 genetic alterations and who have progressed during or following at least one line of prior platinum-containing chemotherapy, including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.[5] In

2008, Janssen entered into an exclusive worldwide license and collaboration agreement with Astex Pharmaceuticals to develop and commercialize BALVERSA™. This indication was approved by the U.S. FDA on April 12, 2019 under an accelerated approval based on tumor response rate. Patients may be suitable for BALVERSA based on an FDA-approved companion diagnostic. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.[5]

For more information about BALVERSA™, visit www.BALVERSA.com.

ERLEADA™ IMPORTANT SAFETY INFORMATION
CONTRAINDICATIONS

Pregnancy — ERLEADA™ (apalutamide) can cause fetal harm and potential loss of pregnancy.

WARNINGS AND PRECAUTIONS

Falls and Fractures — In a randomized study (SPARTAN), falls and fractures occurred in 16% and 12% of patients treated with ERLEADA™ compared to 9% and 7% treated with placebo, respectively. Falls were not associated with loss of consciousness or seizure. Evaluate patients for fracture and fall risk. Monitor and manage patients at risk for fractures according to established treatment guidelines and consider use of bone targeted agents.

Seizure — In a randomized study (SPARTAN), 2 patients (0.2%) treated with ERLEADA™ 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.

ADVERSE REACTIONS

Adverse Reactions — The most common adverse reactions (≥10%) were fatigue, hypertension, rash, diarrhea, nausea, weight decreased, arthralgia, fall, hot flush, decreased appetite, fracture, and peripheral edema.

Laboratory Abnormalities — All Grades (Grade 3-4)

- Hematology — 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 — 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 — Rash was most commonly described as macular or maculo-papular. Adverse reactions were 24% with ERLEADA™ versus 6% with placebo. Grade 3 rashes (defined as covering > 30% body surface area [BSA]) were reported with ERLEADA™ treatment (5%) versus placebo (0.3%).

The onset of rash occurred at a median of 82 days. Rash resolved in 81% of patients within a median of 60 days (range: 2 to 709 days) from onset of rash. Four percent of patients treated with ERLEADA™ received systemic corticosteroids. Rash recurred in approximately half of patients who were re-challenged with ERLEADA™.

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 day 113. 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

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 prior to and during treatment, 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% were: 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

- Strong CYP2C9 or 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 click here for full prescribing information.

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. 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® ZYTIGA®, BALVERSA™ 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, 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 30, 2018, 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.

[1] ERLEADA U.S. Prescribing Information, February 2018.
[2] NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer V.4.2019. © National Comprehensive Cancer Network, Inc. 2019. All rights reserved. Updated August, 2019.
[3] American Urological Association. Castration-Resistant Prostate Cancer Guidelines. http://www.auanet.org/guidelines/castration-resistant-prostate-cancer-(2013-amended-2018). Accessed September 2019.
[4] Niraparib U.S. Prescribing Information, June 2019.
[5] BALVERSA US Prescribing Information, April 2019.