News Release

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Janssen Demonstrates Commitment to Advancing Science and Innovation in the Treatment of Solid Tumors at ESMO Annual Congress

Data for approved and investigational treatments to be presented in bladder cancer, lung cancer and prostate cancer

Investigational RYBREVANT® (amivantamab-vmjw) and lazertinib combination therapy in epidermal growth factor receptor (EGFR)-mutated non-small cell lung cancer (NSCLC) to be featured in oral presentations

September 8, 2021 (RARITAN, N.J.) – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that more than ten data presentations from its lung cancer, bladder cancer and prostate cancer portfolio and pipeline will be featured during the European Society for Medical Oncology (ESMO) Annual Congress 2021 virtual meeting, September 16–21. Further details about these data and the science Janssen is advancing will be made available throughout ESMO via the Janssen Oncology Virtual Newsroom.

"With a diverse oncology portfolio and pipeline spanning bladder cancer, lung cancer and prostate cancer, Janssen is transforming the treatment landscape for patients living with solid tumors," said Kiran Patel, M.D., Vice President, Clinical Development, Solid Tumors, Janssen Research & Development, LLC. "The data to be presented at ESMO represent Janssen's

commitment to push the boundaries of innovation on the path to redefine the treatment landscape for people with cancer."

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

Data Featuring RYBREVANT® as a Monotherapy and in Combination with Lazertinib in EGFR-Mutated NSCLC

- Mini Oral Presentation: Preliminary results from the Phase 1b CHRYSALIS-2 study examines RYBREVANT® and lazertinib in patients with NSCLC and EGFR exon 19 deletion or L858R mutations (Abstract #1193MO)
- Mini Oral Presentation: Phase 1 CHRYSALIS study evaluates RYBREVANT® as a monotherapy and in combination with lazertinib in patients with advanced EGFR-mutated NSCLC, demonstrating the potential benefit of simultaneously targeting the extracellular (outer) and catalytic (internal) domains of EGFR (Abstract #1192MO)

New Study Evaluating a New Drug-Delivery System for Patients with Non-Muscle-Invasive Bladder Cancer (NMIBC)

- E-Poster Presentation: Phase 2b SunRISe-1 study evaluates TAR-200 in combination with cetrelimab, TAR-200 alone, or cetrelimab alone in patients with high-risk non-muscle invasive bladder cancer unresponsive to intravesical bacillus Calmette–Guérin (Abstract # 719TiP)

ERLEADA® (apalutamide) Data Highlighting Survival Benefit, and Rapid and Durable PSA Responses Across a Breadth of Patients with Advanced Prostate Cancer

- E-Poster Presentation: Combined analysis of the Phase 3 TITAN and SPARTAN trials examining ERLEADA® for advanced prostate cancer in older patients (Abstract #618P)
- E-Poster Presentation: Health-related quality of life (HRQoL) analysis from the Phase 3 ACIS trial of ERLEADA® and ZYTIGA® (abiraterone acetate) plus prednisone in metastatic castration-resistant prostate cancer (mCRPC) (Abstract #584P)

Final Analysis of the GALAHAD Study of Niraparib in mCRPC

- E-Poster Presentation: Final analysis of the GALAHAD study of niraparib evaluates HRQoL in patients with mCRPC and DNA repair defects (Abstract #582P)

For a complete list of Janssen-sponsored studies to be presented at ESMO, click here.

About RYBREVANT®

RYBREVANT® (amivantamab-vmjw) received accelerated approval by the U.S. Food and Drug Administration (FDA) for the treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy, in May 2021.[1] Janssen has filed regulatory submissions for RYBREVANT® with health authorities in Europe and other markets. RYBREVANT® is being studied in multiple clinical trials, including a Phase 1/1b study, CHRYSALIS-2 (NCT04077463) to examine RYBREVANT® in combination with lazertinib in patients who have progressed after treatment with osimertinib and chemotherapy; as first-line therapy in untreated advanced EGFR-mutated NSCLC in the Phase 3 MARIPOSA (NCT04487080) study assessing RYBREVANT® in combination with lazertinib**; the planned Phase 3 MARIPOSA-2 (NCT04988295) study assessing the efficacy of lazertinib, RYBREVANT®, carboplatin-pemetrexed vs. with carboplatin-pemetrexed in participants with locally advanced or metastatic EGFR exon 19 deletion or exon 21 L858R substitution NSCLC after osimertinib failure; the Phase 3 PAPILLON (NCT04538664) study assessing RYBREVANT® in combination with carboplatin-pemetrexed for patients with advanced or metastatic EGFR-mutated NSCLC and exon 20 insertion mutations; and the Phase 1 PALOMA (NCT04606381) study assessing the feasibility of subcutaneous (SC) administration of RYBREVANT® based on safety and pharmacokinetics and to determine a dose, dose regimen and formulation for RYBREVANT® SC delivery.[2,3,4,5,6]

About Lazertinib

Lazertinib is an oral, third-generation, brain-penetrant, EGFR tyrosine kinase inhibitor (TKI) that targets both the T790M mutation and activating EGFR mutations while sparing wild type-EGFR.[7] Interim safety and efficacy results from the lazertinib Phase 1-2 study were published in *The Lancet Oncology* in 2019. In 2018, Janssen Biotech, Inc. entered into a license and collaboration agreement with Yuhan Corporation for the development of lazertinib.

About TAR-200

TAR-200 is an investigational drug delivery system, enabling controlled release of gemcitabine into the bladder, increasing dwell time and local drug exposure. The safety and efficacy of TAR-200 is being evaluated in Phase 3 studies in patients with muscle-invasive bladder cancer (MIBC) and non-muscle invasive bladder cancer (NMIBC).

About Cetrelimab

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

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).[8] ERLEADA® received U.S. FDA approval for nmCSPC in February 2018, and was approved for mCSPC in September 2019.[8] To date, more than 40,000 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), 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 mCSPC by the European Commission on November 20, 2017 and by the U.S. FDA on February 8, 2018.[9] 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®.
For more information, visit www.ZYTIGA.com.

About Niraparib

Niraparib is an orally administered, selective poly (adenosine diphosphate -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®.[10]

RYBREVANT® IMPORTANT SAFETY INFORMATION[1]

WARNINGS AND PRECAUTIONS

Infusion Related Reactions[1]

RYBREVANT® can cause infusion related reactions (IRR); signs and symptoms of IRR include dyspnea, flushing, fever, chills, nausea, chest discomfort, hypotension, and vomiting.

Based on the safety population, IRR occurred in 66% of patients treated with RYBREVANT®. Among patients receiving treatment on Week 1 Day 1, 65% experienced an IRR, while the incidence of IRR was 3.4% with the Day 2 infusion, 0.4% with the Week 2 infusion, and cumulatively 1.1% with subsequent infusions. Of the reported IRRs, 97% were Grade 1-2, 2.2% were Grade 3, and 0.4% were Grade 4. The median time to onset was 1 hour (range 0.1 to 18 hours) after start of infusion. The incidence of infusion modifications due to IRR was 62% and 1.3% of patients permanently discontinued RYBREVANT® due to IRR.

Premedicate with antihistamines, antipyretics, and glucocorticoids and infuse RYBREVANT® as recommended. Administer RYBREVANT® via a peripheral line on Week 1 and Week 2. Monitor patients for any signs and symptoms of infusion reactions during RYBREVANT® infusion in a setting where cardiopulmonary resuscitation medication and equipment are available. Interrupt infusion if IRR is suspected. Reduce the infusion rate or permanently discontinue RYBREVANT® based on severity.

Interstitial Lung Disease/Pneumonitis[1]

RYBREVANT® can cause interstitial lung disease (ILD)/pneumonitis. Based on the safety population, ILD/pneumonitis occurred in 3.3% of patients treated with RYBREVANT®, with 0.7% of patients experiencing Grade 3 ILD/pneumonitis. Three patients (1%) discontinued RYBREVANT® due to ILD/pneumonitis.

Monitor patients for new or worsening symptoms indicative of ILD/pneumonitis (e.g., dyspnea, cough, fever). Immediately withhold RYBREVANT® in patients with suspected ILD/pneumonitis and permanently discontinue if ILD/pneumonitis is confirmed.

Dermatologic Adverse Reactions[1]

RYBREVANT® can cause rash (including dermatitis acneiform), pruritus and dry skin. Based on the safety population, rash occurred in 74% of patients treated with RYBREVANT®, including Grade 3 rash in 3.3% of patients. The median time to onset of rash was 14 days (range: 1 to

276 days). Rash leading to dose reduction occurred in 5% of patients, and RYBREVANT® was permanently discontinued due to rash in 0.7% of patients.

Toxic epidermal necrolysis occurred in one patient (0.3%) treated with RYBREVANT®.

Instruct patients to limit sun exposure during and for 2 months after treatment with RYBREVANT®. Advise patients to wear protective clothing and use broad spectrum UVA/UVB sunscreen. Alcohol free emollient cream is recommended for dry skin.

If skin reactions develop, start topical corticosteroids and topical and/or oral antibiotics. For Grade 3 reactions, add oral steroids and consider dermatologic consultation. Promptly refer patients presenting with severe rash, atypical appearance or distribution, or lack of improvement within 2 weeks to a dermatologist. Withhold, dose reduce or permanently discontinue RYBREVANT® based on severity.

Ocular Toxicity[1]

RYBREVANT® can cause ocular toxicity including keratitis, dry eye symptoms, conjunctival redness, blurred vision, visual impairment, ocular itching, and uveitis. Based on the safety population, keratitis occurred in 0.7% and uveitis occurred in 0.3% of patients treated with RYBREVANT®. All events were Grade 1-2. Promptly refer patients presenting with eye symptoms to an ophthalmologist. Withhold, dose reduce or permanently discontinue RYBREVANT® based on severity.

Embryo Fetal Toxicity[1]

Based on its mechanism of action and findings from animal models, RYBREVANT® can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential of the potential risk to the fetus. Advise female patients of reproductive potential to use effective contraception during treatment and for 3 months after the final dose of RYBREVANT®.

Adverse Reactions[1]

The most common adverse reactions (≥20%) were rash, IRR, paronychia, musculoskeletal pain, dyspnea, nausea, fatigue, edema, stomatitis, cough, constipation, and vomiting. The most common Grade 3 or 4 laboratory abnormalities (≥2%) were decreased lymphocytes, decreased albumin, decreased phosphate, decreased potassium, increased alkaline phosphatase, increased glucose, increased gamma-glutamyl transferase, and decreased sodium.

Please see the full Prescribing Information for RYBREVANT®.

ERLEADA® IMPORTANT SAFETY INFORMATION[8]
WARNINGS AND PRECAUTIONS

Cerebrovascular and 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, 5 patients (0.5%) 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 4.7% of patients treated with ERLEADA® and 0.8% 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 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 (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 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

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®.

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 post marketing 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 post marketing 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®.

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology and Pulmonary Hypertension.

Learn more at www.janssen.com. Follow us at @JanssenUS and @JanssenGlobal. Janssen Research & Development, LLC and Janssen Biotech, Inc. are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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 RYBREVANT® (amivantamab-vmjw), lazertinib, TAR-200, cetrelimab, ERLEADA® (apalutamide), ZYTIGA® (abiraterone acetate) 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, Janssen Biotech, Inc. or any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 3, 2021, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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[1] RYBREVANT® Prescribing Information. Horsham, PA: Janssen Biotech, Inc.
[2] ClinicalTrials.gov. A Study of Lazertinib as Monotherapy or in Combination With Amivantamab in Participants With Advanced Non-small Cell Lung Cancer. Available at: https://clinicaltrials.gov/ct2/show/NCT04077463. Accessed September 2021.
[3] ClinicalTrials.gov. A Study of Amivantamab and Lazertinib Combination Therapy Versus Osimertinib in Locally Advanced or Metastatic Non-Small Cell Lung Cancer (MARIPOSA). Available at: https://clinicaltrials.gov/ct2/show/NCT04487080. Accessed September 2021.ClinicalTrials.gov.
[4] ClinicalTrials.gov. A Study of Amivantamab and Lazertinib in Combination With Platinum-Based Chemotherapy Compared With Platinum-Based Chemotherapy in Patients With Epidermal Growth Factor Receptor (EGFR)-Mutated Locally Advanced or Metastatic Non- Small Cell Lung Cancer After Osimertinib Failure (MARIPOSA-2). https://clinicaltrials.gov/ct2/show/NCT04988295. Accessed September 2021.
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