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Abiraterone Acetate Provided Significant Clinical Benefit in Patients with High-Risk Metastatic Hormone-Naïve Prostate Cancer (mHNPC), Improving Overall Survival and Radiographic Progression-Free Survival

CHICAGO and RARITAN, NJ, June 3, 2017 – Janssen Research & Development, LLC today announced data from the pivotal phase 3 LATITUDE clinical trial, which showed ZYTIGA® (abiraterone acetate) plus prednisone, in combination with androgen deprivation therapy (ADT), demonstrated a significant improvement in overall survival (OS) and significantly prolonged radiographic progression-free survival (rPFS) in patients with high-risk metastatic hormone-naïve prostate cancer (mHNPC) compared to placebo plus ADT. This study was selected as one of four for inclusion in the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting Press Program in Chicago, today at 8:00 – 9:00 a.m. CDT. Additionally, the data results will be presented during the "Plenary Session: Including the Science of Oncology Award and Lecture," on Sunday, June 4, at 2:40 – 2:55 p.m. (Abstract LBA3). They have also been selected for Best of ASCO Meetings, which highlight the most cutting-edge science and education from the ASCO Annual Meeting, and reflect the foremost oncology research and strategies that will directly impact patient care.

Study findings indicated abiraterone acetate plus prednisone, in combination with ADT, reduced the risk of death by 38 percent compared to placebo plus ADT (Hazard Ratio [HR]=0.62; 95 percent CI [0.51 to 0.76], P<0.0001). Median OS for the abiraterone acetate plus prednisone in combination with ADT arm was not reached, while the median OS for the placebo plus ADT arm was 34.7

months. Additional study results found abiraterone acetate plus prednisone, in combination with ADT, decreased the risk of progression or death rPFS by 53 percent compared to placebo plus ADT in patients with mHNPC (HR=0.47%, 95% CI [0.39 to 0.55], P <0.0001). Median rPFS was 33.0 months in the abiraterone acetate plus prednisone with ADT group, compared to 14.8 months with placebo plus ADT.

“In the LATITUDE trial, we found that abiraterone acetate plus prednisone, in combination with androgen deprivation therapy, demonstrated statistically significant and clinically meaningful improvements in patients with high-risk metastatic hormone-naïve prostate cancer,” said Dr. Karim Fizazi, Principal Investigator of the trial and Head of the Medical Oncology Department at Institute Gustave Roussy. “This is important new information, as not all patients respond well to the current standard of care. LATITUDE suggests that abiraterone acetate plus prednisone, in combination with androgen deprivation therapy, can offer a new and much-needed option for patients with high-risk newly diagnosed mHNPC.”

Historically, androgen deprivation therapy (ADT) has been the standard of care for patients with metastatic prostate cancer.[1,2] ADT is often very effective at shrinking or slowing the growth of prostate cancer that has spread, but it usually becomes less effective over time.[3]

In addition to meeting the primary endpoints of OS and rPFS, the abiraterone acetate plus prednisone with ADT arm also met all secondary endpoints, with statistically significant improvements in times to pain progression, next subsequent therapy for prostate cancer, initiation of chemotherapy, prostate-specific antigen (PSA) progression (P<0.0001), and symptomatic skeletal events (p=0.0086).[4]

“Improvements in the care and treatment of prostate cancer at all stages of its progression are vital. That is especially true for those men who face high-risk metastatic hormone-naïve prostate cancer, a traditionally difficult type of cancer to treat,” said Marco Gottardis, Ph.D., Vice President and Prostate Cancer Disease Area Stronghold Leader at Janssen. “We are encouraged by these positive results for abiraterone acetate in hormone-naïve advanced prostate cancer and are committed to continue developing medicines that can benefit patients at all stages of this serious disease.”

Overall, the safety profile of ADT in combination with abiraterone acetate plus prednisone was consistent with prior studies in patients with metastatic castration-resistant prostate cancer

(mCRPC). Grade 3/4 events reported in ≥5 percent of patients were hypertension (20%/0% vs. 10%/0.2%), hypokalemia (10%/0.8% vs. 1%/0.2%) and alanine aminotransferase increased (5%/0.3% vs. 1%/0%) in the abiraterone acetate plus prednisone with ADT vs. placebo with ADT groups, respectively.

About High-Risk Metastatic Hormone-Naïve Prostate Cancer

Not all prostate cancer is the same. It ranges from cancer confined to the prostate gland to cancer that has spread outside of the prostate to the lymph nodes, bones, or other parts of the body. The extent or spread of prostate cancer determines the stage. Patients with high-risk metastatic hormone-naïve prostate cancer have at least two of the following factors: Gleason score of eight or above (a grading system used to evaluate the prognosis of someone with prostate cancer), presence of three or more lesions on a bone scan, or presence of measurable visceral metastasis (spread to other organs) on CT or MRI, excluding lymph node disease.

Hormone-naïve prostate cancer (HNPC) refers to a stage of the disease when the patients have not yet received hormone therapy or androgen deprivation therapy. [5] HNPC is further categorized into biochemical recurrence (in which patients have a rising prostate-specific antigen (PSA) after treatment, but the tumor is still localized)[6] and **metastatic prostate cancer** (in which the cancer has spread or metastasized to other parts of the body).

Patients with newly diagnosed mHNPC, particularly with high-risk characteristics, have a poor prognosis.[6] ADT + docetaxel has shown improved outcomes in mHNPC, but many patients are not candidates for docetaxel and may benefit from alternative therapy.[4] Also, while the majority of patients initially start on ADT, it usually becomes less effective over time.[2,3,4]

About the LATITUDE Trial[4]

The Phase 3, multinational, multicenter, randomized, double-blind, placebo-controlled LATITUDE study enrolled 1,199 newly diagnosed patients with high-risk metastatic hormone-naïve prostate cancer and was conducted at 235 sites in 34 countries in Europe, Asia-Pacific, Latin America, and Canada. A total number of 597 patients were randomized to receive ADT in combination with abiraterone acetate plus prednisone (n=597), while 602 patients were randomized to receive ADT and placebo (n=602). Patients included had high-risk mHNPC documented by positive bone scan or metastatic lesions at the time of diagnosis on computed tomography (CT) or magnetic resonance imaging (MRI). Additionally, patients had to have at least two of the three following high-risk factors

associated with poor prognosis: Gleason score ≥8, ≥3 bone lesions and presence of measurable visceral metastases.

Janssen submitted a Type II variation application to the European Medicines Agency (EMA), seeking to expand the existing marketing authorization for abiraterone plus prednisone or prednisolone to include the treatment of men with mHNPC. Similar submissions have been made in Japan, South Korea, Brazil, Switzerland and Taiwan. If approved, these submissions will broaden the use of abiraterone acetate to include an earlier stage of prostate cancer than its current indications.

About ZYTIGA®

ZYTIGA® (abiraterone acetate) is indicated in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC). ZYTIGA® blocks CYP17-mediated androgen production, which fuels prostate cancer growth, at three sources: in the testes, adrenals and the prostate tumor tissue. It has proven efficacy in patients with mCRPC who have progressed on androgen deprivation therapy.

Since its first approval in the U.S. in 2011, ZYTIGA® has been approved in combination with prednisone/prednisolone in 105 countries. More than 290,000 men worldwide have received treatment with it, and it was the number one prescribed therapy in the U.S. for men with mCRPC in 2016.

For more information about ZYTIGA, visit www.ZYTIGA.com.

Important Safety Information

CONTRAINDICATIONS - ZYTIGA® (abiraterone acetate) is not indicated for use in women. ZYTIGA® can cause fetal harm (Pregnancy Category X) when administered to a pregnant woman and is contraindicated in women who are or may become pregnant.

Hypertension, Hypokalemia and Fluid Retention Due to Mineralocorticoid Excess - Use with caution in patients with a history of cardiovascular disease or with medical conditions that might be compromised by increases in blood pressure, hypokalemia, or fluid retention. ZYTIGA® may cause hypertension, hypokalemia, and fluid retention as a consequence of increased mineralocorticoid levels resulting from CYP17 inhibition. Safety has not been established in patients with LVEF <50%

or New York Heart Association (NYHA) Class III or IV heart failure (in Study 1) or NYHA Class II to IV heart failure (in Study 2) because these patients were excluded from these randomized clinical trials. Control hypertension and correct hypokalemia before and during treatment. Monitor blood pressure, serum potassium, and symptoms of fluid retention at least monthly.

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

Hepatotoxicity - In post-marketing experience, there have been ZYTIGA®-associated severe hepatic toxicities, including fulminant hepatitis, acute liver failure and deaths. Monitor liver function and modify, withhold, or discontinue ZYTIGA® dosing as recommended (see Prescribing Information for more information). Measure serum transaminases [alanine aminotransferase (ALT) and aspartate aminotransferase (AST)] and bilirubin levels prior to starting treatment with ZYTIGA®, every two weeks for the first three 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.

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.

Adverse Reactions - The most common adverse reactions (≥10%) are fatigue, joint swelling or discomfort, edema, hot flush, diarrhea, vomiting, cough, hypertension, dyspnea, urinary tract infection and contusion.

The most common laboratory abnormalities (>20%) are anemia, elevated alkaline phosphatase, hypertriglyceridemia, lymphopenia, hypercholesterolemia, hyperglycemia, elevated AST, hypophosphatemia, elevated ALT 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, exercise caution and 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 - Do not use ZYTIGA® in patients with baseline severe hepatic impairment (Child-Pugh Class C).

About the Janssen Pharmaceutical Companies

At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science. We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at www.janssen.com. Follow us at www.twitter.com/JanssenUS and www.twitter.com/JanssenGlobal.

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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 product development, including potential broadened use of abiraterone acetate. 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 and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges inherent in new product research and development, including uncertainty of clinical success and obtaining regulatory approvals; uncertainty of commercial success for new product applications; 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 1, 2017, including under "Item 1A. Risk Factors," its most recently filed Quarterly Report on Form 10-Q, including under the caption "Cautionary Note Regarding Forward-Looking Statements," 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. Janssen Research & Development, LLC and Johnson & Johnson do not undertake to update any forward-looking statement as a result of new information or future events or developments.

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[1] Gillessen S, et al. Management of patients with advanced prostate cancer: recommendations of the St Gallen Advanced Prostate Cancer Consensus Conference. Ann Oncol. 2015;26:1589-1604.

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[3] American Cancer Society. "Treating Prostate Cancer That Doesn't Go Away or Comes Back After Treatment." Available at: https://www.cancer.org/cancer/prostate-cancer/treating/recurrence.html. Accessed May 2017.

[4] Fizazi K., et all. LATITUDE: A phase III, double-blind, randomized trial of androgen deprivation therapy with abiraterone acetate plus prednisone or placebos in newly diagnosed high-risk metastatic hormone-naive prostate cancer. ASCO 2017. Abstract #LBA3.

[5] Harvard University. Prostate Cancer Knowledge. Androgen-Independent Prostate Cancer. Available at: http://www.harvardprostateknowledge.org/androgen-independent-prostate-cancer. Accessed May 2017

[6] Channing, J. Management of Biochemically Recurrent Prostate Cancer After Local Therapy: Evolving Standards of Care and New Directions. National Institute of Health (NIH). Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3624708/. Accessed May 2017.