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Janssen's Heritage of Prostate Cancer Innovation

When Janssen launched ZYTIGA® (abiraterone acetate) in 2011, it was an important moment in prostate cancer treatment. For years, there had been no new treatments developed for patients with metastatic castration-resistant prostate cancer (mCRPC) and the standard of care in such patients, whose cancer had become non-responsive to androgen deprivation therapy, was a chemotherapy agent.

"It was a desert then," describes Marco Gottardis, Ph.D., Prostate Cancer Disease Area Stronghold Leader at Janssen.

ZYTIGA was the first hormone therapy that, in combination with prednisone, increased median overall survival in patients with mCRPC. "Fifteen years ago, survival for patients with castration-resistant prostate cancer was measured in months," says Peter De Porre, M.D., Senior Director, Clinical Oncology. "We've made great progress, but there's more work to do."

Since its launch, more than 290,000 men worldwide —110,000 of them in the United States — have been treated with ZYTIGA.

But ZYTIGA is just one part of Janssen's dedication to improving prostate cancer treatment. When William N. Hait, M.D., Ph.D., joined the company in 2007 as Therapeutic Area Head, Oncology, he set a strategy of targeting its research efforts on three Disease Area Strongholds that focus on specific types of tumors: prostate, lung, and blood cancers, or hematological malignancies, and this meant focusing all of Janssen's scientists on these three areas, instead of spreading their efforts across a wide range of targets.

"With prostate cancer, it's a tumor with a large population of patients," says Gottardis. "It's a tumor that has not been completely solved. The biology is just unfolding. So, there are opportunities to provide new types of therapeutics that can change the course of this disease." Close to 100 Janssen scientists are now working on researching and developing breakthrough prostate cancer treatments.

ZYTIGA was a first step. It was the first CYP17 inhibitor that worked by interrupting androgen production at three sources—the testes, the adrenal glands, AND the tumor itself. And it came about because of Janssen's strategy to really understand the pathophysiology of prostate cancer, and that they needed a drug that blocked all these sources of androgen. This led Janssen to acquire a small biotech company with a compound they thought would achieve that result. That compound became ZYTIGA.

And research is continuing. Apalutamide is an investigational androgen receptor antagonist in Janssen's pipeline, which has shown promising results in patients with various stages of prostate cancer. ZYTIGA is prescribed along with prednisone, and this combination with a steroid isn't needed with apalutamide, potentially making it accessible and preferable for more patients and, importantly, for patients earlier in their treatment.

Gottardis believes there's the potential for apalutamide to significantly influence and change the existing treatment algorithm.

The next step forward will be niraparib. Already used to treat some forms of ovarian cancer, this compound is an inhibitor of poly ADP-ribose polymerase or PARP enzymes, which play a role in DNA repair. In-vitro studies have shown that niraparib-induced cytotoxicity may involve inhibition of PARP enzymatic activity and increase formation of PARP-DNA complexes, resulting in DNA damage, apoptosis and cell death. In simple terms, this has the potential to prevent cancer cells from repairing their DNA after being damaged by other therapies, causing them to die. It's a new mechanism for treating prostate cancer, appropriate for certain patients, with a DNA repair defect. "I think, if eventually approved, it's going to provide another alternative for patients with advanced prostate cancer who have failed all hormonal therapies," Gottardis says.

But in the longer term, Janssen scientists are working not just to treat prostate cancer but to eventually intercept it, and hopefully, one day, prevent it. "The best thing you can do is prevent somebody from getting sick," says De Porre. "We are asking, how can we intercept the disease? How can we prevent an abnormality from becoming a cancer?" Today, the scientists at Janssen believe they're on their way there.

"Ultimately, Janssen's overarching strategy is to make prostate cancer a chronic disease in the late stage, and to cure it in the early stage," Gottardis says. "I can't be flippant, that these are the answers. I think we still have a long way to go. But I think we have what the answers need to be."

About ZYTIGA® (abiraterone acetate)
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 – and 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.