Study Unblinded: ZYTIGA® (abiraterone acetate) Plus Prednisone for Asymptomatic or Mildly Symptomatic Chemotherapy-Naïve Patients with Metastatic Castration-Resistant Prostate Cancer

Second ZYTIGA Phase 3 Study to be Unblinded, Based on Unanimous Recommendation of Independent Data Monitoring Committee

RARITAN, NJ, March 8, 2012 - Janssen Research & Development, LLC today announced that it has unblinded the Phase 3 study of ZYTIGA® (abiraterone acetate) plus prednisone for the treatment of asymptomatic or mildly symptomatic patients with metastatic castration-resistant prostate cancer (CRPC) who have not received chemotherapy.

Study COU-AA-302 is an international, randomized, double-blind, placebo controlled study that included 1,088 patients who were randomized to receive ZYTIGA 1,000 milligrams (mg) administered once daily plus prednisone 5 mg administered twice daily or placebo plus prednisone 5 mg administered twice daily. The co-primary endpoints of the study are radiographic progression-free survival and overall survival.

The Independent Data Monitoring Committee (IDMC) unanimously recommended unblinding the study based on a planned interim analysis in which differences in radiographic progression-free survival, overall survival, and secondary endpoints were observed that constitute evidence of clinical benefit as well as continued evidence of favorable safety in patients receiving abiraterone acetate plus prednisone as compared to those receiving placebo plus prednisone. Based on these results, the IDMC also recommended that patients in the placebo arm be offered treatment with ZYTIGA.

These results will be presented at an upcoming medical meeting and will also be submitted for publication in a peer-reviewed journal.

"The COU-AA-302 study has been a key priority for us as we expand our understanding of the utility of ZYTIGA in metastatic prostate cancer," said William N. Hait, MD, PhD, Global Head, Janssen R&D. "We're delighted that these data will soon be added to the growing body of literature about this important medication."

ZYTIGA has not been approved for use in men with metastatic CRPC who have not yet received chemotherapy. The company plans to submit for regulatory approval in the United States and around the world beginning in the second half of 2012.

The recommendation to unblind a clinical study at an interim analysis is made by an Independent Data Monitoring Committee based on predetermined criteria, such as meeting certain efficacy endpoints and the risk/benefit profile, as well as ethical considerations. In cases where there is compelling evidence of clinical benefit, the IDMC may also recommend that patients in the placebo arm of the study be crossed over to the active arm.

About ZYTIGA
"Since its first approval in the U.S. in 2011, ZYTIGA has been approved in 39 additional countries, many thousands of men have received treatment with it, and it is quickly becoming one of the cornerstones of our oncology offerings," said Hait.
ZYTIGA in combination with prednisone was approved by the U.S. Food and Drug Administration (FDA) in April 2011 for the treatment of men with metastatic castration-resistant prostate cancer who have received prior chemotherapy containing docetaxel. The Phase 3 study for this initial ZYTIGA indication was also unblinded at the interim point, in August 2010, based on a statistically significant improvement in overall survival and an acceptable safety profile. A subsequent analysis with more mature data confirmed the survival benefit and safety profile.

Indication
ZYTIGA® (abiraterone acetate) in combination with prednisone is indicated for the treatment of patients with metastatic castration-resistant prostate cancer (CRPC) who have received prior chemotherapy containing docetaxel.

Important Safety Information

Contraindications - ZYTIGA® (abiraterone acetate) may cause fetal harm (Pregnancy Category X) 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 hypertension,

hypokalemia, and 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 because these patients were excluded from the randomized clinical trial. 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 has been reported in clinical trials 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 - Increases in liver enzymes have led to drug interruption, dose modification, and/or discontinuation. 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.

Food Effect - ZYTIGA® must be taken on an empty stomach. Exposure of abiraterone increases up to 10-fold when abiraterone acetate is taken with meals. No food should be eaten for at least two hours before the dose of ZYTIGA® is taken and for at least one hour after the dose of ZYTIGA® is taken. Abiraterone Cmax and AUC0-∞(exposure) were increased up to 17- and 10-fold higher, respectively, when a single dose of abiraterone acetate was administered with a meal compared to a fasted state.

Adverse Reactions - The most common adverse reactions (≥5%) are joint swelling or discomfort,hypokalemia, edema, muscle discomfort, hot flush, diarrhea, urinary tract infection, cough, hypertension, arrhythmia, urinary frequency, nocturia, dyspepsia, fractures and upper respiratory tract infection.

Drug Interactions - ZYTIGA® is an inhibitor of the hepatic drug-metabolizing enzyme CYP2D6. Avoid coadministration with CYP2D6 substrates that have a narrow therapeutic index. If an alternative cannot be used, exercise caution and consider a dose reduction of the CYP2D6 substrate. Additionally, abiraterone is a substrate of CYP3A4 in vitro. Strong inhibitors and inducers of CYP3A4 should be avoided or used with caution.

Use in Specific Populations - The safety of ZYTIGA® in patients with baseline severe hepatic impairment has not been studied. These patients should not receive ZYTIGA®.

About Janssen Research & Development, LLC
Janssen Research & Development, LLC is headquartered in Raritan, N.J. and has affiliated facilities in Europe, the United States and Asia. Janssen Research & Development is leveraging a combination of internal and external innovation to discover and develop novel medicines and solutions in five distinct therapeutic areas: Neuroscience, Oncology, Immunology, Infectious Diseases and Vaccines, and Cardiovascular and Metabolism. For more information about Janssen Research & Development, LLC visit www.janssenrnd.com.

Janssen Research & Development is part of the Janssen Pharmaceutical Companies of Johnson & Johnson. Driven by our commitment to patients, we work together to bring innovative ideas, products, services and solutions to address serious unmet medical needs around the world.

(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. 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 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, general industry conditions and competition; economic factors, such as interest rate and currency exchange rate fluctuations; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; challenges to patents; changes in behavior and spending patterns or financial distress of purchasers of health care products and services; changes to governmental laws and regulations and domestic and foreign health care reforms; trends toward health care cost containment; and increased scrutiny of the health care industry by government agencies. A further list and description of these risks, uncertainties and other factors can be found in Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 1, 2012. Copies of this Form 10-K, as well as subsequent filings, are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. Neither Janssen Research & Development, LLC nor Johnson & Johnson

undertake to update any forward-looking statements as a result of new information or future events or developments.)