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ZYTIGA® Plus Prednisone Show Improvements in Asymptomatic or Mildly Symptomatic Chemotherapy-Naive Patients with Metastatic Castration-Resistant Prostate Cancer

Phase 3 Results Show Significant Improvement in Radiographic Progression-Free Survival and a Trend for Increased Overall Survival in Patients Receiving ZYTIGA Plus Prednisone

CHICAGO, June 2, 2012 - Results observed from pre-specified interim analyses of the randomized, placebo-controlled Phase 3 study, COU-AA-302, demonstrated that patients with metastatic castration-resistant prostate cancer (mCRPC) treated with abiraterone acetate (ZYTIGA®) plus prednisone showed a statistically significant improvement in radiographic progression-free survival (rPFS) and all secondary endpoints compared to patients treated with placebo plus prednisone. The results, announced today by Janssen Research & Development, LLC, also showed a trend for increased median overall survival (OS), the co-primary endpoint, in patients receiving ZYTIGA plus prednisone. The study included 1,088 asymptomatic or mildly symptomatic patients with mCRPC who had not received chemotherapy.

This is the first randomized study to demonstrate a radiographic progression-free survival benefit and an overall survival trend in this patient population. The COU-AA-302 results are being presented at the 48th Annual Meeting of the American Society of Clinical Oncology (ASCO).

"These results are very promising for abiraterone acetate in the treatment of patients with metastatic castration-resistant prostate cancer who are asymptomatic or mildly symptomatic and have not received chemotherapy. The results also advance our understanding of the role of androgen biosynthesis inhibition in this patient population," said Charles J. Ryan, M.D., lead investigator of the study and Associate Professor of Clinical Medicine at the UCSF Helen Diller Family Comprehensive Cancer Center. "This is an important study with all clinically relevant endpoints favoring treatment with abiraterone acetate plus prednisone, and is also the first to suggest that inhibiting androgen production significantly delays initiation of cytotoxic chemotherapy."

The data demonstrate a statistically significant improvement in rPFS in the abiraterone acetate plus prednisone arm (ZYTIGA arm) of the study compared to the placebo plus prednisone (control) arm. The median rPFS in the control arm was 8.3 months but had not yet been reached in the ZYTIGA arm because progression events were occurring more slowly in the ZYTIGA arm compared to the control arm (N=150 vs. 251, respectively). The Hazard Ratio (HR) equaled 0.43, there was a 95% confidence interval (CI): [0.35, 0.52], and the p-value was <0.0001.

Additionally, treatment with ZYTIGA plus prednisone resulted in an estimated 33 percent improvement in survival (median overall survival in the ZYTIGA arm was not reached and was 27.2 months in the control arm; HR=0.75; 95% CI: [0.61, 0.93], p=0.0097). At the time of these interim analyses, the pre-specified p-value of 0.0008 to achieve statistical significance was not reached.

Secondary Endpoints

Treatment with ZYTIGA plus prednisone also suggested significant improvements in secondary study endpoints compared to the control arm, specifically, longer time until:

- Median time to opiate use for cancer pain: the median time in the ZYTIGA arm was not reached and was 23.7 months in the control arm (HR=0.69; 95% CI: [0.57, 0.83]; p=0.0001).
- Median time to initiation of cytotoxic chemotherapy for prostate cancer: 25.2 months for the ZYTIGA arm vs. 16.8 months for the control arm (HR=0.58 [95% CI: 0.49, 0.69]; p<0.0001).
- Median time to deterioration in performance status: 12.3 months for the ZYTIGA arm vs. 10.9 months for the control arm (HR=0.82; 95% CI: [0.71, 0.94]; p=0.0053) for an increase in the Eastern Cooperative Oncology Group (ECOG) performance score of one point or more. The ECOG performance score is a standard measure used to assess functional status of a patient and is often used to determine prognosis and appropriate treatment.
- Median time to PSA progression: 11.1 months for the ZYTIGA arm vs. 5.6 months for the control arm (HR=0.49; 95% CI: [0.42, 0.57], p<0.0001), based on The Prostate Cancer Clinical Trials Working Group (PCWG2) criteria.

Safety Findings

Patients in the ZYTIGA arm of the study experienced more grade 3 and grade 4 adverse events than those in the control arm, including cardiac disorders (6% vs. 3%) and hypertension (4% vs. 3%), as well as increases in alanine aminotransferase (ALT) and aspartate aminotransferase (AST) (5.4% vs. 0.8% and 3.0% vs. 0.9%, respectively). Fatigue was the most common adverse event observed in the study.

Based on these results, Janssen plans to submit marketing applications with regulatory authorities to extend the use of ZYTIGA in men with mCRPC who have not received chemotherapy, beginning in the second half of 2012.

"These results further suggest evidence of the important clinical benefit of ZYTIGA for men with metastatic castration-resistant prostate cancer," said William N. Hait, M.D., Ph.D., Global Head, Janssen Research & Development and Head, Oncology Therapeutic Area. "The COU-AA-302 study expands our understanding of the utility of treating this disease with ZYTIGA, and is central to our goal of developing extraordinary oncology therapeutic solutions that can have a positive effect on patients' lives."

Janssen Research & Development previously announced that an Independent Data Monitoring Committee (IDMC) unanimously recommended unblinding this Phase 3 study after planned interim analyses found a statistically significant difference in rPFS and a trend in the difference in OS. Based on these results, the IDMC also recommended that patients in the control arm be offered treatment with abiraterone acetate.

Study Design

Study COU-AA-302 is an international, randomized, double-blind, placebo controlled Phase 3 study that included 1,088 men with mCRPC who had not received prior chemotherapy, who were randomized to receive abiraterone acetate (ZYTIGA) 1,000 milligrams (mg) administered orally 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 rPFS and OS.

About ZYTIGA

Since its first approval in the U.S. in 2011, ZYTIGA has been approved in more than 45 countries. Many thousands of men have received treatment with it, and it is quickly becoming one of the cornerstones of treatments for mCRPC.

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 mCRPC who have received prior chemotherapy containing docetaxel. The Phase 3 study for this initial ZYTIGA indication was also unblinded after review of a pre-specified interim analysis and recommendations from the IDMC, in August 2010, based on a statistically significant improvement in median OS and an acceptable safety profile. A subsequent analysis with more mature data confirmed the survival benefit and safety profile.

More information about ZYTIGA can be found at www.zytiga.com.

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 C_{max} and AUC_{0-infinity} (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.janssenrmd.com.

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(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.)

Editors' note: To arrange interviews with Dr. Ryan, please contact UCSF directly:

Elizabeth Fernandez
Senior Public Information Representative
UCSF News Services
415-514-1592
Elizabeth.Fernandez@ucsf.edu