ZYTIGA® Plus Prednisone Demonstrates Statistically Significant Overall Survival After 49-Month Follow-Up Analysis in Chemotherapy-Naïve Men with Metastatic Castration-Resistant Prostate Cancer

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Final analysis of Phase 3 COU-AA-302 study presented at the European Society for Medical Oncology (ESMO) 2014 Congress

NOTE: This press release relates to ESMO 2014 Congress abstract #753O and C. Ryan Oral Presentation, September 28th at 5 a.m. EDT/11 a.m. CET.

HORSHAM, PA, September 28, 2014 - A final analysis of the Phase 3 COU-AA-302 trial presented today at the European Society for Medical Oncology (ESMO) 2014 Congress in Madrid, Spain showed that ZYTIGA® (abiraterone acetate) plus prednisone significantly prolonged overall survival (OS), compared to an active control of placebo plus prednisone, in men with chemotherapy-naïve metastatic castration-resistant prostate cancer (mCRPC). The Janssen Research & Development, LLC ("Janssen")-sponsored registration study demonstrated a 19 percent reduction in risk of death in this study population (median OS, 34.7 vs 30.3 months, respectively; HR= 0.81 [95% CI, 0.70-0.93]; p = 0.0033), after a median follow-up of more than four years (49.2 months).

The final analysis presented today is the first to demonstrate a statistically significant improvement in OS in this study. "OS is particularly noteworthy in COU-AA-302, because 67 percent of men in the ZYTIGA plus prednisone arm and 80 percent in the control arm received subsequent therapy. This includes 44 percent of men in the control arm who subsequently received ZYTIGA plus prednisone," said Charles Ryan, M.D., Professor of Clinical Medicine, Urology at the University of California, San Francisco, and lead investigator of the COU-AA-302 study. "The use of subsequent therapies did not impact the statistical significance between the ZYTIGA and control arms - and makes these results all the more compelling after adjusting for the crossover effect."

The U.S. Food and Drug Administration based its approval of ZYTIGA plus prednisone for treating men with mCRPC prior to chemotherapy on a planned second interim analysis of COU-AA-302, which met the co-primary endpoint of radiographic progression-free survival (rPFS). Based on results from the final analysis, Janssen has initiated regulatory submissions to relevant health authorities for a revision to the ZYTIGA label.

"Since the first report of interim data, ZYTIGA has become a key part of the treatment arsenal that doctors use to treat mCRPC, because it significantly delayed the progression of the disease and prolonged overall survival," Dr. Ryan added. "This final analysis also demonstrates a consistent safety profile with long-term co-administration of prednisone."

In addition, the final analysis demonstrated a significant improvement in median time to opiate use for cancer-related pain compared to placebo plus prednisone (median 33.4 vs. 23.4 months, respectively; HR= 0.72 [95% CI, 0.61-0.85]; p = 0.0001). With two additional years (a total of four years) of follow up since the last clinical cutoff (median 49.2 months), the safety profile of ZYTIGA remained unchanged compared to previous reports.

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, and were randomized to receive ZYTIGA® (abiraterone acetate) 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 were rPFS and OS. Key secondary endpoints included time to opiate use, time to initiation of chemotherapy, time to Eastern Cooperative Oncology Group (ECOG) performance status deterioration and time to prostate-specific antigen (PSA) progression.

"In the last few years, we've entered a new era in prostate cancer treatment, with non-chemotherapy based treatment regimens and medicines based on an increasingly sophisticated understanding of the mechanism of disease. At Janssen, we're proud to be leading on these new innovations," said Peter Lebowitz, M.D., Ph.D., Global Therapeutic Area Head, Oncology, Janssen.

Janssen also presented positive Phase 2 data on ARN-509, an investigational compound currently in Phase 3 development for the treatment of men with high-risk non-metastatic castration-resistant prostate cancer (M0-CRPC). As part of the company's continued focus on advanced prostate cancer, ARN-509 provides an investigational opportunity that may address the unmet needs of patients with advanced prostate cancer.

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