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ZYTIGA^{®*} Plus Prednisone Demonstrates Statistically Significant Overall Survival in Men with Advanced Prostate Cancer Prior to Chemotherapy

Final data after 49-month follow-up analysis in chemotherapy-naïve men with metastatic castration-resistant prostate cancer presented at European Society for Medical Oncology (ESMO) 2014 Congress

Toronto, Ontario, September 29, 2014 – A final analysis of the Phase 3 COU-AA-302 trial presented at the European Society for Medical Oncology (ESMO) conference 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-sponsored registration study demonstrated a 19 per cent 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 this weekend is the first to demonstrate a statistically significant improvement in OS in this study. “OS is particularly noteworthy in COU-AA-302, because 67 per cent of men in the ZYTIGA[®] plus prednisone arm and 80 per cent in the control arm received subsequent therapy. This includes 44 per cent 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.”

Health Canada, the U.S. Food and Drug Administration, European Medicines Agency and regulatory authorities across the globe based approvals of ZYTIGA[®] plus prednisone for treating men with mCRPC prior to chemotherapy on pre-specified interim analyses 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, including 100 Canadians, 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.

About Prostate Cancer in Canada

Prostate cancer is the most common cancer to afflict men in Canada and approximately 23,600 will be diagnosed with prostate cancer in 2014.¹ According to the Canadian Cancer Society, on average, 65 Canadian men are diagnosed with prostate cancer every day, and 11 men die of prostate cancer every

day.² Approximately 10 to 20 per cent of prostate cancer cases will present with metastatic disease, in which the tumour spreads beyond the prostate.³ Fortunately, death rates have been declining since the mid-1990s.⁴

About ZYTIGA®

ZYTIGA® selectively inhibits the enzyme complex that is required for the production of androgens. Androgens are hormones that promote the development and maintenance of male sex characteristics; however, in prostate cancer androgens can work to fuel tumour growth. ZYTIGA® is the first oral treatment that inhibits androgen production at all three sources – the testes, adrenal glands and in the tumour itself.

In July 2011, ZYTIGA® was approved by Health Canada for the treatment of men with metastatic castration-resistant prostate cancer (mCRPC) who had received prior chemotherapy containing docetaxel after failure of androgen deprivation therapy (ADT).⁵ Health Canada approved a second indication for ZYTIGA® in May 2013 for the treatment of men with mCRPC who are asymptomatic or mildly symptomatic after failure of ADT.⁶

In combined data from the Phase 3 pivotal trials, the most common adverse reactions seen with ZYTIGA® are fluid in the legs, low blood potassium, urinary tract infection, liver function test increases, indigestion, presence of blood in the urine, high blood pressure, and bone fractures.⁷

About Janssen Inc.

Janssen Inc. is one of the Janssen Pharmaceutical Companies of Johnson & Johnson, which are dedicated to addressing and solving some of the most important unmet medical needs in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we bring innovative products, services and solutions to people throughout the world. For more information please visit: www.janssen.ca.

References

¹ Canadian Cancer Society. Prostate Cancer Statistics at a glance. Available at: <http://www.cancer.ca/en/cancer-information/cancer-type/prostate/statistics/?region=sk>. Last accessed September 22, 2014.

² Ibid.

³ Bellmunt J, Charles J, Albanell J. Predictive modelling in hormone-refractory prostate cancer (HRPC). Clin Transl Oncol. 2009 Feb;11 (2):82-5.

⁴ Canadian Cancer Society. Prostate Cancer Statistics at a glance. Available at: <http://www.cancer.ca/en/cancer-information/cancer-type/prostate/statistics/?region=sk>. Last accessed September 22, 2014.

⁵ Ibid.

⁶ Ibid.

⁷ ZYTIGA[®] Canadian Product Monograph. Page 7. February 14, 2014.