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

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, 28th September 11 a.m. CET. [1]

Beerse, Belgium, 28 September, 2014 – Janssen-Cilag International NV today announced that data from a final analysis of the Phase 3 COU-AA-302 trial 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).[1]

The final analysis presented today at the European Society for Medical Oncology (ESMO) 2014 Congress in Madrid, Spain, 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 European Commission, U.S. Food and Drug Administration and regulatory authorities across the globe based approvals of ZYTIGA plus prednisone for treatment of 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," said Charles Ryan. *"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 cut-off (median 49.2 months), the safety profile of ZYTIGA remained unchanged compared to previous reports.[1]

COU-AA-302 is an international, randomised, double-blind, placebo controlled Phase 3 study that included 1,088 men with mCRPC who had not received prior chemotherapy and were randomised 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.

"*The treatment paradigm for prostate cancer has significantly evolved over the last few years, primarily as a result of a deeper understanding of the disease that has led to the development of treatment options beyond chemotherapy,*" said Jane Griffiths, Company Group Chairman, Janssen Europe, the Middle East and Africa (EMEA). "*Janssen is proud to be leading the way in innovation in*

this area and today's announcement reinforces the company's commitment to continued research to improve the lives of men with prostate cancer."

-ENDS-

NOTES TO EDITORS

About Metastatic Castration-Resistant Prostate Cancer (mCRPC)

Metastatic castration-resistant prostate cancer occurs when cancer has metastasised (spread) beyond the prostate to other parts of the body and the disease progresses despite serum testosterone below castrate levels.[2]

The prostate is a gland in men that produces part of the seminal fluid and is located around the urethra (under the bladder). In some cases, cancer of the prostate can grow slowly. However, depending on factors including characteristics specific to the patient and the tumour, prostate cancer also can grow very quickly and spread widely.[3]

In 2012, an estimated 417,000 new cases of prostate cancer were diagnosed in Europe, and nearly 92,000 men died from the disease.[4]

About ZYTIGA

Since 2011, ZYTIGA (abiraterone acetate) has been approved in more than 90 countries and been prescribed to more than 140,000 patients worldwide, and it is quickly becoming one of the cornerstones of Janssen's oncology offerings.

ZYTIGA is the only approved therapy that inhibits production of androgen, which fuels prostate cancer growth, via inhibiting the CYP17 enzyme complex present at three sources: the testes, adrenals and the tumour itself.

Indication[5]

In 2011, ZYTIGA in combination with prednisone/prednisolone was approved by the European Commission (EC) for the treatment of metastatic castration-resistant prostate cancer (mCRPC) in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen.

In December 2012, the EC granted an extension of the indication for ZYTIGA (abiraterone acetate) permitting its use, in combination with prednisone or prednisolone, for the treatment of mCRPC, in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated.[5]

Side Effects[5]

Important Safety Information

For a full list of side effects and for further information on dosage and administration, contraindications and other precautions when using ZYTIGA, please refer to the summary of product characteristics, which is available at
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002321/human_med_001499.jsp&mid=WC0b01ac058001d124

Most common: urinary tract infection, hypokalaemia, hypertension, peripheral oedema, diarrhoea

Common: hypertriglyceridaemia, cardiac failure (including congestive heart failure, left ventricular dysfunction and decreased ejection fraction), angina pectoris, arrhythmia, atrial fibrillation, tachycardia, increased alanine aminotransferase and aspartate aminotransferase, fractures (includes all fractures with the exception of pathological fracture), sepsis, dyspepsia, haematuria and rash.

Uncommon: adrenal insufficiency, myopathy, rhabdomyolysis

Rare: allergic alveolitis

Not known: myocardial infarction

About Janssen

Janssen-Cilag International NV is one of the Janssen Pharmaceutical Companies. Janssen Pharmaceutical Companies of Johnson & Johnson are dedicated to addressing and solving the most important unmet medical needs of our time, including oncology (e.g. multiple myeloma and prostate cancer), immunology (e.g. psoriasis), neuroscience (e.g. schizophrenia, dementia and pain), infectious disease (e.g. HIV/AIDS, hepatitis C and tuberculosis) and cardiovascular and metabolic diseases (e.g. diabetes). Driven by our commitment to patients, we develop sustainable, integrated healthcare solutions by working side-by-side with healthcare stakeholders, based on partnerships of

trust and transparency. More information can be found on www.janssen-emea.com. Follow us on www.twitter.com/janssenEMEA for our latest news.

Janssen in Oncology

In oncology, our goal is to fundamentally alter the way cancer is understood, diagnosed, and managed, reinforcing our commitment to the patients who inspire us. In looking to find innovative ways to address the cancer challenge, our primary efforts focus on several treatment and prevention solutions. These include disease area strongholds that focus on haematologic malignancies and prostate cancer; cancer interception with the goal of developing products that interrupt the carcinogenic process; biomarkers that may help guide targeted, individualised use of our therapies; as well as safe and effective identification and treatment of early changes in the tumour microenvironment.

(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development. 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 or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges inherent in new product development, including obtaining regulatory approvals; competition, including technological advances, new products and patents attained by competitors; 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; general industry conditions including 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 Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 29, 2013, including in Exhibit 99 thereto, and our 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. None of the Janssen Pharmaceutical Companies or Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.)

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[1] Ryan C.J et al. Final overall survival (OS) analysis of COU-AA-302, a randomized phase 3 study of abiraterone acetate (AA) in metastatic castration-resistant prostate cancer (mCRPC) patients (pts) without prior chemotherapy. Abstract presented at the European Society for Medical Oncology 2014 Congress, September 26-30, Madrid, Spain. Oral Presentation. ESMO abstract #753O. Available at: https://www.webges.com/cslide/library/esmo/browse/search/eor#9f9k02Lm. Last accessed September 2014.

[2] Hotte SJ, Saad F. Current management of castrate-resistant prostate cancer. *Curr Oncol*. 2010 September; 17 (Supplement 2): S72–S79.

[3] Mayo Clinic. Prostate Cancer. Available at: http://www.mayoclinic.com/health/prostate-cancer/DS00043. Last accessed September 2014.

[4] Ferlay J et al. Cancer incidence and mortality patterns in Europe: Estimates for 40 countries in 2012. *European Journal of Cancer*. 2013; 49: p1374–1403.

[5] ZYTIGA® summary of product characteristics. Available on the EMA website: http://www.ema.europa.eu/ema/. Last accessed September 2014.