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PRODUCTS & OPERATING COMPANY

ZYTIGA® Approved In The EU For Use In The Treatment Of Metastatic Castration-Resistant Prostate Cancer Before Chemotherapy

Beerse, Belgium, 11 January 2013. Janssen-Cilag International NV (Janssen) announced today that the European Commission (EC) has approved an extension to the license of the oral, once-daily medication ZYTIGA® (abiraterone acetate). The approved broader indication for ZYTIGA now includes its use, in combination with prednisone or prednisolone, for the treatment of metastatic castration-resistant prostate cancer (mCRPC), in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated.[1]

Until now, ZYTIGA with prednisone and prednisolone has only been approved to treat men with mCRPC whose disease has progressed on or after a docetaxel-based chemotherapy regimen. This latest approval means that eligible men will potentially be able to benefit from treatment with ZYTIGA® earlier in the treatment pathway.

The EC's decision follows recommendations from the Committee for Medical Products for Human Use (CHMP) of the European Medicines Agency[2] that were based on data from the Phase III COU-AA-302 study[3] This was the first randomised study to demonstrate a radiographic progression-free survival (rPFS) benefit and a strong trend in overall survival (OS) in this patient population.

Jane Griffiths, Company Group Chairman, Janssen Europe, Middle-East, Africa, commented, "This decision by the European Commission is hugely welcomed news. It marks another important step forward in the treatment of men with advanced castration-resistant prostate cancer. Treating men with ZYTIGA before they undergo chemotherapy has been shown to improve outcomes in many patients, both in terms of extending survival and in bettering quality of life. The fact that ZYTIGA's licence has now been extended to include this indication will help fill a critical medical need and, we hope, serve to significantly improve the lives of many men across Europe suffering from this disease."

-ENDS-

NOTES TO EDITORS

About the COU-AA-302 study[3]

Study COU-AA-302 is a Phase III, international, randomised, double-blind, placebo controlled study which evaluated ZYTIGA® plus prednisone/prednisolone compared to placebo plus prednisone/prednisolone in 1,088 asymptomatic or mildly symptomatic men with mCRPC who had not received prior chemotherapy. The co-primary endpoints of the study were radiographic progression-free survival (rPFS) and overall survival (OS).

The results were published in The New England Journal of Medicine in December 2012.[4] The data demonstrated a statistically significant improvement in rPFS in the abiraterone acetate plus prednisone/prednisolone arm (ZYTIGA® arm) of the study compared to the placebo plus prednisone/prednisolone (control) arm. Additionally, treatment with ZYTIGA®

plus prednisone/prednisolone resulted in a longer OS than with placebo (median OS in the ZYTIGA® arm was not reached because progression events occurred more slowly in the ZYTIGA® arm compared to the control arm. At the time of the interim analysis, statistical significance for OS was not reached.

In February 2012 an Independent Data Monitoring Committee (IDMC) unanimously recommended unblinding of this study after the pre-specified analysis. Based on the results, the IDMC also recommended that patients in the control arm be offered treatment with ZYTIGA®.

Secondary Endpoints[3]
Treatment with ZYTIGA® plus prednisone also demonstrated significant improvements in secondary study endpoints compared to the control arm. Specifically, longer time until:

- Opiate use for cancer pain
- Initiation of cytotoxic chemotherapy for prostate cancer
- Deterioration in performance status (Eastern Cooperative Oncology Group (ECOG*) performance score of one point or more)
- PSA progression, based on The Prostate Cancer Clinical Trials Working Group (PCWG2) criteria

* 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.

Safety Findings in the COU-AA-302 study[3]
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.

About metastatic castration-resistant prostate cancer
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.[5]

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.[6]

In 2008, an estimated 370,000 new cases of prostate cancer were diagnosed in Europe, and nearly 90,000 men died from the disease.[7]

About ZYTIGA® [8]
Since its approval in 2011, ZYTIGA® has been approved in more than 60 countries worldwide, many thousands of men have received treatment with it, and it is quickly becoming one of the cornerstones of our 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.

The U.S. Food and Drug Administration also recently approved an expanded indication.[9]

Side effects:[8]

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 ZYTIGA's summary of product characteristics, which will be available at http://www.ema.europa.eu/ema/

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

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

Uncommon: adrenal insufficiency.

About Janssen

The Janssen Pharmaceutical Companies of Johnson & Johnson are dedicated to addressing and solving the most important unmet medical needs of our time, including oncology, immunology, neuroscience, infectious disease, and cardiovascular and metabolic diseases.

Driven by our commitment to patients, we develop innovative products, services and healthcare solutions to help people throughout the world.

More information can be found at **www.janssen-emea.com**

The original language of this press release is English. Translations into French, German, Italian and Spanish are provided by Business Wire as a courtesy.

References

[1] [Link to EC decision] [accessed January 2013]
[2] http://www.ema.europa.eu/docs/en_GB/document_library/Summary_of_opinion/human/002321/WC500134841.pdf [last accessed January 2013]
[3] Ryan C.J et al. Interim analysis (IA) results of COU-AA-302, a randomized, phase III study of abiraterone acetate (AA) in chemotherapy-naive patients (pts) with metastatic castration-resistant prostate cancer (mCRPC). J Clin Oncol 30, 2012 (suppl; abstr LBA4518)
[4] Ryan C.J et al. Abiraterone in Metastatic Prostate Cancer without Previous Chemotherapy. N Engl J Med 2012. DOI: 10.1056/NEJMoa1209096
[5] Hotte SJ, Saad F. Current management of castrate-resistant prostate cancer. Curr Oncol. 2010 September; 17 (Supplement 2): S72–S79.
[6] Mayo Clinic. "Prostate Cancer." http://www.mayoclinic.com/health/prostate-cancer/DS00043. [last accessed January 2013]
[7] http://globocan.iarc.fr/factsheet.asp [last accessed January 2013]
[8] ZYTIGA® summary of product characteristics to be available on the EMA website: http://www.ema.europa.eu/ema/

[9] http://www.prnewswire.com/news-releases/us-fda-approves-expanded-zytiga-indication-for-treatment-of-metastatic-castration-resistant-prostate-cancer-182852141.html [last accessed January 2013]

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