



## ZYTIGA® Receives Positive Regulatory Recommendation in the European Union for Treatment of Metastatic Castration Resistant Prostate Cancer

**Beerse, Belgium, [22nd July 2011]** Janssen-Cilag International NV announced today that the Committee for Medical Products for Human Use (CHMP) of the European Medicines Agency (EMA) has granted a positive opinion recommending approval of ZYTIGA® (abiraterone acetate) under an accelerated regulatory review procedure. ZYTIGA is a novel, once-daily, oral, androgen biosynthesis inhibitor developed for the treatment of prostate cancer. The proposed indication is the treatment - with prednisone or prednisolone - of metastatic castration resistant prostate cancer in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen.<sup>1</sup>

The CHMP is the committee responsible for the scientific assessment of products seeking centralised marketing authorisation throughout the European Union. The CHMP's positive opinion is now referred for approval to the European Commission. Janssen anticipates receiving the regulatory decision from the Commission in the third quarter of 2011.

The CHMP positive opinion is based on data from a large, pivotal phase 3 randomised, double-blind, placebo-controlled clinical trial (study COU-AA-301) (please see notes to editors for further details). The study demonstrated that abiraterone acetate, in combination with prednisone or prednisolone, improved overall survival (OS) in patients with metastatic castration resistant prostate cancer whose disease had progressed following chemotherapy.<sup>2</sup> In August 2010 the Independent Data Monitoring Committee recommended un-blinding the study after a pre-specified interim analysis demonstrated a significant improvement in overall survival. In December 2010 the marketing authorisation application was submitted to the European Medicines Agency, with the procedure starting in January 2011. Key results from study COU-AA-301 were published in the *New England Journal of Medicine* in May 2011.<sup>2</sup>

In April 2011 abiraterone acetate was approved in the US by the Food and Drug Administration (FDA) for use in combination with prednisone or prednisolone for the treatment of patients with metastatic castration-resistant prostate cancer (CRPC) who have received prior chemotherapy containing docetaxel.

"We will continue to work closely with the authorities to ensure abiraterone acetate becomes available as quickly as possible to patients who suffer from metastatic castration resistant prostate cancer that has become resistant to conventional hormone therapies and for whom today there are very few treatment options left," commented Jane Griffiths, Company Group Chairman, Janssen Europe, Middle-East, Africa.

### About metastatic castration resistant prostate cancer

- Metastatic castration resistant prostate cancer occurs when cancer has metastasised (spread into other parts of the body) beyond the prostate and disease progresses despite serum testosterone (androgens) below castrate levels.
- In 2008, an estimated 370,000 new cases of prostate cancer were diagnosed in Europe, and nearly 90,000 men died from the disease.<sup>3</sup>

### About ZYTIGA

- Androgens are hormones that promote the development and maintenance of sex characteristics. In prostate cancer, however, androgens can help fuel the tumour's growth. Androgen production primarily occurs in the testes and adrenal glands; in men with prostate cancer, the tumour tissue is an additional source of androgens.
- Abiraterone acetate is an oral, once-daily androgen biosynthesis inhibitor that works by inhibiting the CYP17 enzyme complex, which is required for the production of androgens at these three sources.

### About study COU-AA-301 ([www.nejm.org/doi/full/10.1056/NEJMoa1014618](http://www.nejm.org/doi/full/10.1056/NEJMoa1014618))

- This randomised, double-blind placebo-controlled Phase 3 study was conducted in 147 centres in 13 countries. The study evaluated whether abiraterone acetate, in combination with prednisone or prednisolone, improved overall survival in patients with metastatic castration resistant prostate cancer whose disease had progressed following chemotherapy.<sup>2</sup>
- Patients with metastatic castration resistant prostate cancer previously treated with docetaxel (N=1,195) were randomly assigned 2:1 to receive abiraterone acetate (1000 mg once daily) plus prednisone/prednisolone (5 mg twice daily) (N=797), or placebo plus prednisone/prednisolone (N=398). The primary endpoint was overall survival. The secondary end points included PSA response rate, time to PSA progression, and progression-free survival on the basis of radiographic findings.<sup>2</sup>
- After a median follow-up of 12.8 months, the study showed that median overall survival for the group receiving abiraterone acetate plus prednisone/prednisolone was 14.8 months vs. 10.9 months for placebo plus prednisone/prednisolone. Treatment with abiraterone acetate also resulted in a 35.4 percent reduction in the risk of death (HR=0.65; 95 percent CI: 0.54, 0.77; p<0.001) compared with placebo.<sup>2</sup>
- The most common adverse reactions (greater than or equal to 5 percent) reported in the clinical study were: joint swelling or discomfort, hypokalaemia, oedema, muscle discomfort, hot flush, diarrhoea, urinary tract infection, cough, hypertension, arrhythmia, urinary frequency, nocturia, dyspepsia and upper respiratory tract infection.<sup>2</sup>

### About Janssen

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](http://www.janssen-emea.com)

*This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialise, actual results could vary materially from the expectations and projections of the Janssen Pharmaceutical Companies. 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 and patents*

attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; domestic and foreign health care reforms and governmental laws and regulations; trends toward health care cost containment; and increased scrutiny of the healthcare 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 2, 2011. Copies of this Form 10-K, as well as subsequent filings, are available online at [www.sec.gov](http://www.sec.gov), [www.jnj.com](http://www.jnj.com) or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies, nor Johnson & Johnson, undertake to update any forward-looking statements as a result of new information or future events or developments.

## References

- <sup>1</sup>. [http://www.ema.europa.eu/ema/index.jsp?curl=pages/news\\_and\\_events/landing/whats\\_new.jsp&murl=menus/news\\_and\\_events/news\\_and\\_events.jsp&mid=WC0b01ac058004d5c4&jsenabled=true](http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/landing/whats_new.jsp&murl=menus/news_and_events/news_and_events.jsp&mid=WC0b01ac058004d5c4&jsenabled=true) [last accessed July 2011]
- <sup>2</sup>. de Bono JS et al. Abiraterone and Increased Survival in Metastatic Prostate Cancer. N Engl J Med 2011; 364(21): 1995-2005. [www.nejm.org/doi/full/10.1056/NEJMoa1014618](http://www.nejm.org/doi/full/10.1056/NEJMoa1014618) [last accessed July 2011]
- <sup>3</sup>. <http://globocan.iarc.fr/> [last accessed July 2011]