

ZYTIGA® APPROVED IN THE EUROPEAN UNION FOR METASTATIC CASTRATION-RESISTANT PROSTATE CANCER

First once-daily, oral treatment inhibits androgen production at all sources

Beerse, Belgium, September 7, 2011 /PRNewswire/ — Janssen-Cilag International NV announced today that, after an accelerated regulatory review process by the European Medicines Agency (EMA) and following a positive CHMP opinion on the 22 July 2011, the European Commission has approved the marketing authorisation for ZYTIGA® (abiraterone acetate), a novel, once-daily, oral, androgen biosynthesis inhibitor. Abiraterone acetate is approved, in combination with prednisone or prednisolone, 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.¹

"The European Commission approval of abiraterone acetate gives new hope to men who are suffering from this late stage of prostate cancer with very few treatment options left," said Professor Karim Fizazi, Department of Cancer Medicine, Institut Gustave Roussy, France, who was an investigator in the abiraterone acetate pivotal Phase 3 study. "The efficacy, safety and ease of use of abiraterone acetate, a medicine that can be taken at home, will address an important unmet medical need for many patients, helping them to live longer with a better quality of life and less pain."

Abiraterone acetate is an androgen biosynthesis inhibitor that inhibits the CYP17 enzyme complex which is required for the production of androgens.¹ Androgens (e.g. testosterone) are hormones that promote the development and maintenance of male sex characteristics.² However, in prostate cancer, androgens can fuel the tumour's growth.³ Androgen production primarily occurs in the testes and adrenal glands but, in men with prostate cancer, the tumour tissue is an additional source of androgens.¹ Abiraterone acetate is the first oral treatment for metastatic castration-resistant prostate cancer that inhibits androgen production at all three sources.¹

Results of the pivotal Phase 3, randomised, placebo-controlled, multicentre study showed that at a pre-specified interim analysis, after a follow-up of 12.8 months, treatment with abiraterone acetate in combination with prednisone or prednisolone resulted in a 35.4 percent reduction in the risk of death [hazard ratio (HR) = 0.65; 95 percent CI: 0.54, 0.77; p<0.001] and an improvement of 3.9 months in median overall survival (14.8 months vs. 10.9 months) compared to placebo plus prednisone or prednisolone.⁴ In an updated analysis (with follow-up period of 20.2 months), results were consistent with those from the interim analysis with a 4.6 month improvement in median overall survival between the two arms (15.8 months

Professor Johann de Bono,
Institute of Cancer Research

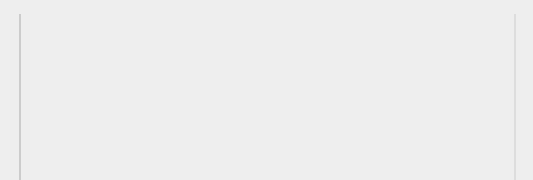
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ZYTIGA® (abiraterone acetate)
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vs. 11.2 months [HR = 0.74]) in favour of abiraterone acetate. The effect of abiraterone acetate and prednisone on overall survival was consistent across all subgroups.⁴

In patients who reported significant pain from their disease (a baseline pain score of 4 or more using the Brief Pain Inventory-Short Form [BPI-SF] scale of 0 to 10) and with at least one post-baseline pain score, the percentage experiencing pain relief (at least a 30% reduction from baseline in the BPI-SF worst pain intensity score over 24 hours without any increase in analgesic usage score observed at two consecutive evaluations four weeks apart) was higher in the abiraterone acetate group than in the placebo group (44% versus 27%, $p=0.002$).⁴

A lower proportion of patients receiving abiraterone acetate had skeletal related events compared with those given placebo (18% vs 28% at six months, 30% vs 40% at 12 months and 35% vs 40% at 18 months).¹ A skeletal related event was defined as a pathological fracture (a broken bone caused by disease weakening the bone), spinal cord compression, palliative radiation to bone (used to lessen bone pain), or surgery to bone.⁴

"In patients who have exhausted standard treatment options, including chemotherapy, abiraterone acetate offers a novel, well tolerated option for treating this devastating disease," explained Professor Johann S. de Bono, MD, FRCP, MSc, PhD, The Institute of Cancer Research, The Royal Marsden NHS Foundation Trust, and one of the co-lead investigators for the Phase 3 clinical study. "In Europe, prostate cancer is the third most common cause of cancer deaths so it is essential that new treatments options like abiraterone acetate are developed."

Overall, compliance with abiraterone acetate treatment was high, and side effects were easily manageable and reversible, despite the advanced age and level of frailty of the study population.⁴ The most common adverse reactions seen with abiraterone acetate are peripheral oedema, hypokalaemia, hypertension and urinary tract infection.¹

Abiraterone acetate should be taken once a day on an empty stomach, at least two hours after eating, and no food should be eaten for at least one hour after taking the tablets.¹

About pivotal phase 3 study -COU-AA-301

(<http://www.nejm.org/doi/full/10.1056/NEJMoa1014618>)

Abiraterone acetate with prednisone was evaluated in a Phase 3, randomised, placebo-controlled, multi-centre clinical study in patients who had received prior chemotherapy containing docetaxel (N = 1,195). Patients were randomised 2:1 to receive abiraterone acetate 1,000 milligrams (mg) daily plus prednisone or prednisolone 5 mg twice daily or placebo in combination with prednisone or prednisolone 5 mg twice daily (control arm). This randomised, double-blind placebo-controlled Phase 3 study was conducted in 147 centres in 13 countries.⁴

About metastatic castration-resistant prostate cancer

Metastatic castration-resistant prostate cancer, or mCRPC, occurs when cancer has metastasised (spread) beyond the prostate and 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).⁶ In some cases, cancer of the prostate can grow



German and French pack shots also available
please contact Kelly Blaney

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