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New Data Presented at ESMO 2017 Shows That Abiraterone Acetate Plus Prednisone Provides Benefits in Patient Reported Outcomes in Both Metastatic Hormone-Sensitive and Castration-Resistant Prostate Cancer

Beerse, Belgium, 8th September, 2017 – Janssen-Cilag International NV today announced additional data from the pivotal Phase 3 LATITUDE clinical trial, which showed that treatment with Zytiga® (abiraterone acetate) plus prednisone, in combination with androgen deprivation therapy (ADT), demonstrated clinically meaningful and statistically significant improvements in a range of patient reported outcomes (PRO) in patients with newly diagnosed, high-risk, metastatic hormone-sensitive prostate cancer (mHSPC), compared to ADT alone.

Abiraterone acetate, in combination with prednisone or prednisolone, is currently indicated for the treatment of mCRPC (metastatic castration-resistant prostate cancer) in adult men who are asymptomatic or mildly symptomatic after failure of ADT in whom chemotherapy is not yet clinically indicated, and in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen.[1]

The LATITUDE study findings, presented at the 2017 European Society for Medical Oncology (ESMO) Annual Conference, indicate that treatment with abiraterone acetate plus prednisone, in combination with ADT, significantly delayed time to progression of worst pain intensity (HR 0.63; 95% CI 0.52-0.77; $P < 0.0001$), pain interference (HR 0.67; 95% CI 0.56-0.80; $P < 0.0001$), worst fatigue (HR 0.65; 95% CI 0.53-0.81; $P = 0.0001$) and fatigue interference (HR 0.59; 95% CI 0.47-0.75; $P < 0.0001$) compared to ADT plus placebos. Findings also show a significant improvement in health-related quality of life (HRQoL), which includes several measures such as physical and emotional

Date of preparation: September 2017
EMEA Zinc number: PHEM/ZYT/0917/0002
UK Zinc number: PHGB/ZYT/0917/0001

wellbeing, demonstrating a reduction in risk of HRQoL degradation (HR 0.85; 95% CI 0.74-0.99; *P* = 0.0322) compared to ADT plus placebos.[2]

"In combination with the significant benefits in survival and disease progression, the new data from the LATITUDE clinical trial suggests that abiraterone acetate plus prednisone, in combination with androgen deprivation therapy, offers a much-needed efficacious treatment option for patients with newly diagnosed metastatic disease," said Dr Karim Fizazi, Principal Investigator of the trial and Head of the Medical Oncology Department at Institute Gustave Roussy, France. "*These results build upon previous LATITUDE findings published in the New England Journal of Medicine in June and presented during ASCO 2017, which found a significant improvement in overall survival and radiographic progression-free survival in patients with newly diagnosed high-risk metastatic hormone-sensitive prostate cancer."*

In addition, an indirect comparison of abiraterone acetate plus prednisone and docetaxel for the treatment of mHSPC was also presented at ESMO. The systematic review, which examined results from LATITUDE as well as several other studies, suggests that abiraterone acetate plus prednisone, in combination with ADT, produces greater reductions in the risk of progression and in risk of death vs ADT plus docetaxel for patients with high risk or high volume disease.[3]

In addition to the benefits of abiraterone acetate plus prednisone seen in early stage disease, additional findings presented at ESMO support the use of abiraterone acetate plus prednisone in its current, mCRPC indications. Preliminary results from the AQUARiUS observational study, which prospectively collects PROs on quality of life, cognition, fatigue and pain, suggest more favourable outcomes for perceived cognitive impairments, functioning and fatigue for mCRPC patients treated with abiraterone acetate plus prednisone compared to those treated with enzalutamide, within the first three months after treatment initiation.[4]

"Janssen remains dedicated to addressing the challenges around treatments and quality of life for both early and late stage prostate cancer, including the thousands of patients with metastatic prostate cancer in Europe that are diagnosed each year," said Dr Ivo Winiger-Candolfi, Oncology Solid Tumour Therapy Area Lead, Janssen Europe, Middle East, Africa. *"We are encouraged by the patient reported outcomes from the AQUARiUS and LATITUDE trials, which further support the use of abiraterone acetate plus prednisone in its current indications, as well as the potential for use in an earlier stage of prostate cancer, respectively. These new results suggest that abiraterone acetate plus*

prednisone in combination with ADT has the potential to become a standard of care for the treatment of newly diagnosed, high-risk metastatic prostate cancer patients."

-ENDS-

NOTES TO EDITORS

About high-risk metastatic hormone-sensitive prostate cancer (mHSPC)

There are approximately 420,000 men diagnosed with prostate cancer in Europe per year.[5] Around 2%-43% (up to 180,000) have metastatic prostate cancer.[6,7,8] Not all prostate cancer is the same. It ranges from cancer confined to the prostate gland to cancer that has spread outside of the prostate to the lymph nodes, bones, or other parts of the body. The extent or spread of prostate cancer determines the stage.[9] Hormone-sensitive prostate cancer (HSPC) refers to a stage of the disease when the patient has not been treated with ADT.[10] Patients with newly diagnosed mHSPC, particularly with high-risk characteristics, have a poor prognosis.[10] ADT plus docetaxel has shown improved outcomes in mHSPC, but many patients are not candidates for docetaxel and may benefit from alternative therapy.[11]

About the LATITUDE Trial[12]

The Phase 3, multinational, multicentre, randomised, double-blind, placebo-controlled LATITUDE study enrolled 1,199 newly diagnosed patients with mHSPC (no prior treatment with ADT or ≤3 months treatment with ADT before baseline) and was conducted at 235 sites in 34 countries in Europe, Asia-Pacific, Latin America, and Canada. A total number of 597 patients were randomised to receive ADT in combination with abiraterone acetate plus prednisone (n=597), while 602 patients were randomised to receive ADT and placebos (n=602). Patients included had high-risk mHSPC documented by positive bone scan or metastatic lesions at the time of diagnosis on computed tomography (CT) or magnetic resonance imaging (MRI). Additionally, patients had to have at least two of the three following high-risk factors associated with poor prognosis:

- Gleason score ≥8
- ≥3 bone lesions
- presence of measurable visceral metastases

These results served the basis for Janssen's Type II variation application submission to the European Medicines Agency (EMA), seeking to expand the existing marketing authorisation for abiraterone acetate plus prednisone or prednisolone to include the treatment of men with newly-diagnosed, high-risk, metastatic hormone-sensitive

prostate cancer (mHSPC). If approved, this will broaden the use of abiraterone acetate plus prednisone to include an earlier stage of prostate cancer than its current indications.

Overall, the safety profile of ADT in combination with abiraterone acetate plus prednisone was consistent with prior studies in patients with metastatic castration-resistant prostate cancer (mCRPC). The most common and anticipated adverse events were elevated incidences of mineralocorticoid-related hypertension and hypokalaemia in the ADT in combination with abiraterone acetate plus prednisone arm compared with ADT and placebos. The incidence rate of grade 3 or higher hypertension (20% vs. 10%) was greater than that observed in prior studies of abiraterone acetate in mCRPC patients. There were no serious sequelae from the increased rate of hypertension. The incidence of hypokalaemia was higher than that reported in prior Phase 3 studies of abiraterone acetate in mCRPC; however, only two patients discontinued treatment due to hypokalaemia and there were no hypokalaemia-related deaths.

The observed degrees of hypertension and hypokalaemia were both medically manageable with antihypertensive medications and potassium supplements as needed, only rarely required treatment discontinuation, and seldom led to serious consequences.

About the AQUARiUS Trial[13]

The prospective, multinational, observational AQUARiUS study investigates the impact that both abiraterone acetate plus prednisone and enzalutamide have on HRQoL, PROs, and medical resource use in patients with mCRPC. The study enrolled 210 patients with mCRPC and has been conducted at 27 sites in three countries in Europe. The estimated study completion date is March 2018. Primary outcomes being measured are HRQoL, fatigue, pain, cognitive function and medical resource use.

About abiraterone acetate

Abiraterone acetate plus prednisone / prednisolone is the only approved therapy in mCRPC that inhibits production of androgens (which fuel prostate cancer growth) at all three sources that are important in prostate cancer - the testes, adrenals and the tumour itself.[1,14,15]

Abiraterone acetate plus prednisone / prednisolone has been approved in more than 90 countries to date, and has been prescribed to approximately 330,000 men worldwide.[16,17]

Indications[1]

In 2011, abiraterone acetate in combination with prednisone / prednisolone was approved by the European Commission (EC) for the treatment of 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 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.[1]

Further Information[1]

The most common adverse reactions seen with abiraterone acetate plus prednisone / prednisolone include urinary tract infection, hypokalaemia, hypertension, and peripheral oedema.

For a full list of side effects and for further information on dosage and administration, contraindications and other precautions when using abiraterone acetate plus prednisone / prednisolone please refer to the summary of product characteristics, which is available at: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/002321/WC500112858.pdf

About the Janssen Pharmaceutical Companies

At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science. We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at www.janssen.com/emea. Follow us on http://www.twitter.com/janssenEMEA for our latest news.

Cilag GmbH International; Janssen Biotech, Inc.; and Janssen-Cilag International NV are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding the continued development and potential of abiraterone acetate plus prednisone. 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 known or unknown risks or uncertainties materialise, actual results could vary materially from the expectations and projections of Janssen-Cilag International NV, any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include,

but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behaviour and spending patterns or financial distress of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions 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 January 1, 2017, including under "Item 1A. Risk Factors," its most recent Quarterly Report on Form 10-Q, including in the section captioned "Cautionary Note Regarding Forward-Looking Statements," and the company's 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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EMEA Zinc number: PHEM/ZYT/0917/0002
UK Zinc number: PHGB/ZYT/0917/0001

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Date of preparation: September 2017
EMEA Zinc number: PHEM/ZYT/0917/0002
UK Zinc number: PHGB/ZYT/0917/0001