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Abiraterone Acetate Plus Prednisone Provided Significant Clinical Benefit in Patients with High-Risk Metastatic Hormone-Naïve Prostate Cancer (mHNPC), Improving Overall Survival and Radiographic Progression-Free Survival

Beerse, Belgium, 3rd June, 2017 – Janssen-Cilag International NV today announced data from the pivotal Phase 3 LATITUDE clinical trial, which showed Zytiga[®] (abiraterone acetate) plus prednisone, in combination with androgen deprivation therapy (ADT), compared to ADT plus placebo, demonstrated a significant improvement in overall survival (OS) and radiographic progression-free survival (rPFS) in patients with newly diagnosed high-risk metastatic hormone-naïve prostate cancer (mHNPC) (patients who had not been previously treated with ADT).¹ These data were selected as one of four data sets for inclusion in the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting Press Program in Chicago, today at 8 – 9 a.m. CDT. Additionally, the data results will be presented during the “Plenary Session: Including the Science of Oncology Award and Lecture,” on Sunday, 4th June, at 2:40 – 2:55 p.m. CDT (Abstract LBA3). The data have been selected for “Best of ASCO” Meetings, which highlight the most cutting-edge science and education from the ASCO Annual Meeting, and reflect the foremost oncology research and strategies that will directly impact patient care.

Study findings indicated that treatment with abiraterone acetate plus prednisone, in combination with ADT, reduced the risk of death by 38% compared to ADT and placebo (hazard ratio [HR]=0.62; 95% CI [0.51 to 0.76], $p < 0.0001$). Additional study results found that treatment with abiraterone acetate plus prednisone, in combination with ADT, reduced the risk of disease progression on scans or death by 53% compared to ADT plus placebo in patients with mHNPC (HR=0.47; 95% CI [0.39 to

0.55], $P < 0.0001$).¹ Median rPFS was 33.0 months with ADT in combination with abiraterone acetate plus prednisone, compared to 14.8 months with ADT and placebo.¹

"In the LATITUDE trial, we found that abiraterone acetate plus prednisone, in combination with androgen deprivation therapy, demonstrated statistically significant and clinically meaningful improvements in patients with high-risk metastatic hormone-naïve prostate cancer," said Dr. Karim Fizazi, Principal Investigator of the trial and Head of the Medical Oncology Department at Institute Gustave Roussy. *"This is important new information, as not all patients respond well to the current standard of care. LATITUDE suggests that abiraterone acetate plus prednisone, in combination with androgen deprivation therapy, can offer a new and much-needed option for patients with high-risk newly diagnosed mHNPc."*

There are approximately 420,000 men diagnosed with prostate cancer in Europe per year.² Around 2%-43% (up to 180,000) have metastatic prostate cancer.^{3,4,5} Historically, ADT and docetaxel have been the standard of care for patients with metastatic prostate cancer. This is often very effective at shrinking or slowing the growth of prostate cancer that has spread, but it usually becomes less effective over time.^{6,7,8}

In addition to achieving significant improvement on both primary endpoints of OS and rPFS, the LATITUDE study met all secondary endpoints, with statistically significant improvements in the abiraterone acetate plus prednisone arm for time to: pain progression, initiation of next subsequent therapy for prostate cancer, initiation of chemotherapy, prostate-specific antigen (PSA) progression (all $p < 0.0001$), and next skeletal-related event ($p = 0.0086$).¹

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). Most common and anticipated adverse events were elevated incidences of mineralocorticoid-related hypertension and hypokalemia in the ADT in combination with abiraterone acetate plus prednisone arm compared with ADT and placebo.

"Prostate cancer is the most common cancer in men in Europe, affecting over three million patients in the region. When the disease metastasises and spreads to other parts of the body, it can become very aggressive and hard to treat," said Dr. Ivo Winiger-Candolfi, Oncology Solid Tumor Therapy Area Lead, Janssen Europe, Middle East, Africa. *"Janssen has played an important role in addressing*

treatment challenges and transforming the way metastatic prostate cancer is managed over the past seven years. We are very excited to see the positive LATITUDE data results for abiraterone acetate plus prednisone in hormone-naïve metastatic prostate cancer. These data have served the basis for our submission to the European Medicines Agency (EMA) to expand the use of abiraterone acetate plus prednisone to include an earlier stage of prostate cancer than its current indications and we remain committed to helping these patients benefit from the treatment in the future.”

-ENDS-

NOTES TO EDITORS

About high-risk metastatic hormone-naïve prostate cancer (mHNPC)

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-naïve prostate cancer (HNPC) refers to a stage of the disease when the patient has not been treated with ADT.¹⁰ Patients with newly diagnosed mHNPC, particularly with high-risk characteristics, have a poor prognosis. ADT plus docetaxel has shown improved outcomes in mHNPC, but many patients are not candidates for docetaxel and may benefit from alternative therapy.¹¹ Also, while the majority of patients initially start on ADT, it usually becomes less effective over time.^{6,7,8}

About the LATITUDE Trial¹

The Phase 3, multinational, multicentre, randomised, double-blind, placebo-controlled LATITUDE study enrolled 1,199 newly diagnosed patients with mHNPC 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 placebo (n=602). Patients included had high-risk mHNPC 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 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). Most common and anticipated adverse events were elevated incidences of mineralocorticoid-related hypertension and hypokalemia in the ADT in combination with abiraterone acetate plus prednisone arm compared with ADT and placebo. 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 hypokalemia was higher than that reported in prior Phase 3 studies of abiraterone acetate in mCRPC; however, only two patients discontinued treatment due to hypokalemia and there were no hypokalemia-related deaths. Mineralocorticoid-associated adverse events were medically manageable, resulting in the use of the lower 5mg prednisone dose, compared with the 10mg in prior studies.

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.^{12,13,14}

Abiraterone acetate plus prednisone / prednisolone has been approved in more than 90 countries to date, and has been prescribed to approximately 290,000 men worldwide.^{15,16}

Indications¹²

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.¹²

Further Information¹²

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 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 known or unknown risks or uncertainties materialise, actual results could vary materially from the expectations and projections of Janssen-Cilag International NV 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 in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," 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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- ¹⁶ Janssen finance reported unit sales (number of pills) from launch to Dec 2016.