FOR IMMEDIATE RELEASE

FOR EU TRADE AND MEDICAL MEDIA ONLY

Media Enquiries:
Natalie Buhl
Phone: +353 85-744-6696

Investor Relations:
Lesley Fishman
Phone: +1 732-524-3922

Joseph J. Wolk
Phone: +1 732-524-1142

European Commission Extends License for Janssen's ZYTIGA® Plus Prednisone / Prednisolone to Include Earlier Stage Prostate Cancer Patients

Oral, Once-Daily Medication ZYTIGA® (abiraterone acetate) ® Plus Prednisone / Prednisolone Now Approved in Newly Diagnosed High-Risk Metastatic Hormone-Sensitive Prostate Cancer (mHSPC)

Beerse, Belgium, 20th November, 2017 – Janssen-Cilag International NV (Janssen) today announced that the European Commission (EC) has granted approval to broaden the existing marketing authorisation for ZYTIGA® (abiraterone acetate) plus prednisone / prednisolone to include an earlier stage of metastatic prostate cancer than its current indications. Abiraterone acetate plus prednisone / prednisolone can now be used for the treatment of newly-diagnosed high-risk metastatic hormone-sensitive prostate cancer (mHSPC) in adult men in combination with androgen deprivation therapy (ADT).[1]

"Prostate cancer is the most common form of cancer in men throughout Europe and today's decision helps to fill a critical medical need for these patients. We hope to significantly improve the lives of many men across Europe living with this disease and the approval of this treatment in an earlier stage of prostate cancer helps address this," said Professor Karim Fizazi, principal investigator of the LATITUDE trial and Head of the Medical Oncology Department at Institute Gustave Roussy, France.

The EC's decision follows a recommendation from the Committee for Medical Products for Human Use (CHMP)[2] that was based on data from the multinational, multicentre, randomised, double-blind, placebo-controlled Phase 3 study, LATITUDE. The trial was designed to determine if newly diagnosed patients with metastatic prostate cancer, who

are naïve to castration and have high-risk prognostic factors, would benefit from the addition of abiraterone acetate and prednisone to androgen deprivation therapy (ADT) vs ADT alone.[3] Data were presented at the 2017 American Society of Clinical Oncology congress in Chicago, USA and published in the New England Journal of Medicine.

"This EC approval is a major step forward for men living with prostate cancer across Europe and offers patients with newly diagnosed high-risk metastatic hormone-sensitive prostate cancer a new treatment option. We are encouraged by the data we have seen to date and remain committed to transforming outcomes for prostate cancer patients," said Dr. Ivo Winiger-Candolfi, Oncology Solid Tumor Therapy Area Lead, Janssen Europe, Middle East and Africa.

Abiraterone acetate plus prednisone / prednisolone has already been approved by the European Commission (EC) for the treatment of metastatic castration-resistant prostate cancer (mCRPC) 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.[4]

In the LATITUDE study, the safety profile of ADT in combination with abiraterone acetate plus prednisone was consistent with prior studies in patients with mCRPC. Most common 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 placebos.[3] The observed degrees of hypertension and hypokalemia were both medically manageable. They only rarely required treatment discontinuation and seldom led to serious consequences.[3]

-ENDS-

NOTES TO EDITORS

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

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 its stage.[5] Hormone-sensitive prostate cancer (HSPC) refers to a stage of the disease when the patient is still sensitive to treatment with ADT.[6] Patients with newly diagnosed mHSPC, particularly with high-risk characteristics, have a poor prognosis. ADT plus docetaxel has shown improved outcomes in mHSPC when compared to ADT alone, but many patients

are not candidates for docetaxel and may benefit from alternative therapy.[7] Also, while the majority of patients initially start on ADT, it usually becomes less effective over time.[8,9,10]

About the LATITUDE Trial[3]

The Phase 3, multinational, multicentre, randomised, double-blind, placebo-controlled LATITUDE study enrolled 1,199 newly diagnosed patients with metastatic prostate cancer naïve to castration 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 metastatic prostate cancer naïve to castration 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:[3]

- 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 / prednisolone for the treatment of newly-diagnosed high-risk metastatic hormone-sensitive prostate cancer (mHSPC) in adult men in combination with androgen deprivation therapy (ADT).

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 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 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 hypokalemia was higher than that reported in prior Phase 3 studies of abiraterone acetate plus prednisone in mCRPC; however, only two patients discontinued treatment due to hypokalemia and there were no hypokalemia-related deaths. Mineralocorticoid-associated adverse events were generally medically manageable.[3]

Date of preparation: October 2017
Job number: PHEM/ZYT/1117/0004

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.[4,11,12]

Indications[4]

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.[4]

On Friday 17th November 2017, the EC granted approval in broadening the existing marketing authorisation for abiraterone acetate plus prednisone / prednisolone for the treatment of newly-diagnosed high-risk metastatic hormone-sensitive prostate cancer (mHSPC) in adult men in combination with androgen deprivation therapy (ADT).[4]

Further Information[4]

The most common adverse reactions seen with abiraterone acetate plus prednisone / prednisolone include urinary tract infection, hypokalemia, 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.; Janssen Oncology, 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 an expanded marketing authorisation for ZYTIGA® (abiraterone acetate) plus prednisone / prednisolone to include an earlier stage of metastatic prostate cancer. 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 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 recently filed Quarterly Report on Form 10-Q, including under the caption "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. Neither the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

Date of preparation: October 2017
Job number: PHEM/ZYT/1117/0004

References:

[1] EC website. Community register of medicinal products for human use. ZYTIGA product information. To be made available at: http://ec.europa.eu/health/documents/community-register/html/h714.htm. Last accessed November 2017.
[2] European Medicines Agency. ZYTIGA CHMP meeting highlights. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Summary_of_opinion/human/002321/WC500236610.pdf. Last accessed October 2017
[3] Fizazi, K. et al. Abiraterone plus Prednisone in Metastatic, Castration-Sensitive Prostate Cancer. New England Journal of Medicine 2017; 377:352-360.
[4] ZYTIGA® summary of product characteristics (February 2017). Available at: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/002321/WC500112858.pdf. Last accessed October 2017.
[5] Prostate Cancer Foundation. Staging the disease. Available at: https://www.pcf.org/c/staging-the-disease/. Last accessed October 2017.
[6] Moul, J.W. Hormone naïve prostate cancer: predicting and maximizing response intervals. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4814946/. Last accessed October 2017.
[7] Engel Ayer Botrel, T. Efficacy and Safety of Combined Androgen Deprivation Therapy (ADT) and Docetaxel Compared with ADT Alone for Metastatic Hormone-Naive Prostate Cancer: A Systematic Review and Meta-Analysis. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4911003/. Last accessed October 2017.
[8] Gillessen S, et al. Management of patients with advanced prostate cancer: recommendations of the St Gallen Advanced Prostate Cancer Consensus Conference. Ann Oncol. 2015;26:1589-1604.
[9] Cornford P, et al. Guidelines on Prostate Cancer. Part II: treatment of relapsing, metastatic, and castration-resistant prostate cancer. Eur Urol. 2017;71:630-642.
[10] American Cancer Society. "Treating Prostate Cancer That Doesn't Go Away or Comes Back After Treatment." Available at: https://www.cancer.org/cancer/prostate-cancer/treating/recurrence.html. Last accessed October 2017.
[11] Hoy, SM. et al. Abiraterone Acetate: A review of its use in patients with metastatic castration-resistant prostate cancer drugs. Drugs 2013; 73:2077-2091.
[12] Ritch, CR. Cookson, MS. Advances in the management of castration resistant prostate cancer. BMJ. 2016 Oct 17;355:i4405. Doi: 10.1136/bmj.i4405.

Date of preparation: October 2017
Job number: PHEM/ZYT/1117/0004