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CHMP Issues a Positive Opinion on Janssen's ZYTIGA® to Include Earlier Stage Prostate Cancer Patients

CHMP Recommends to Broaden Indication to Include the Treatment of Men with Newly Diagnosed High-Risk Metastatic Hormone-Sensitive Prostate Cancer (mHSPC)

Beerse, Belgium, 13th October, 2017 – Janssen-Cilag International NV ("Janssen") today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has recommended broadening the existing marketing authorisation for ZYTIGA® (abiraterone acetate) plus prednisone / prednisolone to include an earlier stage of prostate cancer than its current indications. If approved by the European Commission, abiraterone acetate plus prednisone / prednisolone in combination with androgen deprivation therapy (ADT) can be used for the treatment of adult men with newly diagnosed high-risk metastatic hormone-sensitive prostate cancer (mHSPC).[1]

"As shown by the results from the LATITUDE study, adding abiraterone acetate plus prednisone / prednisolone to ADT alone significantly improves overall survival and radiographic progression-free survival in men with metastatic hormone-sensitive prostate cancer and high-risk features in comparison to treating patients with ADT alone, where median survival is currently less than three years. Today's decision means we are one step forward in ensuring mHSPC men across Europe may be able to benefit from this treatment soon," said Professor Karim Fizazi, principal investigator of the LATITUDE trial and Head of the Medical Oncology Department at Institute Gustave Roussy.

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The CHMP recommendation is 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 mHNPC who have high-risk prognostic factors benefit from the addition of abiraterone acetate and prednisone to androgen deprivation therapy (ADT) vs placebos and ADT.[2] Data were presented at the 2017 American Society of Clinical Oncology congress in Chicago, USA and published in the New England Journal of Medicine.

"We are very pleased with the CHMP's decision which recommends abiraterone acetate plus prednisone / prednisolone in combination with ADT for use in adult patients with newly diagnosed high-risk metastatic hormone-sensitive prostate cancer. Janssen Oncology has played a significant role in transforming the way prostate cancer is treated so far and aims to continue this progress," 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 of mCRPC in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen.[3]

In the LATITUDE study, 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.[4] The observed degrees of hypertension and hypokalemia were both medically manageable with antihypertensive medications and potassium supplements as needed, only rarely required treatment discontinuation, and seldom led to serious consequences.[4]

The CHMP's Positive Opinion will now be reviewed by the European Commission, which has the authority to grant approval of the new indication.

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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[2]

The Phase 3, multinational, multicentre, randomised, double-blind, placebo-controlled LATITUDE study enrolled 1,199 newly diagnosed patients with metastatic hormone-naïve prostate cancer (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 placebos (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:[2]

- 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 adult men with newly-diagnosed, high-risk metastatic hormone-sensitive prostate cancer (mHSPC). If approved, this will broaden the use of abiraterone acetate plus prednisone / prednisolone to include an earlier stage of prostate cancer than its current indications.

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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.

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.[3,11,12]

Indications[3]

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.[3]

Further Information[3]

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

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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 the continued development and potential of abiraterone acetate plus prednisone / prednisolone. 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 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.

References:

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