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Janssen Receives Positive CHMP Opinion for Expanded Use of Erleada® (apalutamide) for Patients with Metastatic Hormone-Sensitive Prostate Cancer

- *Positive Opinion is based on data from the Phase 3 TITAN study which were published in* The New England Journal of Medicine[1]

BEERSE, BELGIUM, 13 December, 2019 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a Positive Opinion recommending approval for expanding the use of Erleada® (apalutamide) to include the treatment of adult men with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy (ADT).[2] The CHMP's Positive Opinion will now be reviewed by the European Commission (EC), which has the authority to grant approval for the new use of apalutamide.

The Positive Opinion is based on data from the Phase 3 TITAN study, which assessed the addition of apalutamide to ADT – the current standard of care in mHSPC – in a broad range of patients with mHSPC, regardless of disease volume, prior treatment with docetaxel or staging at initial diagnosis. The dual primary endpoints of the study were overall survival (OS) and radiographic progression-free survival (rPFS). Apalutamide plus ADT significantly improved OS compared to placebo plus ADT with a 33 percent reduction in the risk of death (HR=0.67; 95% CI, 0.51-0.89; p=0.0053).[1] In both study arms, median OS was not reached.[1] Apalutamide plus ADT also significantly improved rPFS compared to placebo plus ADT with a 52 percent reduction in risk of radiographic progression or death compared to placebo plus ADT (HR=0.48; 95% CI, 0.39-0.60; p<0.0001).[1] The median rPFS was 22.1 months for placebo plus ADT and not reached for apalutamide plus ADT.[1] The two-year OS

rates, after a median follow up of 22.7 months, were 82 percent for apalutamide plus ADT compared to 74 percent for placebo plus ADT.[1] These results were presented at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting and simultaneously published online in *The New England Journal of Medicine.*[1,3]

The safety profiles for apalutamide plus ADT, versus placebo plus ADT, were similar with 42 percent versus 41 percent of Grade 3/4 adverse events (AEs) observed respectively.[1] The most common Grade ≥3 AEs for apalutamide plus ADT versus placebo plus ADT were hypertension (8.4 percent vs. 9.1 percent) and skin rash (6.3 percent vs. 0.6 percent). Treatment discontinuation due to AEs was 8 percent in the apalutamide arm compared to 5 percent in the placebo arm.[1]

"Today's Positive Opinion for apalutamide brings us one step closer to providing a much-needed treatment option for a broad population of patients diagnosed with mHSPC," said Joaquín Casariego, M.D., Janssen Therapeutic Area Lead Oncology for Europe, Middle East & Africa, Janssen-Cilag S.A. "At this stage of disease, it is critical to intervene with another treatment that can prolong survival and delay progression to the fatal stage, without compromising the quality of life of patients. We look forward to the EC approval of apalutamide in this setting so we can bring this innovative medicine to patients as soon as possible."

"We are pleased with the CHMP's Opinion to recommend approval of apalutamide as a treatment for patients with mHSPC," said Craig Tendler, M.D., Vice President, Clinical Development and Global Medical Affairs, Oncology at Janssen Research & Development, LLC. "Results from the TITAN study demonstrated that the addition of apalutamide to ADT improved outcomes for a broad range of patients with mHSPC, compared to ADT alone, highlighting the significance of today's Opinion. At Janssen, we continue to focus on addressing crucial areas of unmet need in prostate cancer within our clinical trial programme and are committed to further exploring how to improve outcomes for patients across the entire disease continuum."

In Europe, apalutamide is approved for use in adults with non-metastatic castration-resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease.[4] In the United States apalutamide is indicated for the treatment of nmCRPC and metastatic castration-sensitive prostate cancer (mCSPC).[5]

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About the TITAN Study[1,3]

TITAN is a Phase 3 randomised, placebo-controlled, double-blind study in men with mHSPC regardless of extent of disease or prior docetaxel treatment history. The study included 1,052 patients in intention-to-treat (ITT) population in 23 countries across 260 sites in North America, Latin America, South America, Europe and Asia Pacific. Patients with mHSPC were randomised 1:1 and received either apalutamide (240 mg) plus continuous androgen deprivation therapy (ADT) (n=525), or placebo plus ADT (n=527). The recruitment period for the study spanned from December 2015 to July 2017. The study included mHSPC patients with both low- and high-volume disease, those who were newly diagnosed, or those who had received prior definitive local therapy or prior treatment with up to six cycles of docetaxel or up to six months of ADT for mHSPC. Participants were treated until disease progression or the occurrence of unacceptable treatment-related toxicity. An independent data-monitoring committee was commissioned by the sponsor to monitor safety and efficacy before unblinding and make study conduct recommendations. Dual primary endpoints of the study were OS and rPFS. Secondary endpoints included time to cytotoxic chemotherapy, time to pain progression, time to chronic opioid use and time to skeletal-related event. Exploratory endpoints included time to PSA progression, time to second progression-free survival and time to symptomatic progression. For additional study information, visit ClinicalTrials.gov.

About apalutamide

Apalutamide is an androgen receptor (AR) inhibitor indicated for use in Europe for the treatment of patients with non-metastatic castration-resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease.[4] In the U.S. apalutamide is indicated for the treatment of nmCRPC and metastatic hormone-sensitive prostate cancer (mHSPC).[5]

About Metastatic Hormone-Sensitive Prostate Cancer

Metastatic hormone-sensitive prostate cancer (mHSPC), also referred to as metastatic castration sensitive prostate cancer (mCSPC), refers to prostate cancer that still responds to androgen deprivation therapy (ADT) and has spread to other parts of the body.[6] Patients with mHSPC tend to have a poor prognosis, with a median overall survival (OS) of less than five years, underscoring the need for new treatment options.[7,8,9]

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About the Janssen Pharmaceutical Companies of Johnson & Johnson

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

Learn more at www.janssen.com/emea. Follow us at www.twitter.com/janssenEMEA for our latest news. Janssen Research & Development, LLC and Janssen-Cilag S.A. 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 potential benefits and further benefits of Erleada (apalutamide). 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 materialize, actual results could vary materially from the expectations and projections of Janssen-Cilag S.A., 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 behavior 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 December 30, 2018, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, 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 nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

References

[1] Chi, K.N. *et al*. Apalutamide for Metastatic, Castration-Sensitive Prostate Cancer. *N Engl J Med* 2019; 381:13-24.
[2] European Medicines Agency. Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 9-12 December 2019. Available at: https://www.ema.europa.eu/en/news/meeting-highlights-committee-medicinal-products-human-use-chmp-9-12-december-2019. Last accessed December 2019.
[3] Chi, K.N. First results from TITAN: A phase III double-blind, randomized study of apalutamide versus placebo in patients with metastatic castration-sensitive prostate cancer receiving androgen deprivation therapy. American Society of Clinical Oncology Annual Meeting 2019. Abstract #5006.
[4] European Medicines Agency. Erleada Summary of Product Characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/erleada-epar-product-information_en.pdf. Last accessed December 2019.
[5] Erleada product information Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/210951s001lbl.pdf. Last accessed December 2019.
[6] Cancer.net. Prostate Cancer: Treatment Options. Available at: http://www.cancer.net/cancer-types/prostate-cancer/treatment-options. Last accessed December 2019.
[7] American Cancer Society. Survival rates for prostate cancer. Available at: https://www.cancer.org/cancer/prostate-cancer/detection-diagnosis-staging/survival-rates.html. Last accessed December 2019.
[8] European Association of Urology. Updated guidelines for metastatic hormone-sensitive prostate cancer: abiraterone acetate combined with castration is another standard. Available at: https://uroweb.org/wp-content/uploads/Mottet-N.-et-al.-Eur-Urol-733316-321.-Updated-Guidelines-for-Metastatic-Hormone-sensitive-PCa-Abiraterone-Acetate.pdf. Last accessed December 2019.
[9] Fizazi K. *et al*. Abiraterone plus Prednisone in Metastatic, Castration-Sensitive Prostate Cancer. *N Engl J Med* 2017; 377:352-360.

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