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Janssen Seeks to Expand Use of ERLEADA® (apalutamide) in the Treatment of Patients with Metastatic Hormone-Sensitive Prostate Cancer

Application supported by data from the Phase 3 TITAN study which were recently presented at the 2019 ASCO Annual Meeting and simultaneously published in The New England Journal of Medicine.[1,2]

BEERSE, BELGIUM, 4th June, 2019 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today the submission of a Type II variation to the European Medicines Agency (EMA) seeking approval of ERLEADA® (apalutamide) for the treatment of patients with metastatic hormone-sensitive prostate cancer (mHSPC), regardless of extent of disease or prior docetaxel treatment history. The submission is based on findings from the Phase 3 TITAN study which were presented at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting and simultaneously published online in *The New England Journal of Medicine.*[1,2]

The submission to the EMA follows the submission of supplemental registration dossiers to the U.S. Food and Drug Administration (FDA) on 29th April 2019 and to the Japanese Ministry of Health, Labour and Welfare (MHLW) on 31st May 2019 seeking approval of a new indication for apalutamide for the treatment of patients with mHSPC.[3,4]

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"Today's application seeking to expand the approval of apalutamide for the treatment of patients with mHSPC marks an important step in our continued focus and commitment to bring innovative medicines forward in the treatment of prostate cancer," said Dr. Joaquín Casariego, Janssen Therapeutic Area Lead Oncology for Europe, Middle East & Africa, Janssen-Cilag S.A. "We look forward to working with the EMA to expand access to this next-generation androgen receptor inhibitor for those patients who may benefit from this treatment in the future."

Results from the Phase 3 TITAN study showed patients with mHSPC, treated with apalutamide plus androgen deprivation therapy (ADT) significantly extended overall survival (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).[2] In both study arms, median OS was not reached.[2] 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.[2] 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.[2]

Adverse events (AEs) were generally consistent with the known apalutamide safety profile. The incidence of Grade 3/4 AEs for apalutamide plus ADT, versus placebo plus ADT were similar (42 percent vs 41 percent).[2] 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).[2] Additional reported Grade ≥3 AEs for apalutamide plus ADT versus placebo plus ADT were back pain (2.3 percent vs. 2.7 percent), blood alkaline phosphatase increased (0.4 percent vs. 2.5 percent) and anemia (1.7 percent vs. 3.2 percent).[2] Treatment discontinuation due to AEs was 8 percent in the apalutamide arm compared to 5 percent in the placebo arm.[1] Rash of any grade was more common among patients treated with apalutamide plus ADT, versus placebo plus ADT (27 percent vs 9 percent, respectively).[2]

In Europe, apalutamide is currently approved for use in adults with non-metastatic castration-resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease.[5] In the U.S. apalutamide is indicated for the treatment of nmCRPC.[6]

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About the TITAN Study[1,2]

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 ERLEADA

ERLEADA® (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.[5] In the U.S. apalutamide is indicated for the treatment of nmCRPC.[6]

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.[7] Patients with mHSPC tend to have a poor prognosis, with a median OS of less than five years, underscoring the need for new treatment options.[8,9,10]

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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-Cilag S.A. is part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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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

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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

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