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Janssen Announces European Commission Approval for Expanded Use of Erleada®▼ (apalutamide) for Treatment of Patients with Metastatic Hormone-Sensitive Prostate Cancer

- *Latest approval for apalutamide could benefit a population of more than 100,000 people living with mHSPC across Europe*[1]

BEERSE, BELGIUM, 29 January, 2020 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced that the European Commission (EC) has granted marketing authorisation for the expanded 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).

"Prostate cancer is the most prevalent form of cancer in men throughout Europe, and the expanded approval of apalutamide marks a significant advancement for those living with mHSPC," said Prof. Dr. med. Axel S. Merseburger, Chairman of the Department of Urology, Campus Lübeck, University Hospital Schleswig-Holstein, Kiel, Germany. *"In prostate cancer treatment, our primary goal is always to delay progression of disease and prolong survival, to ensure the best possible outcomes for patients. Today's news is therefore an encouraging development for patients within Europe, for whom the importance of an additional treatment option that can both delay progression and extend survival cannot be underestimated."*

The EC approval is based on data from the Phase 3 TITAN study, which assessed the addition of apalutamide to ADT 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).[2] 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).[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).[2] 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] These results were published in *The New England Journal of Medicine.*[2,3]

The safety profile observed in the TITAN study for apalutamide plus ADT was consistent with that described in previous studies. In the study, 42 percent of patients on apalutamide plus ADT experienced Grade 3/4 adverse events (AEs), compared to 41 percent of patients on placebo plus ADT.[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). Treatment discontinuation due to AEs was 8 percent in the apalutamide arm compared to 5 percent in the placebo arm.[2]

"We are delighted with the EC's approval of the extended use of apalutamide, which makes an important treatment option potentially available to over 100,000 patients living with mHSPC across Europe," said Joaquín Casariego, M.D., Janssen Therapeutic Area Lead Oncology for Europe, Middle East & Africa, Janssen-Cilag S.A. *"It is vital to fight cancer at this stage of the disease with an efficacious new line of treatment, to delay progression to the late and fatal mCRPC stage and, crucially, prolong survival. Janssen remains committed to transforming treatment outcomes for patients and improving lives throughout the prostate cancer journey."*

"We continue to be encouraged by the clinical trial data for apalutamide, which demonstrates that the addition of apalutamide to ADT improves outcomes for a broad range of patients with mHSPC, compared to ADT alone," said Craig Tendler, M.D., Vice President, Clinical Development and Global Medical Affairs, Oncology at Janssen Research & Development, LLC. *"This approval is welcome news for patients with mHSPC and highlights our focus of addressing areas of high unmet need across the prostate cancer disease continuum."*

In Europe, apalutamide is also approved for use in adults with non-metastatic castration-resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease.[4]

#ENDS#

About the TITAN Study[2,3]

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 a broad population of patients with mHSPC, including 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 and metastatic hormone-sensitive prostate cancer (mHSPC).[4] In the U.S. apalutamide is indicated for the treatment of nmCRPC and 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]

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.

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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 the benefits of apalutamide for the treatment of patients with metastatic hormone-sensitive 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 of the 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 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. Neither the Janssen Pharmaceutical Companies of Johnson & Johnson nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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