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Janssen Announces Treatment with ERLEADA®▼ (apalutamide) Significantly Improved Overall Survival in Patients with Metastatic Hormone-Sensitive Prostate Cancer

Final analysis from Phase 3 TITAN study demonstrated apalutamide provided statistically significant overall survival benefit and consistent safety profile in patients with metastatic hormone-sensitive prostate cancer

BEERSE, BELGIUM February 9, 2021 – Janssen Pharmaceutica NV (Janssen) announced today results from the final analysis of the Phase 3 TITAN study, which demonstrated the continued statistically significant benefit of apalutamide plus androgen deprivation therapy (ADT) in overall survival (OS) in patients with metastatic hormone-sensitive prostate cancer (mHSPC) when compared to placebo plus ADT.[1] Results will be featured in an oral presentation at the American Society of Clinical Oncology's Genitourinary (ASCO GU) Cancers Symposium, taking place virtually February 11-13, 2021 (Abstract #11; Rapid Abstract Session: Prostate Cancer, February 11 9:30 PM-10:15 PM CET).

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With nearly four years of median follow-up, data from the final analysis of the Phase 3 TITAN study confirmed that apalutamide plus ADT provided statistically significant improvement in OS with a 35 percent reduction in risk of death compared to ADT alone (HR 0.65; p<0.0001).[1] This result was almost similar to the OS results in the primary analysis of TITAN despite the subsequent crossover rate of almost 40 percent of the placebo-controlled group to the apalutamide arm.[1] The improvement in OS increased to a 48 percent reduction in risk of death after adjusting for patients who crossed over (HR 0.52; p<0.0001).[1]

"Janssen is committed to uncovering new solutions for patients with prostate cancer as until very recently, there has been little advancement in treatment options for people with metastatic hormone-sensitive prostate cancer,"[2] said Dr Catherine Taylor, Vice-president, Medical Affairs, Therapeutic Area Strategy for Europe, Middle East and Africa, Johnson & Johnson Middle East FZ-LLC. "The results of the TITAN final analysis demonstrate that apalutamide with ADT provides a new therapeutic option for people living with advanced, hormone-sensitive prostate cancer."

There was consistent benefit across other endpoints, including improved second progression-free survival (PFS2) (HR 0.62; p<0.0001) and delayed time to castration resistance (HR 0.34; p<0.0001).[1] In addition, health-related quality of life (HRQoL), per total Functional Assessment of Cancer Therapy–Prostate (FACT-P), continued to be maintained in both groups. Safety of apalutamide was consistent with previously reported studies.[1] Observed adverse events included skin rash, fracture, and falls.[1]

"The TITAN final analysis is a welcome development for the management of metastatic hormone-sensitive-prostate cancer[2] as the data show us that apalutamide with ADT improves long-term clinical benefit and prolonged overall survival, without compromising health-related quality of life for these patients," said Professor Axel Merseburger, Chairman of the Clinic of Urology, Universitatsklinikum Schleswig-Holstein and investigator of the TITAN study. "The results also demonstrate an established safety profile which is encouraging for the management of patients living with advanced forms of prostate cancer."

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Initial results from the TITAN study presented at the 2019 American Society of Clinical Oncology Annual Meeting (ASCO) and simultaneously published in *The New England Journal of Medicine* showed the addition of apalutamide to ADT compared to placebo plus ADT significantly improved the dual primary endpoints of OS and radiographic progression-free survival (rPFS) in patients with mHSPC.[3]

To date, published results on apalutamide include data from more than 2,000 patients across Phase 3 clinical studies.[3] Apalutamide has shown a statistically significant improvement in OS with a consistent safety profile in both approved indications of mHSPC (TITAN) and non-metastatic castration-resistant prostate cancer or nmCRPC (SPARTAN).[3]

**Professor Axel Merseburger is an investigator of the TITAN study and has been compensated for media work.*

#ENDS#

About the TITAN Study[3,4]

TITAN (NCT02489318) is a Phase 3, randomised, placebo-controlled, double-blind study in patients with mHSPC. The study included 1,052 patients 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 ADT (n=525), or placebo plus ADT (n=527). The recruitment period for the study spanned from December 2015 to July 2017.[3,4] The study included patients with mHSPC with both low- and high-volume disease, those who were newly diagnosed, and those who had received prior definitive local therapy or prior treatment with up to six cycles of docetaxel for mHSPC.[3,4]

An Independent Data-Monitoring Committee was commissioned by the sponsor to monitor safety and efficacy.[5] Dual primary endpoints of the study were OS and rPFS.[1] Secondary endpoints included time to cytotoxic chemotherapy, time to pain progression, time to chronic opioid use, and time to skeletal-related events.[3,4] Exploratory endpoints included time to prostate specific antigen (PSA) progression, PFS2 and time to symptomatic progression.[3,4] For additional study information, visit ClinicalTrials.gov.

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About Metastatic Hormone-Sensitive Prostate Cancer

Metastatic hormone-sensitive prostate cancer, also known as metastatic castration-sensitive prostate cancer (mCSPC), refers to prostate cancer that still responds to hormonal therapy and has spread beyond the prostate to other parts of the body.[5]

About apalutamide

Apalutamide is an orally administered, selective androgen receptor (AR) inhibitor approved in Europe and is indicated in:

- adult men for the treatment of non-metastatic castration-resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease, and
- in adult men for the treatment of metastatic hormone-sensitive prostate cancer (mHSPC), also known as metastatic castration-sensitive prostate cancer (mCSPC), in combination with androgen deprivation therapy (ADT).[6]

▼ *This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.*

About 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 Pharmaceutica NV is part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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Cautions Concerning Forward-Looking Statements

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This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding 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 materialise, actual results could vary materially from the expectations and projections of Janssen Pharmaceutica NV, and/or 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 29, 2019, 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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