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Long-Term ERLEADA®▼ (apalutamide) Patient-Reported Outcomes Data in Metastatic Hormone-Sensitive Prostate Cancer Demonstrate Maintenance of Health-Related Quality of Life for Patients

Results at ASCO from Phase 3 TITAN study final analysis confirm survival benefit achieved with the addition of apalutamide to androgen deprivation therapy while maintaining health related quality of life

May 26, 2021 (BEERSE, BELGIUM) – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced patient-reported outcomes (PRO) data from the pre-specified final analysis of the Phase 3 TITAN study in patients with metastatic hormone-sensitive prostate cancer (mHSPC). The TITAN study previously demonstrated improvement in overall survival (OS) after a median follow-up of 44 months in patients receiving apalutamide plus androgen deprivation therapy (ADT).[1] The new PRO data showed that the addition of apalutamide to ADT maintained patients' health-related quality of life (HRQoL) and did not worsen side effect burden, consistent with ADT alone.[2] These data are being presented at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting, June 4-8 (Abstract #5068).

"Patients are often concerned about the added burden of side effects in their disease management," said Professor Axel Merseburger, M.D., PhD, Chairman of the Clinic of Urology at University Hospital Schleswig-Holstein in Lübeck and investigator for TITAN.* "The latest findings from the TITAN clinical trial show us how we can improve patient overall survival without compromising on quality of life, an important step in the right direction for improved advanced prostate cancer care."

HRQoL in both groups, patients who received apalutamide plus ADT and patients who received placebo plus ADT, was maintained throughout the study. Overall, patients in both groups reported a good baseline HRQoL; the outcomes were assessed using the Brief Pain Inventory-Short Form (BPI-SF) and Functional Assessment of Cancer Therapy-Prostate (FACT-P) questionnaires.[2] On the BPI pain severity scale of zero (no pain/interference in daily activities) to 10 (worst pain/interference), median patient scores were 1.1 in the apalutamide group and 1 in the placebo plus ADT group. On the FACT-P HRQoL scale (1-156, higher score = better quality of life), median patient scores were 113 in the apalutamide group and 113.3 in the placebo plus ADT group.[2] Apalutamide plus ADT was also shown to maintain physical, social and family, emotional, functional, and mental well-being beyond two years, as assessed by FACT-P. There were no significant differences between groups in median time to deterioration in any BPI or FACT-P scores, further demonstrating maintenance of quality of life with apalutamide.[2]

Apalutamide has previously shown improvement in OS for both of its approved indications in prostate cancer, specifically mHSPC (TITAN study) and non-metastatic castration-resistant prostate cancer (SPARTAN study).[3] The TITAN final analysis data, presented at the 2021 ASCO Genitourinary Cancers Symposium and recently published in the *Journal of Clinical Oncology,* reaffirmed that the addition of apalutamide to ADT continued to provide OS benefit after 44 months in patients with mHSPC. Apalutamide plus ADT reduced the risk of death by 35 percent compared with ADT alone (hazard ratio [HR]=0.65; 95 percent confidence interval [CI], 0.53-0.79; $P<0.0001$). [1]

"We are pleased to be able to share the patient reported outcome results from the TITAN study at ASCO this year. We know they are essential in providing meaningful context on the patient experience of treatment with apalutamide plus androgen deprivation therapy for metastatic hormone-sensitive prostate cancer that enable healthcare professionals to make informed treatment decisions that are right for individual patients," said Dr Catherine

Taylor, EMEA Vice-president, Medical Affairs Therapy Area Strategy for Europe, Middle East and Africa, Johnson & Johnson Middle East FZ-LLC. "These findings, along with the overall survival benefit, provide further evidence on apalutamide plus ADT as a first-line, therapeutic option for people living with mHSPC."

** Dr. Professor Axel Merseburger has been a paid consultant to Janssen; he has not been paid for any media work.*

About Metastatic Hormone-Sensitive Prostate Cancer

Metastatic hormone-sensitive prostate cancer, also known as metastatic castration-sensitive prostate cancer, refers to prostate cancer that still responds to hormonal therapy and has spread beyond the prostate to other parts of the body.[4]

About the TITAN[3,5]

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.[3,6] 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.[3,6]

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 radiographic progression-free survival (rPFS). Secondary endpoints included time to cytotoxic chemotherapy, time to pain progression, time to chronic opioid use, and time to skeletal-related events.[3,6] Exploratory endpoints included time to prostate specific antigen (PSA) progression, PFS2, time to symptomatic progression and HRQoL measures.[3,6] For additional study information, visit ClinicalTrials.gov.

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).[7]

Please click here to see the full Summary of Product Characteristics for apalutamide.

▼ *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 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 Pharmaceutica NV 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 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 Research & Development, LLC 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 January 3, 2021, 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.

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[2] Agarwal, N. et al. Health-related quality of life (HRQoL) and patient-reported outcomes at final analysis of the TITAN study of apalutamide (APA) versus placebo (PBO) in patients (pts) with metastatic castration-sensitive prostate cancer (mCSPC) receiving androgen deprivation therapy (ADT). https://meetinglibrary.asco.org/record/197750/abstract. Accessed May 2021.
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[6] Chi, K. Final Analysis Results From TITAN: A Phase 3 Study of Apalutamide (APA) vs Placebo (PBO) in Patients (pts) With Metastatic Castration-Sensitive Prostate Cancer (mCSPC) Receiving Androgen Deprivation Therapy (ADT). ASCO GU 2021 oral presentation.
[7] European Medicines Agency. ERLEADA. Available at: https://www.ema.europa.eu/en/documents/product-information/erleada-epar-product-information_en.pdf. Accessed May 2021.