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Health Canada Approves New Indication for ERLEADA®* (apalutamide) for the Treatment of Metastatic Castration-Sensitive Prostate Cancer (mCSPC)

In the Phase 3 TITAN study, ERLEADA®, in combination with androgen deprivation therapy, achieved statistical significance in dual primary endpoints of overall survival and radiographic progression-free survival in patients with mCSPC regardless of extent of disease

TORONTO, ON, December 16, 2019 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that Health Canada, following a Priority Review, has approved ERLEADA® (apalutamide) for the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC).[1]

This approval is based on results from the Phase 3 TITAN study, which achieved statistical significance in the dual primary endpoints of overall survival (OS) and radiographic progression-free survival (rPFS) at the first pre-planned interim analysis.[2] The trial recruited patients with both high- and low-volume disease burden, high- and low-risk disease, and previously treated, relapsed or newly diagnosed disease.[1,3] Results were presented at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting and simultaneously published in *The New England Journal of Medicine*.

Prior to this approval, there has not been a treatment option in Canada that delays disease progression and extends overall survival for patients with prostate cancer regardless of their disease stage, risk or disease volume.

"Given the urgency to delay the progression of metastatic prostate cancer, there continues to be a need for additional therapeutic options beyond traditional androgen deprivation therapy," said Dr. Fred Saad, Professor and Chief of Urology, University of Montreal Hospital Center.** "This new indication for ERLEADA® represents an important advancement for patients regardless of the extent of their disease and may enable some patients with mCSPC to live longer."

In the TITAN study, ERLEADA® plus androgen deprivation therapy (ADT) significantly extended OS compared to placebo plus ADT, with a 33 per cent reduction in the risk of death (HR=0.67; 95 per cent CI, 0.51-0.89; P=0.0053).[1] ERLEADA® plus ADT also significantly improved rPFS compared to placebo plus ADT, with a 52 per cent lower risk of radiographic progression or death (HR=0.48; 95 per cent CI, 0.39-0.60; P<0.0001).[1] As reported in the published results from the TITAN study, the two-year OS rates, after a median follow-up of 22.7 months, were 82 per cent for ERLEADA® plus ADT compared to 74 per cent for placebo plus ADT.[2] Based on these results, the Independent Data-Monitoring Committee recommended unblinding the study to allow crossover of patients receiving placebo plus ADT to receive ERLEADA® plus ADT.

"While the relative survival rate for regional or localized prostate cancer is nearly 100 per cent after five years, we still lose three in four patients with distant or advanced prostate cancer," said Dr. Stuart Edmonds, Vice President, Research, Health Promotion and Survivorship, Prostate Cancer Canada.*** "Canadian families facing mCSPC need more treatment options to help them live longer and spend more time together, and we are pleased that there is an option to fill that gap."

About the TITAN Study[1]

TITAN is a Phase 3, randomized, placebo-controlled, double-blind study in patients with mCSPC. 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 mCSPC were randomized 1:1 and received either ERLEADA® (240 mg) plus ADT (n=525) or placebo plus ADT (n=527).[1] The recruitment period for the study spanned from December 2015 to July 2017.[2] The study included patients with mCSPC, including those with high- or low-volume disease, previous docetaxel use, previous treatment for localized disease, and those who had either relapsed from localized prostate cancer or newly diagnosed disease.[1]

An Independent Data-Monitoring Committee was commissioned to monitor safety and efficacy.[1] 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 event.[1] Exploratory endpoints included time to PSA progression, PFS2, health-related quality of life (HRQOL) and time to symptomatic local progression.[2] For additional study information, visit ClinicalTrials.gov.

The most common adverse reactions (≥15 per cent) that occurred more frequently in ERLEADA®-treated patients (≥2 per cent over placebo) from the randomized placebo-controlled clinical trial were hot flush, fatigue, arthralgia, rash and hypertension.[1]

About Prostate Cancer and mCSPC

Prostate cancer is the most common cancer among Canadian men.[3] Approximately one in seven men will be diagnosed with prostate cancer in their lifetime and one in 29 will die from the disease.[4]

Metastatic castration-sensitive prostate cancer (mCSPC), also known as metastatic hormone-sensitive prostate cancer (mHSPC), refers to prostate cancer that still responds to androgen deprivation therapy (ADT) and has spread beyond the

prostate to other areas of the body.[5]

About ERLEADA®

ERLEADA® is an androgen receptor (AR) inhibitor indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer (nmCRPC) and for the treatment of patients with mCSPC.[1]

ERLEADA® received Health Canada approval for nmCRPC on July 3, 2018 and was approved for mCSPC on December 13, 2019. ERLEADA® is taken orally, once daily, with or without food.[1]

The Canadian Urological Association (CUA) and the Canadian Urological Oncology Group (CUOG) Guidelines for Castration-Resistant Prostate Cancer (CRPC) recommend clinicians offer apalutamide (ERLEADA®) as a treatment option for patients living with high-risk nmCRPC, defined as a PSA doubling time (PSADT) of less than 10 months, with an estimated life expectancy of greater than five years.[6]

For full Product Monograph and more information about ERLEADA®, please visit www.janssen.com/canada.

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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***Dr. Saad was not compensated for any media work. He has been compensated as a consultant.*

****Prostate Cancer Canada was not compensated for any media work. Prostate Cancer Canada has received funds for patient engagement.*

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding ERLEADA®. 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 Inc., 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

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