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ERLEADA® (apalutamide) 240 mg Approved as the Only Androgen Receptor Inhibitor with a Once-Daily Single-Tablet Option in Canada

Health Canada's approval of a new 240mg strength tablet will provide patients and their care providers with additional dosing options to address a variety of treatment needs

Toronto, August 9, 2023/CNW/ – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that Health Canada has issued a Notice of Compliance (NOC) authorizing the use of ERLEADA® (apalutamide) in an additional strength of a 240mg tablet. ERLEADA® 240 mg is now the only *once-daily, single-tablet* Androgen Receptor Inhibitor (ARI) approved by Health Canada for the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC) as well as patients with non-metastatic castration-resistant prostate cancer (nmCRPC).[1]

The introduction of the 240mg tablet allows healthcare professionals to prescribe ERLEADA® in either one 240mg tablet or four 60mg tablets[1] based on the needs and preferences of each patient. The *once-daily tablet option* of the 240 mg tablet also provides patients with additional methods of dosing[1] which may support medication adherence and be a convenient solution for patients who wish to reduce their total number of daily pills.[2]

"The availability of one tablet, administered once daily, with or without food, will give patients more flexibility in their treatment options and potentially simplify their daily medication routines," says Dr. Shawn Malone*, Professor, University of Ottawa, and Radiation Oncologist, The Ottawa Hospital. "No two cancer journeys are the same. A simple change like expanding available dosing and administration options can make a significant difference in how someone manages their disease."

It is estimated that 24,600 Canadians were diagnosed with prostate cancer in 2022.[3] It remains one of the most common cancers among Canadians.[3]

"At Janssen, we have remained steadfast in our dedication to bring treatment options that truly support the cancer journey," says Berkeley Vincent, President, Janssen Inc. "Expanding dosing and administration options for ERLEADA® means patients can receive treatment in a way that better aligns with their lifestyles and could help improve their quality of life."

The recommended dose of ERLEADA® is 240 mg (one 240 mg tablet or four 60 mg tablets) administered orally once daily.[1] For patients who have difficulty swallowing whole tablets, the 240mg tablet is approved for additional methods of administration when mixed in non-fizzy beverages or soft foods: orange juice, green tea, applesauce or drinkable yogurt. In addition, ERLEADA® 240 mg tablet can also be administered through a nasogastric tube (NG tube) for patients on enteral tube feeding. The ERLEADA® 60mg tablet was approved by Health Canada in 2021 for optional administration in applesauce.[1]

Both tablet strengths are available via prescription through a healthcare professional.

About ERLEADA®

ERLEADA® (apalutamide) is an androgen receptor inhibitor indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer (nmCRPC) and for the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC).[1] ERLEADA® received Health Canada approval for the treatment of patients with non-metastatic castration-resistant prostate cancer (nmCRPC) in July 2018, and received Health Canada approval for the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC) in December 2019.

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 & Retina; Immunology; Infectious Diseases & Vaccines; Neuroscience; Oncology; and Pulmonary Hypertension.

Learn more at www.janssen.com/canada. Follow us at www.twitter.com/JanssenCanada. Janssen Inc. 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 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 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 January 1, 2023, including in the sections captioned

"Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other 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.

*Dr. Shawn Malone was not compensated for any media work. He has been compensated previously by Janssen for other professional engagements.

References

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