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Janssen receives positive CHMP opinion for ERLEADA™ (apalutamide) for patients with non-metastatic castration-resistant prostate cancer who are at high risk of developing metastatic disease

- *Approval is based on Phase 3 SPARTAN clinical study data which showed apalutamide decreased the risk of distant metastasis or death by 72 percent and improved median metastasis-free survival by more than two years*[1]
- *The major efficacy outcome was supported by statistically significant improvements for secondary endpoints, including time to metastasis, progression-free survival, and time to symptomatic progression*[1]

BEERSE, BELGIUM, November 16, 2018 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion for apalutamide, a next generation oral androgen receptor inhibitor for the treatment of adult patients with non-metastatic castration-resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease.[2] The CHMP's positive opinion will now be reviewed by the European Commission (EC), which has the authority to grant approval for the use of apalutamide.

The CHMP's positive opinion is based on data from the pivotal SPARTAN Phase 3 clinical study which assessed the safety and efficacy of apalutamide versus placebo in patients with nmCRPC who have a rapidly rising prostate specific antigen (PSA) level despite receiving continuous androgen deprivation therapy (ADT). The SPARTAN clinical study showed that apalutamide, when added to ADT, significantly reduced the risk of developing distant metastasis or death (metastasis free survival [MFS]) by 72 percent, compared to placebo in combination with ADT (HR = 0.28; 95% CI, 0.23-0.35; P < 0.001). The median MFS was improved by over two years (40.5 months vs 16.2 months)

in patients with nmCRPC whose PSA is rapidly rising.[1] This study was published in *The New England Journal of Medicine*.

The most common Grade 3/4 treatment-emergent adverse events in the SPARTAN study were hypertension (14.3 percent vs. 11.8 percent), rash (5.2 percent vs. 0.3 percent), fall (1.7 percent vs. 0.8 percent) and fracture (2.7 percent vs. 0.8 percent). Treatment discontinuation due to adverse events was 11 percent in the apalutamide arm compared to 7 percent in the placebo arm. Rates of serious adverse events were similar in the apalutamide in combination with ADT arm versus placebo in combination with ADT arm (25 percent vs. 23 percent respectively).[1]

"Data from the SPARTAN study showed that apalutamide significantly improves metastasis free survival for patients with castration-resistant prostate cancer," said Dr Simon Chowdhury, Consultant Medical Oncologist, Guy's and St Thomas' Hospitals. *"Nearly 90 percent of patients with castration-resistant prostate cancer will eventually develop bone metastases. At that point their prognosis worsens dramatically. Delaying the spread of cancer is therefore critical for patients living with prostate cancer."*

"*We are pleased with the CHMP's decision to recommend approval of apalutamide for the treatment of patients with high-risk non-metastatic castration-resistant prostate cancer*," said Dr. Ivo Winiger-Candolfi M.D., Janssen Oncology Solid Tumor Therapy Area Lead, Europe, Middle East and Africa, Cilag GmbH International. "*We know that each prostate cancer patient journey is unique and today's positive CHMP opinion brings us one step closer to offering patients an effective treatment option that delays the spread of their disease."*

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About Non-Metastatic Castration-Resistant Prostate Cancer

Non-metastatic castration-resistant prostate cancer (CRPC) refers to a disease stage when the cancer no longer responds to medical or surgical treatments that lower testosterone, but has not yet been discovered in other parts of the body using a bone scan or CT scan.[3] Features include: lack of detectable metastatic disease; rapidly rising prostate-specific antigen while on androgen deprivation therapy (ADT) and serum testosterone level below 50 ng/dL.[3] Ninety percent of patients with non-metastatic CRPC will eventually develop bone metastases, which can lead to pain,

fractures and spinal cord compression.[4] The relative 5-year survival rate for patients with distant stage castration sensitive or castration resistant prostate cancer is 30 percent.[5,6]

About apalutamide

Apalutamide is an investigational, next-generation oral androgen receptor (AR) inhibitor that blocks the androgen signaling pathway in prostate cancer cells. Apalutamide inhibits the growth of cancer cells in three ways: by preventing the binding of androgen to the AR; by stopping the AR from entering the cancer cells; and by preventing the AR from binding to the DNA of the cancer cell.[7]

Janssen submitted a Marketing Authorisation Application to the European Medicines Agency (EMA) in February 2018 seeking approval for apalutamide for the treatment of patients with high-risk non-metastatic castration-resistant prostate cancer (nmCRPC). Apalutamide received approval from the United States Food and Drug Administration for the treatment of patients with nmCRPC in February 2018, shortly followed by approvals in Canada, Australia, Argentina and Brazil.[8,9,10,11]

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science. We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at www.janssen.com/emea. Follow us at http://www.twitter.com/janssenEMEA. Janssen-Cilag International N.V. and Cilag GmbH International are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

[*]Dr Chowdhury is lead investigator on the SPARTAN study. He was not compensated for any media work.

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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 product development and the potential benefits and treatment impact of 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 materialise, actual results could vary materially from the expectations and projections of Janssen-Cilag International NV, 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 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 31, 2017, 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 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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