

Media Enquiries:

Laura Coughlan
Phone: +353 87 147 9356

Investor Relations:

Christopher DeLorefice
Office: +1 732-524-2955

Lesley Fishman
Office: +1 732-524-3922

Janssen announces European Commission approval of ERLEADA[®] (apalutamide) for non-metastatic castration-resistant prostate cancer patients who are at high risk of developing metastatic disease

- *Phase 3 SPARTAN data served as basis for approval, which showed apalutamide decreased the risk of distant metastasis or death by 72 percent and improved median metastasis-free survival by more than two years¹*

BEERSE, BELGIUM, XX, 2019 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced that the European Commission (EC) has granted marketing authorisation for ERLEADA[®] (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.

The EC approval is based on data from the pivotal Phase 3 SPARTAN study, which was published in [The New England Journal of Medicine](#). The study assessed the efficacy and safety of apalutamide plus androgen deprivation therapy (ADT) versus placebo plus ADT in patients with nmCRPC who had a rapidly rising prostate specific antigen (PSA) level despite receiving continuous ADT. Findings from the study showed that apalutamide plus 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

"One of the key goals in prostate cancer treatment is to delay the disease from spreading. Once the cancer spreads, it can become less responsive to treatment, impacting patients' quality of life and ultimately worsening their prognosis. Median survival for these patients is approximately three years," said Dr Simon Chowdhury,

Consultant Medical Oncologist, Guy's and St Thomas' Hospitals, London. *"It is crucial that we delay the development of metastases for as long as possible. Therefore, the approval of apalutamide, a treatment which can significantly increase time without metastases, is a major step-forward for patients with prostate cancer."*^{1*}

"Today's approval of apalutamide is a significant milestone and we are pleased that we can now offer patients with high-risk non-metastatic castration-resistant prostate cancer a new treatment option," said Dr Ivo Winiger-Candolfi M.D., Janssen Oncology Solid Tumor Therapy Area Lead, Europe, Middle East and Africa, Cilag GmbH International. *"Bringing medicines to patients at earlier stages of disease is vital, and the approval of apalutamide could mark a step change in how we treat prostate cancer in the future. Crucially, treating patients at this stage could delay the cancer from spreading, a key part of our commitment to patients living with this disease and to their families."*

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

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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.² 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.² Ninety percent of patients with non-metastatic CRPC will eventually develop bone metastases, which can lead to pain, fractures and spinal cord compression.³ The relative 5-year survival rate for patients with distant stage castration sensitive or castration resistant prostate cancer is 30 percent.^{4,5}

About apalutamide

Apalutamide is a 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.⁶

In the United States, apalutamide received approval from the Food and Drug Administration for the treatment of patients with nmCRPC in February 2018, shortly followed by approvals in Canada, Australia, Argentina and Brazil.^{7,8,9,10}

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 <http://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, Cilag GmbH International, 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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References

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- ⁹ ERLYAND[®]. Australian Product Information. Available at: https://www.janssen.com/australia/sites/www.janssen.com_australia/files/prod_files/live/erlyand_pi.pdf Last accessed December 2018.
- ¹⁰ ERLLEADA[®] Identificação Do Medicamento. Available at: https://www.janssen.com/brasil/sites/www.janssen.com_brazil/files/prod_files/live/erleada_pub_vp.pdf. Last accessed December 2018.