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Janssen announces European licence extension for Erleada®▼ (apalutamide) for patients with metastatic hormone-sensitive prostate cancer

High Wycombe, 29 January 2020 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced that the European Commission has granted a licence extension for Erleada® (apalutamide), making it licensed for adult men in the UK with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy (ADT). This builds on the original licence granted in 2019 which included treatment of men with non-metastatic castration-resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease.[1]

Prostate cancer is the most common cancer in men in the UK,[2] resulting in over 47,500 diagnoses each year, or 130 each day.[3] Every 45 minutes, one man dies from prostate cancer, totalling more than 11,500 deaths each year.[3] mHSPC accounts for around 5% of cases of prostate cancer.[4] Those with mHSPC tend to have a poor prognosis, with a median overall survival (OS) of less than five years, underscoring the need for new treatment options.[5,6,7]

The licence extension is based on data from the Phase 3 TITAN study, which assessed the addition of apalutamide to ADT in a broad range of patients with mHSPC, regardless of disease volume, prior treatment with docetaxel or staging at initial diagnosis.[8] The dual primary endpoints of the study were overall survival (OS) and radiographic progression-free survival (rPFS). Apalutamide plus ADT significantly improved OS compared to placebo plus ADT with

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a 33 percent reduction in the risk of death (HR=0.67; 95% CI, 0.51-0.89; p=0.0053).[8] In both study arms, median OS was not reached.[8] Apalutamide plus ADT also significantly improved rPFS compared to placebo plus ADT with a 52 percent reduction in risk of radiographic progression or death compared to placebo plus ADT (HR=0.48; 95% CI, 0.39-0.60; p<0.001).[8] The median rPFS was 22.1 months for placebo plus ADT and not reached for apalutamide plus ADT.[8] The two-year OS rates, after a median follow up of 22.7 months, were 82 percent for apalutamide plus ADT compared to 74 percent for placebo plus ADT.[8]

The safety profiles for apalutamide plus ADT was consistent with that described in previous studies. In TITAN, 42 percent of patients on APA/ADT experienced Grade 3/4 adverse events (AEs) as compared to 41 percent of patients on placebo plus ADT.[8] The most common Grade ≥3 AEs for apalutamide plus ADT versus placebo plus ADT were hypertension (8.4 percent vs. 9.1 percent) and skin rash (6.3 percent vs. 0.6 percent).[8] Treatment discontinuation due to AEs was 8 percent in the apalutamide arm compared to 5 percent in the placebo arm.[8]

Prof Rob Jones, Professor of Clinical Cancer Research at the University of Glasgow said:
“Men who have evidence of cancer having spread to other parts of the body are at high risk of suffering significant symptoms from their disease in the future. Better ways of treating men who have cancer spread are needed not only to allow them to live longer, but also to allow them to continue to live a normal quality of life for as long as possible. This announcement means that there is a new option for these men which can be taken along with standard hormonal therapies which has been shown to prolong the time until the cancer starts to grow again and also to improve survival. It’s important that we acknowledge all the patients who took part in the TITAN trial, including patients in Glasgow, and their families without whom this progress would not have been made.”

Bernardo Soares, Medical Director, Janssen UK said: “We are pleased that the European licence for apalutamide has been extended to include patients with metastatic hormone-sensitive prostate cancer, providing an important treatment option for men in the UK. At Janssen, we remain committed to our goal of developing and delivering innovative medicines that transform treatment outcomes for patients throughout the prostate cancer journey, and today’s approval does just that.”

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About Metastatic Hormone-Sensitive Prostate Cancer

Metastatic hormone-sensitive prostate cancer (mHSPC), also referred to as metastatic castration sensitive prostate cancer (mCSPC), refers to prostate cancer that still responds to androgen deprivation therapy (ADT) and has spread to other parts of the body.[9]

About Apalutamide

Apalutamide is an androgen receptor (AR) inhibitor indicated for use in Europe for the treatment of patients with non-metastatic castration-resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease,[1] and in adult men with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy (ADT).

For a full list of side effects and information on dosage and administration, contraindications and other precautions when using apalutamide please refer to the Summary of Product Characteristics for further information.

About the TITAN Study[8]

TITAN is a Phase 3 randomised, placebo-controlled, double-blind study in men with mHSPC regardless of extent of disease or prior docetaxel treatment history. The study included 1,052 patients in intention-to-treat (ITT) population 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 continuous androgen deprivation therapy (ADT) (n=525), or placebo plus ADT (n=527). The recruitment period for the study spanned from December 2015 to July 2017. The study included mHSPC patients with both low- and high-volume disease, those who were newly diagnosed, or those who had received prior definitive local therapy or prior treatment with up to six cycles of docetaxel or up to six months of ADT for mHSPC. Participants were treated until disease progression or the occurrence of unacceptable treatment-related toxicity.

An independent data-monitoring committee was commissioned by the sponsor to monitor safety and efficacy before unblinding and make study conduct recommendations. Dual primary endpoints of the study were OS and rPFS. Secondary endpoints included time to cytotoxic chemotherapy, time to pain progression, time to chronic opioid use and time to skeletal-related event. Exploratory endpoints included time to PSA progression, time to second progression-free survival and time to symptomatic progression. For additional study information, visit ClinicalTrials.gov.

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/uk. Follow us at www.twitter.com/JanssenUK. Janssen-Cilag Limited is one of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Adverse events should be reported. ▼This medicinal product is subject to additional monitoring and it is therefore important to report any suspected adverse events related to this medicinal product. Reporting forms and information can be found at www.yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Janssen-Cilag Limited on 01494 567447 or at dsafety@its.jnj.com.

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