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Janssen Presents Results from Phase 3 ACIS Study in Patients with Metastatic Castration-Resistant Prostate Cancer Treated with Apalutamide▼ and Abiraterone Acetate Combination

ACIS study meets primary endpoint of improving time to radiographic progression or death in patients with mCRPC

BEERSE, BELGIUM February 9, 2021– Janssen Pharmaceutica NV (Janssen) today announced results from the randomised, double-blind, placebo-controlled Phase 3 ACIS study, which met the primary endpoint of radiographic progression-free survival (rPFS) with a 31 percent reduction in the risk of radiographic progression or death in patients with chemotherapy-naïve metastatic castration-resistant prostate cancer (mCRPC) receiving androgen deprivation therapy (ADT). Patients in the trial received either a combination of apalutamide and abiraterone acetate plus prednisone (combination arm) or placebo and abiraterone acetate plus prednisone (control arm).[1] Results will be featured in an oral presentation at the American Society of Clinical Oncology's Genitourinary (ASCO GU) Cancers Symposium, taking place virtually February 11-13, 2021 (Abstract #9; Rapid Abstract Session: Prostate Cancer, February 11, 06:45 AM-8:00 PM CET).

The primary efficacy analysis showed median rPFS was extended by six months in patients treated in the combination arm compared with patients in the control arm (22.6 vs 16.6 months; hazard ratio [HR] 0.69 [95% CI, 0.58-0.83]; p<0.0001). The HR for radiographic progression or death as assessed by blinded independent central review (BICR) was 0.864 [95% CI, 0.718–1.040]. According to an updated analysis performed at a median follow-up of 54.8 months, a 30 percent reduction in the risk of radiographic progression or death was shown in the combination arm compared with the control arm (median time to rPFS 24 vs 16.6 months: HR 0.70 [95% CI, 0.60-0.83]). No statistically significant difference was demonstrated for secondary endpoints including overall survival (OS), time to initiation of cytotoxic chemotherapy, chronic opioid use, and pain progression between treatment arms.

The safety profile was consistent with prior studies of apalutamide, with no new safety signals observed. Grade 3/4 treatment emergent adverse events (TEAEs) were reported in 63.3 percent in the combination arm versus 56.2 percent in the control arm.[1] Grade 3/4 TEAEs that occurred more frequently in the combination versus control arm included fatigue (4.7 percent versus 3.9 percent), hypertension (20.6 percent vs. 12.5 percent), fall (3.3 percent vs. 0.6 percent), skin rash (4.5 percent vs. 0.4 percent), cardiac disorders (9 percent vs. 5.7 percent), fractures and osteoporosis (4.1 percent vs. 1.4 percent), and seizures (0.2 percent vs. 0).[1] Quality-of-life was comparable between treatment arms per Functional Assessment of Cancer Therapy–Prostate – (FACT-P Total).

##ENDS##

About the ACIS Study[1]

ACIS is a Phase 3 randomised, double-blind, placebo-controlled, multicentre clinical study evaluating the efficacy and safety of apalutamide and abiraterone acetate plus prednisone compared to placebo and abiraterone acetate plus prednisone in 982 patients with chemotherapy-naïve mCRPC disease who received ADT.[1] Patients were randomised to receive either apalutamide and abiraterone acetate plus prednisone, or placebo and abiraterone acetate plus prednisone. The primary endpoint of the study was rPFS. Secondary endpoints of the study included OS, time to chronic opioid use, time to initiation of cytotoxic chemotherapy, and time to pain progression.[1]

About Metastatic Castration-Resistant Prostate Cancer

Metastatic castration-resistant prostate cancer (mCRPC) characterises cancer that no longer responds to ADT and has spread to other parts of the body. The most common metastatic sites are bones, followed by lymph nodes, lungs, and liver.[2] Prostate cancer is the most common cancer in men in Europe, representing 25 percent of all male new cancer cases diagnosed.[3] More than one million men around the world are diagnosed with prostate cancer each year.[4]

About apalutamide

Apalutamide is an orally administered, selective androgen receptor (AR) inhibitor approved in Europe and is indicated

- in adult men for the treatment of non-metastatic castration-resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease and
- in adult men for the treatment of metastatic hormone-sensitive prostate cancer (mHSPC), also known as metastatic castration-sensitive prostate cancer (mCSPC), in combination with androgen deprivation therapy (ADT).[5]

▼ *This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.*

About abiraterone acetate

Abiraterone acetate, an orally administered androgen biosynthesis inhibitor, in combination with prednisone or prednisolone is approved in Europe for

- the treatment of newly diagnosed high risk metastatic hormone sensitive prostate cancer (mHSPC) in adult men in combination with androgen deprivation therapy (ADT);
- the treatment of metastatic castration resistant prostate cancer (mCRPC) in adult men who are asymptomatic or mildly symptomatic after failure of ADT in whom chemotherapy is not yet clinically indicated, and
- the treatment of mCRPC in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen.[6]

Additionally, abiraterone acetate was approved for the treatment of high-risk metastatic hormone-sensitive prostate cancer (mHSPC) by the U.S. Food and Drug Administration (FDA) on February 8, 2018.[7,8] Since its first approval in Europe in 2011, abiraterone acetate has been approved in combination with prednisone or prednisolone, in more than 105 countries and has been prescribed to more than 700,000 patients worldwide.[9]

About 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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Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding potential benefits and further benefits of 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 Pharmaceutica 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 29, 2019, 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.

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[9] Data on file

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