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Janssen Submits Marketing Authorisation Application to EMA Seeking Approval of Niraparib and Abiraterone Acetate Dual Action Tablet Plus Prednisone for the Treatment of Patients with HRR Gene-Mutated Metastatic Castration Resistant Prostate Cancer

The submission to the European Medicines Agency is based on results from the Phase 3 MAGNITUDE study evaluating niraparib in combination with abiraterone acetate plus prednisonefor the treatment of patients with mCRPC who are positive for HRR gene alterations.[1]

APRIL 28, 2022 (BEERSE, BELGIUM) – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced the submission of a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) seeking approval of niraparib in combination with abiraterone acetate, in the form of a dual action tablet (DAT)[*] plus prednisolone, for the treatment of patients with prostate cancer who have progressed to metastatic castration-resistant prostate cancer (mCRPC) and are positive for homologous recombination repair (HRR)[†] gene alterations. When approved by the European Commission, niraparib in combination with AAP will be the first dual action tablet formulation in the European Union specifically targeting HRR gene alterations in mCRPC.

[*] DAT is a single tablet combining niraparib and abiraterone acetate

[†] HRR gene alterations include Ataxia Telangiectasia (ATM), breast cancer gene 1 and 2 (BRCA1/BRCA2), BRCA1 interacting protein 1 (BRIP1), cyclin-dependent kinase 12 (CDK12), Checkpoint Kinase 2 (CHEK2), fanconi anaemia (FANCA), Histone Deacetylase 2 (HDAC2) and partner and localiser of BRCA 2 (PALB2).

The combination of niraparib, a PARP (poly adenosine diphosphate-ribose polymerase) inhibitor, and abiraterone acetate, a CYP17 inhibitor, targets two oncogenic drivers in patients with mCRPC, AR-axis and HRR gene alterations. The DAT formulation is also intended to be more convenient for patients, and thus aims to improve treatment compliance. Prostate cancer is one of the most common cancers in Europe with approximately 473,000 patients diagnosed in 2020.[2] Up to approximately 30% of patients with mCRPC have HRR gene alterations which are associated with a worse prognosis compared to patients without HRR gene alterations.[1]

"People with prostate cancer harbouring BRCA alterations face a more aggressive form of disease with worse outcomes and faster progression, sadly leading to a shorter life expectancy," commented Professor Gerhardt Attard[‡], Primary Study Investigator and Clinician Scientist and Team Leader at University College London Cancer Institute. "This submission is an important step towards improving the outcomes for people with metastatic prostate cancer harbouring BRCA alterations using a targeted therapy that significantly delays the time to their cancer progressing."

The EU MAA is supported by data from the MAGNITUDE study (NCT03748641), a Phase 3, randomised, double-blind, placebo-controlled, multicentre study evaluating the safety and efficacy of niraparib combined with abiraterone acetate plus prednisone (AAP) in patients with mCRPC. The study showed that at the final analysis for radiographic progression-free survival (rPFS), the treatment combination of niraparib and AAP demonstrated a statistically significant improvement in patients with HRR gene alterations as compared to placebo and AAP.[1] First results from the study were presented at the American Society of Clinical Oncology – Genitourinary Cancers Symposium (ASCO GU 2022) Annual Meeting (Abstract #12). The study continues to collect data on the secondary endpoints, which include time-to-initiation of cytotoxic chemotherapy, time to symptomatic progression and overall survival.[1]

"The data supporting this submission demonstrate the benefit of niraparib in combination with AAP in patients with specific gene alterations and reinforce the importance of biomarker testing in helping to provide an individualised treatment for these patients," said Kiran Patel, M.D., Vice President, Clinical Development, Solid Tumors, Janssen Research & Development, LLC. "We are committed to advancing targeted therapeutic options for

[‡] Professor Attard has served as a consultant to Janssen; he has not been paid for any media work.

patients with prostate cancer as we build upon our deep understanding of the disease, with a focus on improving outcomes for patients."

"The submission of niraparib in combination with AAP to the European Medicines Agency marks an important milestone in addressing specific genetic alterations in prostate cancer," said Mathai Mammen, M.D., Ph.D., Executive Vice President, Pharmaceuticals, R&D, Johnson & Johnson. "We are determined to transform this complex disease through innovation, science and ingenuity."

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About Niraparib

Niraparib is an orally administered, selective poly-ADP ribose polymerase (PARP) inhibitor, that is currently being studied by Janssen for the treatment of patients with prostate cancer.[1] Additional ongoing studies include the Phase 3 AMPLITUDE study evaluating the combination of niraparib and AAP in a biomarker-selected patient population with metastatic hormone-sensitive prostate cancer (mHSPC).[3]

In April 2016, Janssen Biotech, Inc. entered a worldwide (except Japan) collaboration and license agreement with TESARO, Inc. (acquired by GSK in 2018), for exclusive rights to niraparib in prostate cancer. In the European Union, niraparib is indicated for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy; for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy (Zejula SmPC 2021). Niraparib is currently marketed by GSK as ZEJULA®.[4]

About abiraterone acetate

Abiraterone acetate is an orally-administered androgen biosynthesis inhibitor. In the European Union, abiraterone acetate is indicated with prednisone or prednisolone for the treatment of newly diagnosed high risk mHSPC in adult men in combination with ADT; the treatment of 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 (ZYTIGA SmPC 2020).[5]

Abiraterone acetate is currently marketed by Janssen Janssen-Cilag International NV as ZYTIGA®.[5]

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 lungs and liver.[6] Prostate cancer is the most common cancer in men in Europe.[7] More than one million men around the world are diagnosed with prostate cancer each year.[8] Patients with mCRPC and HRR gene alterations have a worse prognosis than those without HRR alterations.[9]

About MAGNITUDE

MAGNITUDE (NCT03748641) is a Phase 3 randomised, double-blind, placebo-controlled, multicentre clinical study evaluating the safety and efficacy of the combination of niraparib and AAP for patients with mCRPC, with or without certain HRR gene alterations. The study includes two cohorts in which patients were randomised to receive either niraparib and AAP or placebo and AAP cohorts: one cohort of patients with predefined HRR gene alterations (including ATM, BRCA1, BRCA2, BRIP1, CDK12, CHEK2, FANCA, HDAC2, PALB2 alterations) and one cohort of patients without HRR gene alterations. In a third, open-label cohort, all patients received the dual action tablet formulation of niraparib and AAP.[1]

The primary endpoint of the MAGNITUDE trial is rPFS. Secondary endpoints include time-to-initiation of cytotoxic chemotherapy, time to symptomatic progression and overall survival.[1]

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/emea/. Follow us at www.twitter.com/JanssenEMEA for our latest news. Janssen Research & Development, LLC; Janssen-Cilag, S.A.; and Janssen Biotech, Inc. are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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 niraparib. 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 Research & Development, LLC, Janssen Biotech, Inc., or 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 2, 2022, 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.

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References

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