News Release

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Janssen Submits New Drug Application to the U.S. Food and Drug Administration Seeking Approval of Niraparib and Abiraterone Acetate Dual-Action Tablet, Plus Prednisone, as a First-Line Targeted Treatment for Patients with Metastatic Castration-Resistant Prostate Cancer with BRCA Gene Mutations

Niraparib and Abiraterone Acetate Plus Prednisone Has Potential to Address Unmet Need for Patients with BRCA-Positive mCRPC

RARITAN, N.J., February 28, 2023 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking approval of niraparib in combination with abiraterone acetate, in the form of a dual-action tablet (DAT), plus prednisone, for the treatment of patients with BRCA-positive metastatic castration-resistant prostate cancer (mCRPC). If approved, this will be the first DAT formulation available in the U.S. to patients with mCRPC with BRCA mutations, which are a type of homologous recombination repair (HRR) gene alteration.

"Patients with mCRPC and BRCA mutations face a more aggressive form of prostate cancer and high unmet needs in terms of treatment options. The data supporting this submission reinforce the importance of biomarker testing to identify the subgroups of patients that are most likely to respond to a targeted treatment option," said Peter Lebowitz, M.D., Ph.D., Global Therapeutic Area Head, Oncology, Janssen Research & Development, LLC. "This submission further represents our commitment at Janssen to discover and develop precision

medicine approaches and combination therapies to help improve outcomes for patients living with genetically defined disease."

Prostate cancer is one of the most common cancers in the U.S., with an estimated 268,490 new cases diagnosed in 2022.[1] Approximately 10 to 50 percent of patients progress to mCRPC within three years of diagnosis,[2] of which an estimated 10 to 15 percent harbor a BRCA mutation.[3,4]

The combination of niraparib, a highly selective poly (ADP-ribose) polymerase (PARP) inhibitor, and abiraterone acetate, a prodrug of abiraterone, a CYP17 inhibitor, plus prednisone, targets two oncogenic drivers in patients with mCRPC: the androgen receptor axis and HRR gene alterations. The combination of niraparib with abiraterone acetate plus prednisone (AAP) is intended for patients with BRCA mutations who have not received prior treatment for mCRPC except for standard of care, next-generation androgen receptor inhibitors and up to four months of AAP. Through the DAT formulation, this therapeutic option may help improve compliance and reduce pill burden.

The NDA is supported by data from the MAGNITUDE study (NCT03748641), a Phase 3, randomized, double-blind, placebo-controlled, multicenter study evaluating the safety and efficacy of niraparib plus AAP as a first-line treatment in patients with mCRPC, with or without alterations in HRR associated genes.[1] Patients with HRR gene alterations were randomized to receive niraparib 200 mg once daily plus AAP [n=212], or placebo plus AAP [n=211].

First results from MAGNITUDE were presented at the American Society of Clinical Oncology – Genitourinary Cancers Symposium (ASCO GU) 2022 Annual Meeting (Abstract #12) for the primary endpoint of investigator-evaluated radiographic progression-free survival (rPFS) in all HRR-positive patients, as well as patients with BRCA mutations, receiving niraparib plus AAP.[5] Results from the secondary interim analysis (IA2) were presented at the ASCO GU 2023 Annual Meeting (Abstract #170). In IA2, at 26.8 months of median follow-up, researchers further reviewed time to symptomatic progression (TSP) and time-to-initiation of cytotoxic chemotherapy (TCC) in the HRR-positive population and the BRCA subgroup.

The study continues to collect data on the secondary endpoints, which include TCC, TSP and overall survival.

About niraparib

Niraparib is an orally administered, highly selective poly (ADP-ribose) polymerase (PARP) inhibitor that is currently being studied by Janssen for the treatment of patients with prostate cancer.

Additional ongoing studies include the Phase 3 AMPLITUDE study, evaluating the combination of niraparib and AAP in a biomarker-selected patient population with metastatic castration-sensitive prostate cancer (mCSPC).[6]

In April 2016, Janssen Biotech, Inc. entered a worldwide (except Japan) collaboration and license agreement with TESARO, Inc. (acquired by GlaxoSmithKline [GSK] in 2019) for exclusive rights to niraparib in prostate cancer.

In the United States, 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; and for the maintenance treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. Niraparib is currently marketed by GSK as ZEJULA®.[7]

In April 2022, Janssen submitted a marketing authorisation application to the European Medicines Agency seeking approval for niraparib in combination with abiraterone acetate in the form of a DAT, plus prednisone or prednisolone, based on data from the MAGNITUDE study. Marketing authorisation applications are under review across a number of countries globally.

On February 24, 2023, the European Medicines Agency's Committee for Medicinal Products for Human Use issued a positive opinion for niraparib in combination with abiraterone acetate in the form of a DAT, plus prednisone or prednisolone, for the treatment of adult patients with mCRPC and BRCA mutations (germline and/or somatic) in whom chemotherapy is not clinically indicated.

About metastatic castration-resistant prostate cancer

Metastatic castration-resistant prostate cancer characterizes cancer that no longer responds

to androgen deprivation therapy and has spread to other parts of the body. The most common metastatic sites are bones, followed by lungs and liver.[8] Prostate cancer is the second most common cancer in men worldwide, behind lung cancer.[Error! Bookmark not defined.] More than one million patients around the world are diagnosed with prostate cancer each year.[9] Patients with mCRPC and HRR gene alterations, of which BRCA mutations are the most common, are more likely to have aggressive disease, poor outcomes and a shorter survival time.[Error! Bookmark not defined.,Error! Bookmark not defined.,Error! Bookmark not defined.,Error! Bookmark not defined.]

About MAGNITUDE

MAGNITUDE (NCT03748641) is a Phase 3, randomized, double-blind, placebo-controlled, multicenter 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, and who have not received prior therapy for mCRPC except for standard of care, next-generation androgen receptor inhibitors and up to four months of AAP. Patients were randomized to receive either niraparib and AAP or placebo and AAP. Additionally in an open-label cohort of HRR-positive patients, all patients received the DAT formulation of niraparib and abiraterone acetate plus prednisone.[Error! Bookmark not defined.] The primary endpoint of the MAGNITUDE trial is rPFS determined by blinded independent central review. Secondary endpoints include TCC, TSP and overall survival.[Error! Bookmark not defined.]

About abiraterone acetate

Abiraterone acetate is an orally administered androgen biosynthesis inhibitor. In the United States, abiraterone acetate is indicated with prednisone for the treatment of mCRPC and high-risk mCSPC.

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 & Retina; Immunology; Infectious Diseases & Vaccines; Neuroscience; Oncology; and Pulmonary Hypertension.

Learn more at www.janssen.com. Follow us at @JanssenGlobal and @JanssenUS. Janssen Research & Development, LLC and Janssen Biotech, Inc. belong to 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, abiraterone acetate + prednisone. 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 materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC; Janssen Biotech, Inc., 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; competition, including technological advances, new products and patents attained by competitors; challenges to patents; 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 1, 2023, 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 Janssen Research & Development, Janssen Biotech, Inc., 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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[1] American Cancer Society. Key Statistics for Prostate Cancer. https://www.cancer.org/cancer/prostate-cancer/about/key-statistics.html. Last accessed December 2022.

[2] DOI: 10.1200/JGO.18.00009 *Journal of Global Oncology* no. 4 (2018) 1-12. Published online September 27, 2018.

[3] DOI: 10.1200/PO.17.00029 *JCO Precision Oncology*. Published online May 31, 2017

[4] Shore, N., Oliver, L., Shui, I., Gayle, A., Wong, O. Y., Kim, J., Payne, S., Amin, S., & Ghate, S. (2021). Systematic Literature Review of the Epidemiology of Advanced Prostate Cancer and Associated Homologous Recombination Repair Gene Alterations. The Journal of Urology, 205(4), 977–986. https://doi.org/10.1097/JU.0000000000001570

[5] Chi et al. Phase 3 MAGNITUDE study: First results of niraparib (NIRA) with abiraterone acetate and prednisone (AAP) as first-line therapy in patients (pts) with metastatic castration-resistant prostate cancer (mCRPC) with and without homologous recombination repair (HRR) gene alterations. Meeting Abstract - ASCO GU 2022.

[6] Clinical Trials.Gov. A Study of Niraparib in Combination With Abiraterone Acetate and Prednisone Versus Abiraterone Acetate and Prednisone for the Treatment of Participants With Deleterious Germline or Somatic Homologous Recombination Repair (HRR) Gene-Mutated Metastatic Castration Sensitive Prostate Cancer (mCSPC) (AMPLITUDE). Available at: https://clinicaltrials.gov/ct2/show/NCT04497844. Last accessed November 2022.

[7] ZEJULA® U.S. Prescribing Information, September 2022.

[8] Urology Care Foundation. Metastatic Castration-Resistant Prostate Cancer (mCRPC): What You Should Know. Available at: https://www.urologyhealth.org/documents/Product-Store/English/mCRPC-What-You-Should-Know-Fact-Sheet.pdf. Last accessed: February 2023.

[9] Leith A et al. Real-World Treatment Patterns in Metastatic Castration-Resistant Prostate Cancer Across Europe (France, Germany, Italy, Spain, and the United Kingdom) and Japan. Advances in Therapy. 2022;39(5):2236-2255.