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News Release

Media Contacts:
Magda Palhota
Mobile: +351 91 2799282
Email: mpalhota@its.jnj.com

Investor Relations:
Raychel Kruper
Investor-relations@its.jnj.com

Final Multivariate Analysis from the Phase 3 MAGNITUDE Study Shows Improvement in Overall Survival in Patients with Metastatic Castration-Resistant Prostate Cancer with BRCA Alterations Treated with Niraparib and Abiraterone Acetate Plus Prednisone

Niraparib and abiraterone acetate plus prednisone combination therapy also showed clinically relevant improvement versus standard of care in time to symptomatic progression and time to cytotoxic chemotherapy[1]

BEERSE, BELGIUM, 22 October, 2023 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced results from the final analysis (FA) of the Phase 3 MAGNITUDE study, in which a pre-planned multivariate analysis (MVA) showed niraparib, a highly selective poly (ADP-ribose) polymerase (PARP) inhibitor, combined with abiraterone acetate and given with prednisone, improved overall survival (OS) in patients with metastatic castration-resistant prostate cancer (mCRPC) with *BRCA1/2 (BRCA+)* alterations. A continued improvement in time to symptomatic progression (TSP) and time to cytotoxic chemotherapy (TCC) was also observed in the FA.[1] These data were featured today in a Late-Breaking Mini Oral Presentation Session at the European Society for Medical Oncology (ESMO) 2023 Congress taking place 20-24 October in Madrid, Spain (Abstract #LBA85).[1]

The FA of the MAGNITUDE study included 225 patients with first-line *BRCA*+ mCRPC (the largest population studied to date), where 113 patients were randomised to niraparib plus abiraterone acetate and prednisone (AAP) and 112 patients were assigned to placebo plus AAP.[1] At 35.9 months median follow-up (9.1 additional months follow-up from the second interim analysis, presented at ASCO GU 2023,[2] which reported on the primary endpoint (radiographic progression-free survival), OS of 30.4 months favoured patients who received

niraparib plus AAP compared to 28.6 months for the placebo plus AAP arm (Hazard Ratio [HR]=0.79; 95 percent Confidence Interval [CI], 0.55-1.12; nominal *P*=0.183).[2] A prespecified MVA, adjusting for baseline imbalances, showed an OS benefit favouring patients who received niraparib plus AAP versus the comparator (HR=0.66; 95 percent CI, 0.46-0.95; nominal *P*=0.024).[1] Continued improvement in TSP was also observed in patients who received niraparib and AAP compared to patients randomised to placebo plus AAP (HR 0.56; 95 percent CI, 0.37-0.85; nominal *P*=0.006).[1] Additionally, an evaluation of TCC indicated a clinically meaningful improvement among patients with *BRCA*+ mutations treated with niraparib and AAP (HR 0.60; 95 percent CI, 0.39-0.92; nominal *P*=0.019).[1] Finally, 70 percent of the patients in the niraparib and AAP arm received subsequent life-prolonging therapy compared to 86 percent of the patients assigned to placebo plus AAP.[1]

"At Janssen, we believe in the transformative potential of precision medicine and we are committed to investigating how it can help patients have the best possible outcomes in mCRPC." said Martin Vogel, EMEA Therapeutic Area Lead Oncology, Janssen-Cilag GmbH. "The MAGNITUDE study was specifically designed to identify the population of mCRPC patients who would most benefit from this niraparib-based combination. We are pleased to see that the three-year final analysis of the study reinforces the potential of niraparib and AAP as a new standard of care for mCRPC patients with BRCA mutations."

Patient-reported outcomes were also assessed in the FA. Results indicate that patients with mCRPC and *BRCA*+ mutations treated with niraparib and AAP experienced a trend towards delayed time to worst pain progression (HR 0.81; 95 percent CI, 0.52-1.25) and pain interference progression (HR 0.77; 95 percent CI, 0.48-1.23) compared with the placebo arm.[1]

"Despite treatment advances, mCRPC remains an incurable, deadly disease and patients with BRCA1/2 alterations are more likely to suffer poor outcomes and a shorter survival time," said Guilhem Roubaud*, M.D., Medical Oncologist at Institut Bergonie, Bordeaux, France and investigator in the MAGNITUDE study. "The favourable overall survival, along with key signals of improvements in disease progression, seen in the MAGNITUDE final analysis is promising for patients and underscores the potential significance of this new treatment option."

The FA observed no new safety signals and no cases of myelodysplastic syndrome or acute myeloid leukemia were observed among patients in the niraparib and AAP arm.[1] Niraparib plus AAP had higher rates of adverse events (AEs) of special interest than the placebo arm,

with the most common of any grade including anaemia (52.4 percent versus 22.7 percent) and thrombocytopenia (24.1 percent versus 9.5 percent), respectively. The differences in safety between treatment arms was driven by known hematologic toxicities with niraparib.[1]

"We are dedicated to advancing the science of prostate cancer and developing new targeted treatment options to extend patients' lives," said Angela Lopez-Gitlitz, M.D., Vice President, Late Development Oncology, Prostate Cancer, Janssen Research & Development, LLC. "These data highlight the importance of identifying patients with genetically defined cancer to better inform treatment protocols and ensure they receive available therapies tailored to their unique needs."

#ENDS#

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, and who have not received prior therapy for mCRPC except for standard of care, next-generation androgen receptor inhibitors and up to 4 months of AAP.[2,3] Patients were randomised 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 predisone.[2,3] The primary endpoint of the MAGNITUDE trial is radiographic progression-free survival determined by blinded independent central review. Secondary endpoints include TCC, TSP and OS.[3]

On 21 April 2023, the European Commission granted approval of AKEEGA® (niraparib and AA), in the form of a dual action tablet (DAT), given with prednisone or prednisolone, for the treatment of adults with metastatic castration-resistant prostate cancer (mCRPC) and BRCA1/2 mutations (germline and/or somatic) in whom chemotherapy is not clinically indicated.[4,5] This approval was based on results from the MAGNITUDE study.

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.[4,6] 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.[7,8]

In the European Union, niraparib is indicated as monotherapy for the maintenance treatment of adult patients with advanced epithelial high-grade ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response following completion of first-line platinum-based chemotherapy; and as monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high grade serious epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete or partial response to platinum-based chemotherapy.[9] Niraparib is currently marketed by GSK as ZEJULA®.[9]

About Metastatic Castration-Resistant Prostate Cancer

Metastatic castration-resistant prostate cancer (mCRPC) characterises cancer that no longer responds to androgen deprivation therapy (ADT) and has spread to other parts of the body.[10] The most common metastatic sites are bones, followed by lymph nodes, lungs and liver.[11] Prostate cancer is the most common cancer in men in Europe.[12] More than one million men around the world are diagnosed with prostate cancer each year.[13] 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.[14,15,16,17]

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.[18]

Abiraterone acetate is currently marketed by Janssen Janssen-Cilag International NV as ZYTIGA®.[18]

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: Oncology, Immunology, Neuroscience, Cardiovascular, Pulmonary Hypertension, and Retina.

Learn more at www.janssen.com/EMEA. Follow us at www.twitter.com/janssenEMEA for our latest news. Janssen Pharmaceutica NV, Janssen-Cilag GmbH and Janssen Research & Development, LLC 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, 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, actual results could vary materially from the expectations and projections of Janssen Pharmaceutica NV, Janssen-Cilag GmbH, Janssen Research & Development, LLC, 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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*Dr. Roubaud has served as a consultant to Janssen; he has not been paid for any media work.

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