News Release

Media Contacts:
Brian Kenney
+1 (215) 620-0111

Suzanne Frost
+1 (416) 317-0304

Investor Relations:
Raychel Kruper
+1 (732) 524-6164

U.S. Medical Inquiries:
+1 (800) 526-7736

Janssen Presents Updated Data Demonstrating Improved Outcomes from the Use of Niraparib in Combination with Abiraterone Acetate Plus Prednisone as a First-Line Therapy in Patients with BRCA-Positive Metastatic Castration-Resistant Prostate Cancer

Results from the Phase 3 MAGNITUDE study second interim analysis to be featured in an oral presentation at ASCO GU

SAN FRANCISCO, February 16, 2023 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced updated results from the Phase 3 MAGNITUDE study evaluating the investigational use of niraparib, a highly selective poly (ADP-ribose) polymerase (PARP) inhibitor, in combination with abiraterone acetate plus prednisone (AAP) in patients with metastatic castration-resistant prostate cancer (mCRPC) with or without specific homologous recombination repair (HRR) gene alterations, including BRCA mutations. Results will be featured today in a Rapid Abstract Session (Abstract #170) at the American Society of Clinical Oncology's Genitourinary (ASCO GU) Cancers Symposium, taking place February 16-18.

In the second interim analysis (IA2) of the MAGNITUDE study, the treatment combination of niraparib and AAP, in comparison to placebo at 26.8 months of median follow-up, demonstrated a statistically significant prolongation in time to symptomatic progression (TSP) and continued consistent improvement of time-to-initiation of cytotoxic chemotherapy (TCC) in the HRR-positive population, and a strong improvement in TSP for the BRCA subgroup of the HRR-positive population. Updated review of the primary endpoints in radiographic

progression free survival (rPFS) were consistent with the initial results, which showed a statistically significant benefit in both the HRR-positive population and BRCA subgroup. Additionally, a trend toward improvement in overall survival (OS) was observed in the BRCA subgroup. No new safety signals were identified. The most common adverse events for niraparib and AAP versus placebo and AAP, regardless of causality, were anemia (50.0 percent vs. 22.7 percent, respectively), hypertension (33.0 percent vs. 22.3 percent) and constipation (33.0 percent vs. 15.6 percent). Patients without HRR gene alterations had no improvement in outcomes from the use of niraparib in combination with AAP.

"Patients with HRR-positive mCRPC, especially those with BRCA mutations, are more likely to experience poor outcomes. Although additional follow-up for overall survival continues, it is encouraging to see a trend toward improvement in overall survival among patients with BRCA-positive mCRPC who received niraparib and AAP as compared to placebo and AAP," said Kim Chi*, M.D., Medical Oncologist at BC Cancer - Vancouver and principal investigator of the MAGNITUDE study. "Taken together, these data continue to support the potential use of niraparib in combination with AAP in patients with mCRPC and BRCA mutations."

Notably, in the BRCA subgroup (8.1 months additional follow-up at IA2), rPFS by central review demonstrated a consistent and clinically meaningful treatment effect favoring niraparib and AAP, with a median rPFS of 19.5 months at IA2 compared with 10.9 months for placebo and AAP (hazard ratio [HR], 0.55 [95 percent confidence interval [CI], 0.39-0.78]). For patients with BRCA-positive mCRPC, preplanned sensitivity analysis evaluating rPFS by investigator review also showed benefit for niraparib and AAP (HR, 0.46 [95 percent CI, 0.32-0.67]). Further, results of the IA2 indicate that patients with BRCA mutations treated with niraparib and AAP experienced a trend towards delayed time to worst pain intensity (HR, 0.70 [95 percent CI, 0.44-1.12]) and pain interference (HR, 0.67 [95 percent CI, 0.40-1.12]) compared with placebo and AAP.

"We have confirmed the unmet need in patients with BRCA-mutated mCRPC and have shown that niraparib and abiraterone acetate plus prednisone overcomes the poor prognostic outcome in these patients. These MAGNITUDE results underscore the importance of identifying patients with BRCA mutations to better inform treatment strategies and ensure the right patients receive add-on therapy with a PARP inhibitor," said Mary Guckert, RN, MSN, Vice President, Development Leader, Prostate Cancer, Janssen Research & Development, LLC. "As the treatment landscape for prostate cancer continues to evolve, we are committed to

evaluating innovative targeted therapies to help improve outcomes for patients with HRR-positive prostate cancer."

Prostate cancer is one of the most common cancers in the U.S., with an estimated 288,300 new cases of prostate cancer and nearly 35,000 deaths expected in 2023.[1] 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.[2,3,4,5] Between 20 and 30 percent of mCRPC cases have alterations in genes associated with HRR.[6,7] Approximately 10 to 15 percent of patients with mCRPC have BRCA gene alterations.[8,9]

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 4 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 dual-action tablet (DAT) formulation of niraparib and abiraterone acetate plus predisone.**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 OS.**Error! Bookmark not defined.**

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).[10]

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®.[11]

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.

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.[12] 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.[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.**Error! Bookmark not defined.**,**Error! Bookmark not defined.**,**Error! Bookmark not defined.**,**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. Janssen Research & Development, LLC is one 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 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.

# # #

*Dr. Chi has served as a consultant to Janssen; he has not been paid for any media work.

[1] American Cancer Society (n.d.). Prostate Cancer Statistics. Cancer Statistics Center. Retrieved January 17, 2023, from https://cancerstatisticscenter.cancer.org/#!/cancer-site/Prostate

[2] Castro E, Romero-Laorden N, Del Pozo A, et al. PROREPAIR-B: A Prospective Cohort Study of the Impact of Germline DNA Repair Mutations on the Outcomes of Patients With Metastatic Castration-Resistant Prostate Cancer. J Clin Oncol. 2019;37(6):490-503. doi:10.1200/JCO.18.00358.

[3] Cavanagh, H., & Rogers, K. M. (2015). The role of BRCA1 and BRCA2 mutations in prostate, pancreatic and stomach cancers. Hereditary cancer in clinical practice, 13(1), 16. https://doi.org/10.1186/s13053-015-0038-x

[4] Messina, C., Cattrini, C., Soldato, D., Vallome, G., Caffo, O., Castro, E., Olmos, D., Boccardo, F., & Zanardi, E. (2020). BRCA Mutations in Prostate Cancer: Prognostic and Predictive Implications. Journal of oncology, 2020, 4986365. https://doi.org/10.1155/2020/4986365

[5] Na, R., Zheng, S. L., Han, M., Yu, H., Jiang, D., Shah, S., Ewing, C. M., Zhang, L., Novakovic, K., Petkewicz, J., Gulukota, K., Helseth, D. L., Jr, Quinn, M., Humphries, E., Wiley, K. E., Isaacs, S. D., Wu, Y., Liu, X., Zhang, N., Wang, C. H., … Isaacs, W. B. (2017). Germline Mutations in ATM and BRCA1/2 Distinguish Risk for Lethal and Indolent Prostate Cancer and are Associated with Early Age at Death. European urology, 71(5), 740–747. https://doi.org/10.1016/j.eururo.2016.11.033

[6] 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. ASCO GU 2022.

[7] Scott, R. J., Mehta, A., Macedo, G. S., Borisov, P. S., Kanesvaran, R., & El Metnawy, W. (2021). Genetic testing for homologous recombination repair (HRR) in metastatic castration-resistant prostate cancer (mCRPC): challenges and solutions. Oncotarget, 12(16), 1600–1614. https://doi.org/10.18632/oncotarget.28015

[8] DOI: 10.1200/PO.17.00029 JCO Precision Oncology - published online May 31, 2017

[9] 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

[10] 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.

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

[12] National Cancer Institute. Metastatic Cancer: When Cancer Spreads. https://www.cancer.gov/types/metastatic-cancer. Last accessed November 2022.

[13] World Health Organization. "Globocan 2012: Prostate Cancer: Incidence, Mortality and Prevalence Worldwide, 2012." http://gco.iarc.fr/today/data/pdf/fact-sheets/cancers/cancer-fact-sheets-19.pdf. Last accessed November 2022.