



Media Inquiries:

Suzanne Frost
Phone: 416-317-0304

Brian Kenney
Phone: 215-628-7010

Investor Relations:

Christopher DeLorefice
Phone: 1-732-524-2955

Lesley Fishman
Phone: 1-732-524-3922

U.S. Medical Inquiries:

1-800-526-7736

Janssen Announces U.S. FDA Breakthrough Therapy Designation Granted for Niraparib for the Treatment of Metastatic Castration-Resistant Prostate Cancer

Niraparib, an orally-administered PARP inhibitor, is currently being investigated for the treatment of patients with metastatic castration-resistant prostate cancer and BRCA1/2 DNA repair gene defects

RARITAN, N.J., October 3, 2019 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation for niraparib, an orally-administered poly ADP-ribose polymerase (PARP) inhibitor, for the treatment of patients with BRCA1/2 gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have received prior taxane chemotherapy and androgen receptor (AR)-targeted therapy. A Breakthrough Therapy Designation is granted to expedite the development and regulatory review of an investigational medicine that is intended to treat a serious or life-threatening condition.¹ The criteria for Breakthrough Therapy Designation require preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy.¹

BRCA1/2 mutations are the most common DNA-repair gene defects (DRD) in patients with mCRPC.² Patients with a DRD in BRCA1/2 are at an elevated risk for both prostate cancer occurrence and more aggressive disease.²



“Niraparib is a PARP inhibitor that we believe may help address an important unmet need for patients with metastatic castration-resistant prostate cancer who have mutations in DNA-repair genes,” said Kiran Patel, M.D., Vice President, Clinical Development, Solid Tumors, Janssen Research & Development, LLC. “We are pleased with the FDA’s Breakthrough Therapy Designation as we continue the clinical development of niraparib, and we look forward to working with the agency in our continued focus and commitment to bring new advancements to patients diagnosed with prostate cancer.”

The Breakthrough Therapy Designation is based on data from the GALAHAD study, a Phase 2, multicenter, open-label clinical trial evaluating the efficacy and safety of niraparib in the treatment of adult patients with mCRPC and DRD who had received treatment with next-generation androgen-receptor targeting therapies and docetaxel.³ Data from the Phase 2 [GALAHAD](#) study were recently [presented](#) at the European Society for Medical Oncology (ESMO) 2019 Annual Congress as a late-breaking abstract.

About Metastatic Castration-Resistant Prostate Cancer

Metastatic castration-resistant prostate cancer is a form of prostate cancer that has spread to other parts of the body and keeps growing even when the amount of testosterone in the body is reduced to very low levels.^{4,5} The most common metastatic sites are bones, followed by distant lymph nodes, liver and thorax.⁶ Prostate cancer is the second most common type of cancer in men worldwide.⁷ More than one million people around the world are diagnosed with prostate cancer each year.^{7,8}

Other Ongoing Studies with Niraparib

Ongoing studies for niraparib include the Phase 3 [MAGNITUDE](#) study evaluating niraparib in combination with ZYTIGA® (abiraterone acetate) and prednisone in adults with metastatic prostate cancer. The MAGNITUDE study is evaluating niraparib plus ZYTIGA® and prednisone in a broader population than GALAHAD in patients with frontline mCRPC disease. In addition, [QUEST](#), a Phase 1b/2 study of niraparib combination therapies for the treatment of mCRPC, is ongoing.

About Niraparib

Niraparib is an orally-administered selective PARP inhibitor that is currently being studied by Janssen for the treatment of patients with prostate cancer. In April 2016, Janssen entered a worldwide (except Japan) collaboration and license agreement with TESARO, Inc., for exclusive rights to niraparib in prostate cancer. In the U.S., niraparib is indicated 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.⁹ Niraparib is currently marketed as ZEJULA[®] by TESARO, an oncology-focused business within GSK, devoted to providing transformative therapies to people facing cancer. Please refer to the full Prescribing Information available at <https://www.zejula.com/prescribing-information>.

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science. We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at www.janssen.com. Follow us at www.twitter.com/JanssenGlobal. Janssen Research & Development, LLC is one of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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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 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 materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC, 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 December 30, 2018, 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. Neither the Janssen Pharmaceutical Companies of Johnson & Johnson 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 The U.S. Food and Drug Administration. "Expedited Programs for Serious Conditions." Available at: <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM358301.pdf>. Accessed October 2019.

² Castro E, Eeles R. The role of BRCA1 and BRCA2 in prostate cancer. *Asian J Androl.* 2012;14(3):409-14. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3720154/>. Accessed October 2019.

³ Smith, M. et. Al. Pre-specified interim analysis of GALAHAD: A Phase 2 study of niraparib in patients (pts) with metastatic castration-resistant prostate cancer (mCRPC) and biallelic DNA-repair gene defects Available at <https://oncologypro.esmo.org/Meeting-Resources/ESMO-2019-Congress/Pre-specified-interim-analysis-of-GALAHAD-A-phase-2-study-of-niraparib-in-patients-pts-with-metastatic-castration-resistant-prostate-cancer-mCRPC-and-biallelic-DNA-repair-gene-defects-DRD>. Accessed October 2019.

⁴ National Cancer Institute. NCI Dictionary of Terms. <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/castrate-resistant-prostate-cancer>. Accessed October 2019.

⁵ Abala, David M. Imaging and treatment recommendations in patients with castrate-resistant prostate cancer. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5737351/>. Accessed October 2019.

⁶ Gandaglia, G et al. Distribution of metastatic sites in patients with prostate cancer: A population-based analysis. <https://www.ncbi.nlm.nih.gov/pubmed/24132735>. Accessed October 2019.

⁷ Rawla, P. Epidemiology of Prostate Cancer. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6497009/>. Accessed October 2019.

⁸ International Agency for Cancer Research. Estimated number of new cases in 2018, worldwide, males, all ages. https://gco.iarc.fr/today/online-analysis-table?v=2018&mode=cancer&mode_population=continents&population=900&populations=900&key=asr&sex=1&cancer=39&type=0&statistic=5&prevalence=0&population_group=0&ages_group%5B%5D=0&ages_group%5B%5D=17&nb_items=5&group_cancer=1&include_nmssc=1&include_nmssc_other=1. Accessed October 2019.

⁹ USPI Prescribing Information. https://www.zejula.com/application/files/4415/3151/1118/Zejula_USPI_May_2018.pdf. Accessed October 2019.