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Janssen Announces Preliminary Results from Phase 2 GALAHAD Study in Adults with Metastatic Castration-Resistant Prostate Cancer and DNA-Repair Pathway Defects (DRD)

Data showed niraparib demonstrated an objective response rate of approximately 40 percent in patients with metastatic castration-resistant prostate cancer and DNA-repair pathway defects, specifically BRCA1/2

SAN FRANCISCO, February 14, 2019 – The Janssen Pharmaceutical Companies of Johnson & Johnson will present today at the American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU) early results from the ongoing Phase 2 GALAHAD study evaluating niraparib, a poly (ADP-ribose) polymerase (PARP) inhibitor, in patients with metastatic castration-resistant prostate cancer (mCRPC) and DNA-repair pathway defects (DRD) (Abstract #202).[1] These preliminary data showed that approximately 40 percent of patients with DRD in BRCA1/2 receiving treatment with niraparib (300 mg daily) demonstrated an objective response, defined by the Response Evaluation Criteria in Solid Tumors (RECIST) guideline, version 1.1, as a standard measure of tumor response.[1,2] In addition, a composite response rate of more than 60 percent was seen, with composite response rate defined as achieving one or more of the following: objective response; conversion of circulating tumor cell (CTC) to less than 5 per 7.5 mL blood; or ≥50 percent decline in prostate specific antigen (PSA).[1] BRCA1/2 mutations are the most common DRD in patients with mCRPC.[3]

"These preliminary results suggest that PARP inhibition with niraparib may play an important role in the treatment of men with metastatic castration-resistant prostate cancer who have mutations in

DNA-repair genes," said Matthew R. Smith, M.D., Ph.D., Director of the Genitourinary Malignancies Program at the Massachusetts General Hospital Cancer Center, Professor of Medicine at Harvard Medical School, and lead GALAHAD study investigator. "Additional therapies are needed to address unmet medical needs in metastatic castration-resistant prostate cancer and we look forward to accumulating more evidence about the role of niraparib in this important setting."

GALAHAD is an ongoing open-label Phase 2 study assessing niraparib in patients with DRD who had progressed after treatment with next-generation androgen-receptor signaling therapies (ARSIs) and docetaxel.[1] In addition, patients tested positive by a validated plasma-based assay for a DRD mutation in one of eight genes.[1] At the time of this analysis, the study enrolled 50 patients (29 with BRCA1/2 and 21 with non-BRCA1/2) with mCRPC and a biallelic loss or a defect in both copies of a DNA-repair pathway gene.[1] Treatment with niraparib in the 29 patients with mCRPC and BRCA1/2 mutations achieved a 38 percent objective response rate and a 62 percent composite response rate.[1] In those 21 patients with mCRPC with non-BRCA1/2, an objective response rate of 13 percent and a 24 percent composite response rate were observed.[1] Approximately half of the patients with DRD have been on treatment for six months or longer without disease progression.[1]

The most common Grade 3/4 adverse events (AEs) were primarily hematologic, which included anemia (26 percent), thrombocytopenia (15 percent), neutropenia (8 percent) and leukopenia (6 percent).[1] The most common Grade 3/4 non-hematologic AEs were asthenia (6 percent) and back pain (5 percent).[1]

"It is encouraging to see this promising response rate, since patients with this DNA-repair pathway defect typically only have an objective response rate of less than 15 percent and a median progression-free survival of three months with currently available therapies," said Margaret Yu, M.D., Vice President, Clinical Development, Prostate, Janssen Research & Development, LLC. "Given these results, prospective biomarker testing could enable healthcare professionals to personalize therapy for patients with metastatic castration-resistant prostate cancer in the future."

About the GALAHAD Study

GALAHAD is an ongoing open-label Phase 2 study assessing niraparib (300 mg daily) that has currently enrolled 120 patients with DRD who had prior treatment with next-generation ARSIs and docetaxel.[1] The primary endpoint is the objective response rate; the key secondary endpoint is the composite response rate.[1]

Other Ongoing Studies with Niraparib

Janssen has also initiated a Phase 3 study, MAGNITUDE, which is evaluating niraparib in combination with ZYTIGA® (abiraterone acetate) and prednisone in adults with metastatic prostate cancer. The MAGNITUDE study is evaluating niraparib plus ZYTIGA in a broader population than GALAHAD – in patients with frontline mCRPC disease. In addition, QUEST, a Phase 2 study of niraparib combination therapies for the treatment of mCRPC, is ongoing.

About Metastatic Castration-Resistant Prostate Cancer

Metastatic castration-resistant prostate cancer (mCRPC) characterizes cancer that no longer responds to hormone treatment that lowers androgens and has spread to other parts of the body. The most common metastatic sites are bones, followed by lymph nodes, lungs and liver.[4] Prostate cancer is the second most common type of cancer in men worldwide. More than one million men around the world are diagnosed with prostate cancer each year.[5]

About niraparib

Niraparib is an orally-administered highly-selective PARP inhibitor that is currently being studied for the treatment of patients with prostate cancer by Janssen. In April 2016, Janssen entered a worldwide (except Japan) collaboration and license agreement with TESARO, Inc., for exclusive rights to niraparib in prostate cancer. Niraparib is approved in Europe, Switzerland and the United States for the treatment of ovarian cancer and is marketed by TESARO,[6,7] an oncology-focused business within GSK, devoted to providing transformative therapies to people facing cancer.

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 and www.twitter.com/JanssenUS. Janssen Research & Development, LLC is part 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 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 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 31, 2017, 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, 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] Smith, M. et. Al. Phase 2 study of niraparib in patients with metastatic castration-resistant prostate cancer (mCRPC) and biallelic DNA-repair gene defects (DRD): preliminary results of GALAHAD. Abstract #202.

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