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Tesaro Announces Priority Review Designation for Niraparib NDA

- **Niraparib New Drug Application accepted for review by FDA with a PDUFA goal date of June 30, 2017**
- **Niraparib Expanded Access Program (EAP) expected to open in U.S. in January 2017**

WALTHAM, Mass., Dec. 20, 2016 (GLOBE NEWSWIRE) -- TESARO, Inc. (NASDAQ:TSRO), an oncology-focused biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has granted Priority Review for the niraparib New Drug Application (NDA). Niraparib is a PARP inhibitor that is being evaluated as a potential new treatment option for patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer following response to platinum-based chemotherapy. The FDA has established a target action date under the Prescription Drug User Fee Act (PDUFA) of June 30, 2017, and is not currently planning to hold an advisory committee meeting to discuss this application.

Priority Review status is given to drugs that might offer significant improvements in treatment or provide a treatment where no adequate therapy exists.

The niraparib NDA is supported by data from the ENGOT-OV16/NOVA trial, a double-blind, placebo-controlled, international Phase 3 study that enrolled 553 patients with recurrent ovarian cancer who had achieved either a partial response (PR) or a complete response (CR) to their most recent platinum-based chemotherapy. This trial was designed to assess progression free survival (PFS) in patients who were assigned to one of two cohorts based upon germline BRCA mutation status. The full results of the ENGOT-OV16/NOVA trial were presented in detail at the European Society for Medical Oncology (ESMO) 2016 Congress in Copenhagen on October 8, 2016 and were published simultaneously in *The New England Journal of Medicine*.

"FDA's acceptance of the niraparib NDA with a Priority Review designation is an important milestone for TESARO, and represents a significant step in our efforts to bring meaningful therapies to women with ovarian cancer," said Mary Lynne Hedley, Ph.D., President and COO of TESARO. "We believe niraparib could become an important new treatment option for patients with recurrent ovarian cancer, and we look forward to working with the FDA during the review process."

The ENGOT-OV16/NOVA trial successfully achieved its primary endpoint in both patient cohorts, demonstrating that niraparib treatment significantly prolonged PFS compared to control. Among patients who were germline BRCA mutation carriers, the niraparib arm successfully achieved statistical significance over the control arm for the primary endpoint of PFS, with a hazard ratio of 0.27 (95% CI, 0.173-0.410). The median PFS for patients treated with niraparib was 21.0 months, compared to 5.5 months for control ($p<0.0001$). Among patients in the non-germline BRCA mutant cohort, the niraparib arm successfully achieved statistical significance over the control arm for the primary endpoint of PFS, with a hazard ratio of 0.45 (95% CI, 0.338-0.607). The median PFS for patients treated with niraparib was 9.3 months, compared to 3.9 months for control ($p<0.0001$). Based upon the results of this trial, the indication proposed in the NDA provides for the use of niraparib regardless of tumor biomarker status, and it is anticipated that the BRACAnalysis® CDx and myChoice® HRD tests would be available to physicians as complementary diagnostics.

The most common (≥10%) treatment-emergent grade 3/4 adverse events in the niraparib arm were thrombocytopenia (33.8%), anemia (25.3%), and neutropenia (19.6%) with treatment discontinuation for these events of 3.3%, 1.4% and 1.9%, respectively. Thrombocytopenia was not associated with grade 3/4 bleeding events. The majority of these hematological laboratory abnormalities occurred within the first three cycles; following dose modifications based on individual patient tolerability, the incidence of these lab abnormalities decreased and thrombocytopenia and neutropenia were infrequent beyond cycle 3. The rates of MDS/AML in the niraparib (1.4%) and control (1.1%) arms were similar. There were no deaths among patients during study treatment.

An Expanded Access Program (EAP) for niraparib in the United States is planned to open in January 2017. Expanded access programs enable patients with serious or life-threatening illnesses who do not otherwise qualify for participation in a clinical trial and for whom there are no comparable or satisfactory alternate therapies to access investigational medicines. Through the program, niraparib will be made available for patients with recurrent ovarian cancer following response to platinum-based chemotherapy.

About Niraparib
Niraparib is an oral, once-daily PARP inhibitor that is currently being evaluated in three pivotal trials. TESARO is building a robust niraparib franchise by assessing activity across multiple tumor types and by evaluating several potential

combinations of niraparib with other therapeutics. The ongoing development program for niraparib includes a Phase 3 trial in patients with first-line ovarian cancer (the PRIMA trial), a Phase 3 trial for the treatment of patients with germline BRCA-mutated, metastatic breast cancer (the BRAVO trial), and a registrational Phase 2 treatment trial in patients with ovarian cancer (the QUADRA trial). Several combination studies are also underway, including trials of niraparib plus pembrolizumab in metastatic, triple-negative breast cancer and advanced, platinum-resistant ovarian cancer (the TOPACIO trial) and niraparib plus bevacizumab in recurrent, platinum-sensitive ovarian cancer (the ENGOT-OV24/AVANOVA trial). Janssen Biotech has licensed rights to develop and commercialize niraparib specifically for patients with prostate cancer worldwide, except in Japan.

In September 2016, the FDA granted Fast Track designation to niraparib. The FDA Fast Track designation is designed to facilitate the development and expedite the review of medicines that are intended to treat serious conditions and address unmet medical needs. As part of the Fast Track program, the FDA allows for the submission of completed portions of an NDA on an ongoing or rolling basis.

Niraparib is an investigational agent and, as such, has not been approved by the U.S. FDA, European Medicines Agency (EMA), or any other regulatory agencies.

About Ovarian Cancer
Approximately 22,000 women are diagnosed each year with ovarian cancer in the United States, and more than 65,000 women are diagnosed annually in Europe. Ovarian cancer is the fifth most frequent cause of cancer death among women. Despite high response rates to platinum-based chemotherapy in the second-line advanced treatment setting, approximately 85% of patients will experience recurrence within two years. If approved, niraparib may address the difficult "watchful waiting" periods experienced by patients with recurrent ovarian cancer in between cycles of platinum-based chemotherapy.

About TESARO
TESARO is an oncology-focused biopharmaceutical company devoted to providing transformative therapies to people bravely facing cancer. For more information, visit www.tesarobio.com, and follow us on Twitter and LinkedIn.

To the extent that statements contained in this press release are not descriptions of historical facts regarding TESARO, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "anticipate," "estimate," "intend," and similar expressions (as well as other words or expressions referencing future events, conditions, or circumstances) are intended to identify forward-looking statements. Forward-looking statements in this release, including statements regarding the potential indication for niraparib and the potential complementary use of the Myriad myChoice® HRD test and BRACAnalysis CDx® in connection with niraparib, whether the FDA will hold an advisory committee meeting to discuss the niraparib NDA and the potential initiation of an Expanded Access Program, involve substantial risks and uncertainties that could cause future results, performance, or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, risks related to our intellectual property, the uncertainties inherent in the execution and completion of clinical trials, risks regarding ongoing discussions with and actions by regulatory authorities, including the FDA, uncertainties regarding regulatory approvals, and other matters that could affect the ultimate approval and indication for niraparib. TESARO undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of the Company in general, see TESARO's Annual Report on Form 10-K for the year ended December 31, 2015 and its Quarterly Report on Form 10-Q for the quarter ended September 30, 2016.

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