March 12, 2017

TESARO Announces Niraparib Data Presentations at the 2017 SGO Annual Meeting on Women's Cancer

WALTHAM, Mass., March 12, 2017 (GLOBE NEWSWIRE) -- TESARO, Inc. (NASDAQ:TSRO), an oncology-focused biopharmaceutical company, today announced two niraparib presentations at the 2017 Society for Gynecologic Oncology (SGO) Annual Meeting on Women's Cancer, March 12 to 15, 2017, in National Harbor, Maryland.

Please visit TESARO during SGO at Booth #325 for information about VARUBI®, niraparib and our pipeline.

Presentation Details:

Monday, March 13, 2017 10:45 AM to 11:45 AM
ENGOT-OV16/NOVA: Results of secondary efficacy endpoints of niraparib maintenance therapy in ovarian cancer
Abstract: 8084, Oral Presentation, Location: Hall A, Time: 11:10 AM

Monday, March 13, 2017 3:30 PM — 5:00 PM and Tuesday, March 14, 2017 3:30 PM — 4:30 PM
A Phase 3, randomized, double-blind, placebo-controlled, multicenter study of niraparib maintenance treatment in patients with advanced ovarian cancer following response on frontline platinum-based chemotherapy — Trial-in-progress (PRIMA)
Abstract:8121, Poster Presentation 203, Location: Hall BC

About Niraparib

Niraparib is an oral, once-daily PARP inhibitor that is currently being evaluated in three pivotal trials. In pre-clinical studies, niraparib was found to concentrate in the tumor relative to plasma, delivering selective, greater than 90% durable PARP inhibition and a persistent anti-tumor effect.

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 who have received first-line treatment for ovarian cancer (the PRIMA trial), a registrational Phase 2 trial in patients who have received multiple lines of treatment for ovarian cancer (the QUADRA trial), and a Phase 3 trial for the treatment of patients with germline *BRCA*-mutated, metastatic breast cancer (the BRAVO trial). Several combination studies are also underway, including trials of niraparib plus pembrolizumab and niraparib plus bevacizumab. Janssen Biotech has licensed rights to develop and commercialize niraparib specifically for patients with prostate cancer worldwide, except in Japan.

The niraparib New Drug Application (NDA) has been accepted for priority review by the FDA and is supported by data from the ENGOT-OV16/NOVA trial, a double-blind, placebo-controlled, international Phase 3 study that enrolled 553 patients, either with or without a germline *BRCA* mutation, with recurrent ovarian cancer following complete or partial response to their most recent platinum-based chemotherapy. 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 by Dr. Mansoor Raza Mirza, M.D., Medical Director of the Nordic Society of Gynecologic Oncology (NSGO) and principal investigator. These data were simultaneously published in the *New England Journal of Medicine*.

Regulatory applications are under review for niraparib in the U.S. and Europe and TESARO expects to launch niraparib in the U.S. in the first half of 2017 and in Europe by year-end 2017, pending regulatory approvals. 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. Without an active treatment following chemotherapy, the majority of women who have responded to platinum-based chemotherapy undergo "watchful waiting" — a period without any anti-cancer treatment during which a patient and their healthcare provider will monitor signs of the disease returning. 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 dedicated to improving the lives of cancer patients by acquiring, developing and commercializing safer and more effective therapeutics. For more information, visit www.tesarobio.com.

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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 involve substantial risks and uncertainties that could cause our clinical development programs, 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, the uncertainties inherent in expectations with respect to niraparib regulatory submissions and approvals, and other matters that could affect the availability or commercial potential of our drug candidates. TESARO undertakes no obligation to update or revise any forward-looking statements. 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.