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Tesaro Announces Opening of Niraparib Expanded Access Program for U.S. Patients With Ovarian Cancer

WALTHAM, Mass., Jan. 17, 2017 (GLOBE NEWSWIRE) -- TESARO, Inc. (NASDAQ:TSRO), an oncology-focused biopharmaceutical company, today announced the opening of an expanded access program (EAP) in the United States for the investigational PARP inhibitor, niraparib. Through this program, niraparib is being made available for eligible women with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer following a complete or partial response to platinum-based chemotherapy. Healthcare professionals can learn more about the niraparib EAP by visiting www.niraparibEAP.com. An EAP for niraparib in Europe is planned to open in the first half of 2017, and will be initiated on a country-by-country basis.

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.

"Ovarian cancer is the fifth most frequent cause of cancer death among women in the United States, yet there have been few advances in the treatment of ovarian cancer in over a decade," said Mary Lynne Hedley, Ph.D., President and COO of TESARO. "The niraparib EAP will provide a mechanism by which eligible women with ovarian cancer may benefit from access to this investigational therapy, which has been accepted for priority review by the U.S. FDA."

About the Niraparib Expanded Access Program
The niraparib EAP is a program for women with recurrent, ovarian, fallopian tube, or primary peritoneal cancer following a complete or partial response to platinum. This EAP is being administered on behalf of TESARO by the Idis Managed Access division of Clinigen Group plc. U.S. based healthcare professionals seeking more information about the niraparib EAP can call Idis Managed Access at 1-877-768-4303 or email niraparibUSEAP@clinigengroup.com for further details. Patients who are interested in enrolling in the niraparib EAP should speak with their physician to understand if niraparib is an appropriate option. Niraparib is an investigational agent and, as such, has not been approved by the U.S. Food and Drug Administration (FDA) or any other regulatory agencies in any markets. Additional information about the niraparib EAP, including a list of Frequently Asked Questions, is available at www.niraparibEAP.com.

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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 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 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*.

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.

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