March 27, 2017

TESARO Announces Expanded Development Program for Niraparib Focused on the Treatment of Front-Line Metastatic Ovarian and Lung Cancers and Metastatic Breast Cancer

- **Expanded niraparib ovarian cancer program intended to potentially transform the treatment of front-line ovarian cancer**
- **New breast cancer clinical program for niraparib to address greatest area of unmet need and broader patient population**
- **BRAVO trial no longer expected to serve as a registration study**
- **Niraparib in combination with an anti-PD-1 antibody to be developed for front-line, non-small cell lung cancer**
- **Investor conference call and webcast to be held at 4:30 PM ET today**

WALTHAM, Mass., March 27, 2017 (GLOBE NEWSWIRE) -- TESARO, Inc. (NASDAQ:TSRO), an oncology-focused biopharmaceutical company, today announced a substantial expansion of its niraparib clinical development program. Following the landmark results of the Phase 3 NOVA trial of niraparib, a comprehensive portfolio review, and the FDA approval of ZEJULA™ (niraparib) for patients with recurrent ovarian cancer, TESARO is implementing its plans to initiate registration strategies in the settings of metastatic ovarian, breast and lung cancers.

"Based on the unprecedented results of the NOVA trial in women with recurrent ovarian cancer, we previously announced the expansion and refinement of our PRIMA and QUADRA trials to include a broad patient population, and in the case of PRIMA, eliminated the enrollment requirement for a biomarker selected tumor. With the approval of ZEJULA in hand, we will now begin to execute on our plans to pursue potentially transformational applications of niraparib in a broad range of metastatic cancer indications," said Mary Lynne Hedley, Ph.D., President and COO of TESARO. "We plan to expand our first-line ovarian cancer strategy to include a combination study that assesses the potential benefit of niraparib plus an anti-PD-1 antibody in the maintenance setting and initiate a clinical study of niraparib in combination with bevacizumab in patients with a first recurrence of ovarian cancer, with an intent to replace chemotherapy in this setting. We remain strongly committed to studying niraparib in the breast cancer setting and also expect to initiate a new trial of niraparib in combination with an anti-PD-1 antibody in women with metastatic triple-negative breast cancer. Finally, our goal to move niraparib into indications beyond ovarian and breast cancers encompasses plans to initiate a registration strategy for the first-line treatment of patients with metastatic non-small cell lung cancer that includes a phase 2 trial of niraparib in combination with an anti-PD-1 antibody in patients, regardless of PDL-1 tumor expression, and a phase 3 trial of niraparib in combination with an anti-PD-1 antibody in patients with high levels of PDL-1 tumor expression."

Niraparib is the only PARP inhibitor approved in the U.S. for the maintenance treatment of women with recurrent ovarian, fallopian or primary peritoneal cancers. This approval was based upon the results of a randomized, prospectively designed Phase 3 clinical trial where niraparib demonstrated a clinically meaningful increase in progression-free survival (PFS) in women with recurrent ovarian cancer following a response to platinum-based chemotherapy.

The BRAVO study is assessing niraparib in patients with breast cancer who are germline *BRCA* mutation carriers. This study is sponsored by TESARO and is being conducted by Breast International Group (BIG) and the European Organisation for Research and Treatment of Cancer (EORTC). Following a recent interim analysis of data by the independent data monitoring committee (IDMC), TESARO believes the BRAVO study is unlikely to produce data that is interpretable and therefore suitable for registration in this indication. A large number of patients in the chemotherapy control arm did not continue in the trial long enough to receive their first radiological scan, which is required to assess disease progression, resulting in an unusually high rate of censoring in the control arm. At this time, TESARO believes this is likely associated with the desire of patients who carry germline BRCA mutations to be treated with a PARP inhibitor rather than chemotherapy and the increased availability of PARP inhibitors. A final determination as to whether the planned enrollment in BRAVO should be completed will be made by the Steering Committee in the near term. No safety concerns have been noted by the IDMC with respect to niraparib. Approximately 5-10% of women with breast cancer are germline *BRCA* mutation carriers. TESARO expects the results and experience gained from the BRAVO trial to be supportive of the planned trial of niraparib in combination with an anti-PD-1 antibody in women with metastatic triple-negative breast cancer. Approximately 15-20% of women with breast cancer have triple negative breast cancer.

The expanded niraparib clinical development program now includes the following:

Ovarian Cancer

OvCa 3000-03-003: A Phase 3 clinical trial of niraparib in combination with an anti-PD-1 antibody in comparison to niraparib in first-line maintenance treatment of patients with advanced ovarian cancer who have responded to platinum induction therapy.

OvCa 3000-03-002: A Phase 3 clinical trial of niraparib in combination with bevacizumab in comparison to standard of care in patients with a first recurrence of ovarian cancer.

PRIMA: A Phase 3 clinical trial of niraparib in patients with advanced ovarian cancer who have responded to platinum induction therapy.

TOPACIO: A Phase 2 trial to evaluate the preliminary safety and efficacy of niraparib plus KEYTRUDA® in patients with triple negative breast cancer and in patients with platinum resistant recurrent ovarian cancer being conducted by TESARO in collaboration with Merck.

QUADRA: A registration trial of niraparib for the treatment of patients with recurrent ovarian cancer who have received three or four regimens of therapy.

AVANOVA: An NSGO (Nordic Society of Gynaecological Oncology) Phase 1/2 trial (in collaboration with ENGOT) evaluating niraparib plus bevacizumab in patients with recurrent ovarian cancer.

Breast Cancer

TNBC 3000-03-004: A Phase 3 clinical trial of niraparib in combination with anti- PD-1 antibody in comparison to standard of care in patients with advanced triple negative breast cancer.

TOPACIO: A Phase 2 clinical trial to evaluate the safety and efficacy of niraparib plus KEYTRUDA® in patients with triple negative breast cancer and patients with platinum resistant recurrent ovarian cancer being conducted by TESARO in collaboration with Merck.

Lung Cancer

Lung 3000-02-001: A Phase 2 clinical trial of niraparib in combination with an anti-PD-1 antibody in patients with advanced NSCLC and niraparib alone in patients with advanced squamous cell carcinoma of the lung.

Lung 3000-03-001: A Phase 3 clinical trial of niraparib in combination with an anti-PD-1 antibody in comparison to anti-PD-1 alone in patients with advanced NSCLC and high levels of PDL-1 tumor expression.

Prostate Cancer

Janssen Biotech has licensed rights to develop and commercialize niraparib specifically for patients with prostate cancer worldwide, except in Japan.

TESARO Investor Conference Call and Webcast
TESARO will webcast a conference call with investors and analysts today, March 27, 2017 at 4:30 PM ET. Investors and analysts may access this call by dialing (877) 853-5334 (U.S. and Canada) or (970) 315-0307 (international); no passcode is necessary. During this conference call, TESARO management will review the approval of ZEJULA and expanded niraparib development program, as well as answer questions from investors and analysts. This event will be webcast live and archived for 30 days, and may be accessed from the TESARO Investor Events and Presentations webpage at www.tesarobio.com.

About ZEJULA (Niraparib)
ZEJULA (niraparib) is an oral, once-daily poly(ADP-ribose) polymerase (PARP) 1/2 inhibitor that is indicated in the U.S. 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. In preclinical studies, ZEJULA concentrates in the tumor relative to plasma, delivering greater than 90% durable inhibition of PARP 1/2 and a persistent antitumor effect.

Select Important Safety Information
Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML) was reported in patients treated with ZEJULA in all clinical studies. Discontinue ZEJULA if MDS/AML is confirmed.

Hematologic adverse reactions (thrombocytopenia, anemia and neutropenia) have been reported in patients treated with ZEJULA. Do not start ZEJULA until patients have recovered from hematological toxicity caused by previous chemotherapy

(≤ Grade 1). Monitor complete blood counts weekly for the first month, monthly for the next 11 months of treatment, and periodically after this time.

Hypertension and hypertensive crisis have been reported in patients treated with ZEJULA. Monitor blood pressure and heart rate monthly for the first year and periodically thereafter during treatment with ZEJULA. Closely monitor patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.

Based on its mechanism of action, ZEJULA can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception during treatment and for six months after receiving the final dose. Because of the potential for serious adverse reactions in breastfed infants from ZEJULA, advise a lactating woman not to breastfeed during treatment with ZEJULA and for one month after receiving the final dose.

In clinical studies, the most common adverse reactions included: thrombocytopenia, anemia, neutropenia, nausea, constipation, vomiting, abdominal pain/distension, mucositis/stomatitis, diarrhea, fatigue/asthenia, decreased appetite, headache, insomnia, nasopharyngitis, dyspnea, rash and hypertension.

Please see full Prescribing Information for additional Safety Information.

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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Forward Looking Statements

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 include statements regarding the proposed design, details and timing of our plans for new niraparib clinical studies for the first-line treatment of patients in ovarian, breast and lung cancer indications, the potential transformational nature of those proposed indications, and our belief that the BRAVO trial is unlikely to produce interpretable data suitable to support a registration of niraparib in breast cancer. These forward-looking statements 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, uncertainties inherent in the execution and completion of clinical trials, uncertainties surrounding the timing of availability of data from clinical trials, uncertainties surrounding discussions with and potential actions by regulatory authorities, uncertainties surrounding enrollment in clinical trials, risks associated with our reliance upon third parties for the conduct of clinical trials, risks related to manufacturing and supply, and other matters that could affect the timing of availability of data from or initiation of our clinical trials. 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, 2016.