April 19, 2017

TESARO Announces Availability of Zejula™ (Niraparib) for Patients With Recurrent Ovarian Cancer in the U.S.

- **ZEJULA is the first and only PARP inhibitor to be approved for the maintenance treatment of women with recurrent ovarian cancer**
- **ZEJULA is the only PARP inhibitor that has demonstrated a clinically meaningful increase in PFS regardless of *BRCA* mutation or biomarker status**

WALTHAM, Mass., April 19, 2017 (GLOBE NEWSWIRE) -- TESARO, Inc. (NASDAQ:TSRO), an oncology-focused biopharmaceutical company, today announced that ZEJULA™ (niraparib), an oral, once-daily poly(ADP-ribose) polymerase (PARP) inhibitor, is now available by prescription in the United States. The U.S. Food and Drug Administration (FDA) approved ZEJULA on March 27, 2017 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 (CR or PR) to platinum-based chemotherapy. The National Comprehensive Cancer Network (NCCN) recently added ZEJULA to the NCCN Clinical Practice Guidelines in Oncology Ovarian Cancer version 1.2017—April 12, 2017—as maintenance therapy for patients with platinum-sensitive disease who are in partial or complete response after completion of two or more lines of platinum-based therapy.

"TESARO is committed to the responsible development and commercialization of transformative therapies for people bravely facing cancer, and we are proud to bring ZEJULA to women who until today had limited treatment options," said Lonnie Moulder, CEO of TESARO. "Increasing progression-free survival after platinum therapy is a truly meaningful benefit for patients and their families, and the once-daily, individualized dosing of ZEJULA allows healthcare providers to ensure the optimal dose per patient without compromising efficacy. We are committed to ensuring access for patients through TOGETHER with TESARO, our patient assistance program for ZEJULA, and we look forward to delivering this important new treatment option to patients and their caregivers."

ZEJULA is the only PARP inhibitor that has demonstrated a clinically meaningful increase in progression-free survival (PFS) in women with recurrent ovarian cancer, regardless of *BRCA* mutation or biomarker status, in a randomized, prospectively designed Phase 3 clinical trial. ZEJULA offers oral, once-daily dosing, enabling convenient administration for maintenance treatment. FDA approval of ZEJULA is based upon data from the international Phase 3 ENGOT-OV16/NOVA trial, a double-blind, placebo-controlled study that enrolled 553 patients with recurrent ovarian cancer who had achieved either a PR or CR to their most recent platinum-based chemotherapy. Approximately two-thirds of study participants did not have germline *BRCA* mutations. Progression in the NOVA study was determined by robust, unbiased, blinded central review, to be the earlier of radiographic or clinical progression. ZEJULA significantly increased PFS in patients with and without germline *BRCA* mutations as compared to control. Treatment with ZEJULA reduced the risk of disease progression or death by 74% in patients with germline *BRCA* mutations (HR 0.26) and by 55% in patients without germline *BRCA* mutations (HR 0.45). The magnitude of benefit was similar for patients entering the trial with a PR or a CR.

The most common grade 3/4 adverse reactions to ZEJULA in the NOVA trial included thrombocytopenia (29%), anemia (25%), neutropenia (20%), and hypertension (9%). The majority of hematologic adverse events were successfully managed via dose modification, and discontinuation of therapy due to thrombocytopenia, neutropenia and anemia occurred in 3.3%, 1.9% and 1.4% of patients, respectively. Following dose adjustment based on individual tolerability, the incidence of grade 3/4 thrombocytopenia was low; approximately $\leq$1% after month 2. Please see the "Select Important Safety Information" below for warnings, precautions and adverse events.

"Women with recurrent ovarian cancer often experience considerable fear and anxiety about future recurrences," said Audra Moran, President and CEO of Ovarian Cancer Research Fund Alliance. "ZEJULA may offer patients and their families a treatment option during this stressful period. The ovarian cancer community is eager for new treatment options, and we are glad that ZEJULA will be available to women that have completed their platinum-based chemotherapy."

The Wholesale Acquisition Cost (WAC) of ZEJULA is $9,833 for a one-month supply of ZEJULA at a dose of 200 milligrams once per day, the most commonly administered dose over the course of the Phase 3 NOVA clinical trial. The approved starting dose of ZEJULA is 300 milligrams once per day.

TESARO is committed to ensuring access to ZEJULA. The Company's patient assistance program, TOGETHER with TESARO™, is a reflection of TESARO's commitment to the patient community and includes comprehensive services such as commercial copay assistance, assistance for the uninsured or underinsured, and access to other organizations that support

ovarian cancer patients, among others.

About TOGETHER with TESARO™
TOGETHER with TESARO™ is a patient resource program dedicated to supporting people living with cancer. The program assists with access issues, so that patients with cancer can be free to focus on treatment goals and simply living life. It provides a full suite of services to meet each patient's needs and individual experience. A team of access and affordability experts is available to help oncology practices and patients gain access to the medication they require. TOGETHER with TESARO will continue to evolve and grow to meet provider and patient needs. For more information, please visit www.togetherwithtesaro.com or call 1-844-2TESARO (1-844-283-7276).

About Ovarian Cancer
Approximately 22,000 women are diagnosed with ovarian cancer each year 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. Per NCCN guidelines, *BRCA* testing and genetic counseling remain important components of the medical workup for all patients upon a diagnosis with ovarian cancer.

About the ZEJULA™ (Niraparib) ENGOT-OV16/NOVA Clinical Trial
ENGOT-OV16/NOVA was a double-blind, placebo-controlled, international Phase 3 trial of niraparib that enrolled 553 patients with recurrent ovarian cancer who were in a response to their most recent platinum-based chemotherapy. Patients were enrolled into one of two independent cohorts based on germline *BRCA* mutation status. One cohort enrolled patients who were germline *BRCA* mutation carriers (g*BRCA*mut), and the second cohort enrolled patients who were not germline *BRCA* mutation carriers (non-g*BRCA*mut) and included patients with HRD-positive and HRD-negative tumors. Within each cohort, patients were randomized 2:1 to receive niraparib or placebo and were treated continuously with placebo or 300 milligrams of niraparib, dosed as three 100 milligram tablets once per day, until progression. The primary endpoint of this study was progression-free survival (PFS). Secondary endpoints included patient-reported outcomes, chemotherapy-free interval length, PFS 2, overall survival, and other measures of safety and tolerability. More information about this trial is available at http://clinicaltrials.gov/show/NCT01847274.

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 0.26 (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 ($p<0.0001$). Niraparib also showed statistical significance for 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 ($p<0.0001$). Secondary endpoint analyses, including chemotherapy-free interval, time to first subsequent treatment, and PFS 2 were all statistically significant and favored niraparib over control for patients in both the g*BRCA*mut and non-g*BRCA*mut cohorts. Patient-reported outcome results from validated survey tools indicated that niraparib-treated patients reported no difference from control in measures associated with quality of life.

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*.

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 at www.zejula.com.

Additional Clinical Trials of Niraparib
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) and a registrational Phase 2 trial in patients who have received multiple lines of treatment for ovarian cancer (the QUADRA trial). Several combination studies are also underway, including trials of niraparib plus pembrolizumab (the TOPACIO trial) and niraparib plus bevacizumab (the AVANOVA trial).

Additional trials of niraparib in ovarian, breast and lung cancers are planned. The studies will assess the effect of niraparib alone and in combination with other therapies, such as bevacizumab and an anti-PD-1 antibody, in a variety of treatment settings.

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

About ZEJULA (Niraparib)
ZEJULA 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. The National Comprehensive Cancer Network (NCCN) recently added ZEJULA to the NCCN Clinical Practice Guidelines in Oncology Ovarian Cancer version 1.2017—April 12, 2017—as maintenance therapy for patients with platinum-sensitive disease who are in partial or complete response after completion of 2 or more lines of 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.

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.

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 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, risks associated with competition in the PARP market, risks related to pricing and reimbursement, risks related to manufacturing and supply, risks related to intellectual property, and other risks and uncertainties that could affect the availability or commercial potential of ZEJULA. 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.

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