# TESARO Announces Positive Top-Line Results From Quadra Trial of ZEJULA®

April 24, 2018

- **Results demonstrate ZEJULA activity beyond patients with *BRCA* mutations in late-line ovarian cancer treatment setting**
- **QUADRA data accepted for presentation at 2018 ASCO annual meeting**
- **Data intended to support label expansion with biomarker in the treatment setting**

WALTHAM, Mass., April 24, 2018 (GLOBE NEWSWIRE) -- TESARO, Inc. (NASDAQ:TSRO), an oncology-focused biopharmaceutical company, today announced results from the QUADRA study, which was designed to assess clinical benefit of ZEJULA® treatment in heavily pre-treated patients with ovarian cancer. Results successfully achieved the pre-specified primary endpoint and demonstrated ZEJULA monotherapy activity in a biomarker selected patient population.

Previous studies have shown PARP inhibitor activity in the late-line treatment of patients with *BRCA* mutations. QUADRA, a single arm study (n=461), was conducted to assess the activity of ZEJULA monotherapy in the fourth-line plus treatment of specific ovarian cancer patient populations. Of the 92% of QUADRA participants who were PARP inhibitor naïve, 15% had a *BRCA* mutation, over two-thirds were platinum resistant/refractory and 63% had received prior bevacizumab.

ZEJULA demonstrated activity in the primary efficacy population of fourth and fifth-line HRD positive patients who were PARP inhibitor naïve, and platinum sensitive (n=45), with an objective response rate (ORR) of 29%, and duration of response (DOR) of 9.2 months. In patients who were fourth line or greater with *BRCA* mutations, including platinum-sensitive, resistant and refractory, (n=55), the ORR was 31% and the median DOR was 9.4 months.

At a starting dose of 300 milligrams of ZEJULA, the most commonly observed adverse events were consistent with prior clinical experience and included myelosuppression, which was generally managed via dose modifications. TESARO intends to discuss a biomarker focused regulatory submission with the U.S. Food and Drug Administration (FDA) for a potential supplemental New Drug Application (sNDA) in the second half of 2018.

“These results demonstrated that ZEJULA is active as a late-line treatment for patients beyond those with *BRCA* mutations, which is the only treatment setting in which PARP inhibitors are approved today. In addition, the QUADRA data describe ZEJULA monotherapy activity in platinum-resistant/refractory patients, providing important context for our TOPACIO study of ZEJULA in combination with an anti-PD-1 inhibitor,” said Mary Lynne Hedley, President and COO of TESARO. “With QUADRA data in hand, we continue to advance our mission to provide all patients with ovarian cancer an opportunity to benefit from treatment with ZEJULA, and we are extremely grateful to the patients, caregivers, and investigators who took part in this study.”

Beyond QUADRA, clinical trials of niraparib in ovarian cancer include:

**First Line:**

- PRIMA: Monotherapy Phase 3 trial for patients with first-line ovarian cancer regardless of biomarker status expected to complete enrollment in Q2 2018; data anticipated in 2019
- OVARIO: Combination Phase 2 trial assessing ZEJULA with bevacizumab for patients with newly diagnosed ovarian cancer
- FIRST: Combination Phase 3 clinical trial of chemotherapy ± TSR-042, and ZEJULA in first-line ovarian cancer to be initiated in 1H 2018

**Recurrent:**

- NOVA: Monotherapy Phase 3 trial for patients with platinum sensitive, recurrent ovarian cancer, regardless of biomarker status (complete; patients being followed for overall survival)
- AVANOVA: Combination Phase 2 trial with bevacizumab for patients with recurrent ovarian cancer; anticipate data to be available in 2H 2018 to support data submission for a meeting held in 2019

**Platinum-Resistant:**

- TOPACIO: Combination Phase 2 trial with anti-PD-1 for patients with platinum-resistant ovarian cancer or triple negative breast cancer (abstracts accepted for presentation at ASCO)

**Product Lifecycle:**

- A tablet formulation of ZEJULA is in development.

**About the QUADRA Clinical Trial**
QUADRA is an open-label, single arm trial designed to evaluate the safety and efficacy of ZEJULA in the treatment setting of ovarian cancer. Patients were enrolled and received a starting dose of 300 milligrams of niraparib once per day. The primary endpoint of this study was objective response rate (ORR) per RECIST in the fourth and fifth-line HRD positive patients who were PARP inhibitor naïve, and platinum sensitive. Other endpoints include durability of response, disease control rate, progression free survival (PFS), overall survival (OS) and safety and tolerability.

**About ZEJULA® (Niraparib)**
Niraparib is marketed in the United States and Europe under trade name ZEJULA®. ZEJULA (niraparib) is a poly(ADP-ribose) polymerase (PARP) inhibitor indicated 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.

**ZEJULA (niraparib) Select Important Safety Information**
Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML) was reported in patients treated with ZEJULA in some 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.

**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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**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. Examples of forward-looking statements contained in this press release include, among others, statements regarding our biomarker and regulatory strategy and our intent to file an sNDA in the second half of 2018. Forward-looking statements in this release involve substantial risks and uncertainties that could cause our 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 the execution and completion of clinical trials and regulatory submissions, uncertainties surrounding the timing of availability of data from clinical trials, uncertainties surrounding potential actions by regulatory authorities such as the US FDA, risks related to manufacturing and supply, risks related to intellectual property, and other matters that could affect our ongoing and planned development programs, and/or 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, 2017.*


Primary Logo

Source: TESARO, Inc.