TESARO Announces Expansion to Second Stage of JASPER Trial of ZEJULA® in Combination With TSR-042 in Non-Small Cell Lung Cancer

September 4, 2018

- **All evaluable patients experienced tumor shrinkage**
- **Protocol defined response criteria achieved and trial expansion ongoing**

WALTHAM, Mass., Sept. 04, 2018 (GLOBE NEWSWIRE) -- TESARO, Inc. (NASDAQ: TSRO), an oncology-focused biopharmaceutical company, today announced it has initiated the second stage of the JASPER study that is designed to assess clinical benefit of ZEJULA® in combination with an anti-PD-1 antibody in first-line non-small cell lung cancer (NSCLC) patients. The decision to advance the trial was based on achieving the protocol defined response criteria in the initial cohort of 16 treated patients with high PD-L1 expression, of which 14 were evaluable for a response. Nine of the 14 patients had objective responses by RECIST criteria at the time of the analysis[1]; with all 14 patients experiencing tumor shrinkage.

"These JASPER data provide preliminary evidence that the combination of ZEJULA and an anti-PD-1 antibody could be active as a first-line treatment for patients with non-small cell lung cancer and high levels of PD-L1 expression," said Mary Lynne Hedley, Ph.D., President and COO of TESARO. "In the second stage of the trial, 36 additional patients will be enrolled and treated with ZEJULA in combination with TSR-042, our anti-PD-1 antibody. TSR-042 is the foundation of our lung cancer strategy, and is also being studied as a monotherapy in our GARNET trial in anti-PD-(L)1 naïve patients who have progressed on chemotherapy, and in combination with TSR-022, our anti-TIM-3 antibody, in AMBER, a study in late-line NSCLC patients that have progressed after anti-PD-(L)1 therapy. We look forward to sharing lung cancer data from both GARNET and AMBER at the Society for the Immunotherapy of Cancer (SITC) Annual Meeting in November."

About the JASPER Clinical Trial
JASPER is a Phase 2, open-label, single arm trial designed to evaluate the safety and efficacy of ZEJULA in combination with an anti-PD-1 antibody for the treatment of first-line NSCLC. Patients were enrolled in stage 1 of the study and received a starting dose of 200 milligrams of niraparib once per day and 200 milligrams Q3 weeks of an anti-PD-1 antibody. The primary endpoint of stage 1 of the study was objective response rate (ORR) per RECIST. 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.

Investor/Media Contact:
Jennifer Davis
Vice President, Corporate Affairs & Investor Relations
+1.781.325.1116 or jdavis@tesarobio.com

Kate Rausch
Director, Investor Relations
+1.781.257.2505 or krausch@tesarobio.com

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 clinical development plans, our intent to enroll the second stage or the JASPER trial, and our intent to present GARNET and AMBER data 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, and Quarterly Report on Form 10-Q for the quarter ended June 30, 2018.

[1] Includes both confirmed and unconfirmed responses.


TESARO®
logo_RGB_small.png

Source: TESARO, Inc.