TESARO Announces Data Presentations at the ESMO 2018 Congress

October 9, 2018

WALTHAM, Mass., Oct. 09, 2018 (GLOBE NEWSWIRE) -- TESARO, Inc. (NASDAQ: TSRO), an oncology-focused biopharmaceutical company, today announced that data from six abstracts will be presented at the European Society for Medical Oncology (ESMO) Congress from October 19-23, 2018 in Munich, Germany.

“At this year’s ESMO Congress, blinded, pooled interim safety data from PRIMA will be presented, which demonstrated that an individualized starting dose of ZEJULA resulted in a favorable tolerability profile compared to a fixed starting dose of 300 milligrams. PRIMA is a fully-enrolled Phase 3 trial for patients with first-line ovarian cancer regardless of biomarker status and we expect top-line results to be available in late 2019,” said Mary Lynne Hedley, Ph.D., President and COO of TESARO. “TESARO is also advancing a robust immuno-oncology portfolio. Data will be presented in a poster discussion from the MSI-H endometrial cohort of the GARNET trial of TSR-042, our anti-PD-1 antibody, for which we are planning to submit a biologic license application (BLA) next year.”

Please plan to visit TESARO at Booth #212 for information about ZEJULA and our pipeline.

Details of TESARO’s poster presentations are as follows (all times local):
All posters will be on display beginning Saturday, October 20, 7:30 AM.

ZEJULA® (niraparib)

Saturday, October 20, 2018, 9:15 AM – 10:45 AM; Lecture time: 9:59 AM
A prospective evaluation of tolerability of niraparib dosing based upon baseline body weight (wt) and platelet (plt) count: Blinded pooled interim safety data from the PRIMA Study
Poster Discussion, Abstract: 941PD, Location: ICM – Room 13, Poster Displayed: Hall B4

Saturday, October 20, 2018, 12:30 PM – 1:30 PM
QUADRA: A phase 2, open-label, single-arm study to evaluate niraparib in patients with relapsed ovarian cancer in 4th or later line of therapy: results from the tBRCAmut subset
Poster Session, Abstract: 944P, Location: Hall A3

Saturday, October 20, 2018, 12:30 PM – 1:30 PM
OVARIO: A single-arm, open-label phase 2 study of maintenance therapy with niraparib + bevacizumab in patients with advanced ovarian cancer after response to frontline platinum-based chemotherapy
Poster Session, Abstract: 999TiP, Location: Hall A3

Saturday, October 20, 2018, 12:30 PM – 1:30 PM
Real world occurrence of top three clinical-trial reported adverse events of PARP inhibitor niraparib maintenance therapy in platinum-sensitive recurrent ovarian cancer, a national retrospective observational study of a 200 mg/day starting-dose cohort
Poster Session, Abstract: 986P, Location: Hall A3

Saturday, October 20, 2018, 12:30 PM – 1:30 PM
Brain metastases in primary ovarian cancer: real-world data
Poster Session, Abstract: 946P, Location: Hall A3

TSR-042 (anti-PD-1)

Saturday, October 20, 2018, 9:15 – 10:45 AM; Lecture time: 9:15 AM
Preliminary safety, efficacy, and PK/PD characterization from GARNET, a phase 1 clinical trial of the anti–PD-1 monoclonal antibody, TSR-042, in patients with recurrent or advanced MSI-H endometrial cancer
Poster Discussion, Abstract: 935PD, Location: ICM – Room 13, Poster displayed: Hall B4

Niraparib is marketed in the United States and Europe under trade name ZEJULA®.

About ZEJULA (Niraparib)
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. Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML), including some fatal cases, was reported in patients treated with ZEJULA. Discontinue ZEJULA if MDS/AML is confirmed. Hematologic adverse reactions (thrombocytopenia, anemia and neutropenia), as well as cardiovascular effects (hypertension and hypertensive crisis) have been reported in patients treated with ZEJULA. Monitor complete blood counts to detect hematologic adverse reactions, as well as to detect cardiovascular disorders, during treatment. ZEJULA can cause fetal harm and females of reproductive potential should use effective contraception. Please see full U.S. prescribing information, including additional important safety information, available at www.zejula.com.

About TSR-042
TSR-042 is a monoclonal antibody targeting PD-1 and was developed as part of the collaboration between TESARO and AnaptysBio, Inc. This collaboration was initiated in March of 2014, and is focused on the development of monospecific antibody drugs targeting PD-1, TIM-3 (TSR-022), and LAG-3 (TSR-033), in addition to a bi-specific antibody drug candidate targeting PD-1/LAG-3 (TSR-075).

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, 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. Examples of forward-looking statements contained in this press release include, among others, statements regarding: expected timing of PRIMA top-line results and the expecting timing of TSR-042 data presentation and BLA filing. Forward-looking statements in this release involve substantial risks and uncertainties that could cause our research and development programs, future financial and other 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 related to the uncertainties inherent in the execution and completion of clinical trials, uncertainties surrounding the timing of availability of data from clinical trials, and uncertainties regarding the expected timing or regulatory filings. 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.

Source: TESARO, Inc.