April 27, 2017

TESARO Initiates Registrational Development Program for Anti-PD-1 Antibody TSR-042

- **TSR-042 is the first TESARO immuno-oncology candidate to enter a registration program**
- **Ongoing clinical trial expanded to enroll patients with endometrial cancer**
- **Patient-centric administration schedule with every 6 week dosing**

WALTHAM, Mass., April 27, 2017 (GLOBE NEWSWIRE) -- TESARO, Inc. (NASDAQ:TSRO), an oncology-focused biopharmaceutical company, today announced that following the recent identification of a fixed dose and patient-centric dosing schedule, the ongoing clinical trial of TSR-042 has been expanded to enroll patients with metastatic microsatellite instability high (MSI-H) endometrial cancer who have progressed following one or two prior chemotherapy treatments. During the first 12 weeks of treatment, TSR-042 is administered once every three weeks, followed by a single dose administration every six weeks until disease progression. The intent of this study is to support a request for accelerated approval and Biologics License Application (BLA) submission to the U.S. Food and Drug Administration (FDA). The primary endpoints of this trial are overall response rate (ORR) and duration of response, and secondary endpoints include disease control rate, progression free survival (PFS), and overall survival (OS). The addition of cohorts for patients with other tumor types is also planned. This is the first clinical development program within a broader plan that includes potential label expansion trials of TSR-042 in multiple cancers in combination with ZEJULA®, TSR-022, TESARO's anti-TIM-3 antibody, and TSR-033, TESARO's anti-LAG-3 antibody.

"TSR-042 was the first antibody from our immuno-oncology portfolio to enter clinical trials, and following identification of a fixed dose and schedule, we are pleased to be advancing TSR-042 into a registration program," said Mary Lynne Hedley, Ph.D., President and COO of TESARO. "With the recent approval of ZEJULA in the U.S., the initiation of this development program furthers our commitment to women with gynecologic tumors, including ovarian, fallopian tube, and peritoneal cancer. We intend to continue our efforts with future combination studies of TSR-042 and ZEJULA, and to someday eliminate these terrible diseases and benefit women who were until recently largely underserved by new therapeutic options."

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.

About Endometrial Cancer

Endometrial cancer is the most common type of uterine cancer, accounting for more than 95 percent of cases. Endometrial cancer develops in the lining of the uterus, called the endometrium. The annual number of new cases of endometrial cancer is estimated at 325,000 worldwide. The most common histologic form is endometrioid adenocarcinoma originating in the glandular tissue, which represents about 75-80% of diagnosed cases. In 2017, SEER[1] estimates 61,380 patients will be diagnosed with endometrial cancer, with approximately 30% or 18,414 being stage III/IV patients. Based on genomic characterization studies of endometrial cancer, 20-25% of patients have tumors with a microsatellite instability phenotype (MSI-H)[2]. Microsatellite instability arises from a failure to repair replication-associated errors due to a defective DNA mismatch repair system. This failure allows persistence of mismatch mutations all over the genome, but especially in regions of repetitive DNA known as microsatellites, leading to increased mutational load that has been demonstrated to improve responses to anti-PD-1 therapies.[3,4]

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. Examples of forward-looking statements contained in this press release include our plans to submit a BLA and seek accelerated FDA approval for TSR-042, our plans to add cohorts for patients with other tumor types, and our plans to pursue future combination studies with TSR-042 and ZEJULA. 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, the uncertainties inherent in the execution and completion of clinical trials, risks associated with our reliance upon third parties for the conduct of clinical trials, uncertainties surrounding our ongoing discussions with and potential actions by regulatory authorities, risks related to manufacturing and supply, risks related to intellectual property, and other matters that could affect the timing of availability of data from or initiation of our planned clinical trials or the availability or commercial potential of TSR-042. 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.

1. SEER: National Cancer Institute's Surveillance, Epidemiology, and End Results Program
2. Kandoth C, Schultz N, Cherniack AD, et al: Integrated genomic characterization of endometrial carcinoma. Nature 497:67-73, 2013.
3. Le DT, Uram JN, Wang H, et al: PD-1 Blockade in Tumors with Mismatch-Repair Deficiency. N Engl J Med 372:2509-20, 2015.
4. Westdorp H, Fennemann FL, Weren RD, et al: Opportunities for immunotherapy in microsatellite instable colorectal cancer. Cancer Immunol Immunother 65:1249-59, 2016.

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