# TESARO Summarizes TSR-042 Clinical Data Presented at AACR

April 16, 2018

- **Activity of TSR-042 (anti-PD-1 antibody) monotherapy demonstrated in patients with MSI-high endometrial and non-small cell lung cancers**
- **Data support unique and convenient dosing schedule**
- **Regulatory submission for TSR-042 for MSI-high tumors planned in 2H 2019**

CHICAGO, April 16, 2018 (GLOBE NEWSWIRE) -- TESARO, Inc. (NASDAQ:TSRO), an oncology-focused biopharmaceutical company, today summarized initial data from the Phase 1 GARNET trial of TSR-042 (anti-PD-1 antibody) in patients with microsatellite instability high (MSI-H) endometrial cancer and non-small cell lung cancer (NSCLC) presented during the American Association for Cancer Research (AACR) Annual Meeting.

“Preliminary results from GARNET presented today at AACR are the first clinical data from expansion cohorts for TSR-042, our anti-PD-1 antibody,” said Mary Lynne Hedley, Ph.D., President and COO of TESARO. “These results demonstrate the clinical activity of TSR-042 and support our unique patient-centric dosing regimen that includes dosing every 6 weeks. We expect to complete enrollment in the MSI-H endometrial cohort of the GARNET trial by the end of the year. A regulatory submission for TSR-042 is planned in 2019. The breadth of TESARO’s immuno-oncology portfolio, which also includes antibodies targeting TIM-3 and LAG-3, enables us to evaluate both monotherapy and novel combination approaches with a goal of providing transformative therapies for people living with cancer.”

**Preliminary Activity in MSI-H Endometrial Cancer and Non-Small Cell Lung Cancer**
GARNET is a multicenter, open-label, Phase 1 dose-escalation study designed to assess the safety, pharmacokinetics, pharmacodynamics, and clinical activity of TSR-042 in patients with advanced solid tumors. Part 1, a weight-based dose escalation study, and part 2A, a fixed-dose safety study, of GARNET have been completed. The ongoing part 2B expansion portion of GARNET is evaluating TSR-042 at a dose of 500 milligrams every 3 weeks for the first 4 cycles, and 1000 milligrams every 6 weeks thereafter in four open cohorts: MSI-H endometrial cancer, MSI-high non-endometrial cancer, MSS endometrial cancer and NSCLC. Data presented at AACR included efficacy data from the cohorts of patients with MSI-H endometrial cancer and NSCLC from part 2B of the trial.

At the time of data cutoff, 15 patients with MSI-H endometrial cancer and 24 patients with NSCLC had at least 1 tumor assessment. Among the 15 patients with MSI-H endometrial cancer, 7 had partial responses by immune related RECIST (irRECIST) criteria (ORR 47%). Eleven patients continue on therapy, including one patient with a partial response who has thus far received over 42 weeks of TSR-042. Three additional patients (20%) had stable disease.

Among the 24 patients with NSCLC, 7 had partial responses by irRECIST criteria (ORR 29%). Twelve patients continue on therapy, including one patient with a partial response who has thus far received over 36 weeks of TSR-042. Ten additional patients had stable disease (42%), one of whom has continued treatment for over 36 weeks.

Preliminary safety findings among the 120 evaluable patients (including patients with MSI-H endometrial, NSCLC, and other tumor types) indicate TSR-042 is well-tolerated. Grade ≥3 treatment-related treatment-emergent adverse events (TEAEs) were reported in 9 of 120 patients (7%).

Serum concentrations of TSR-042 observed 6 weeks after the 1000 milligram dose were comparable to those observed 3 weeks after the 500 milligram dose, and maximal receptor occupancy was maintained throughout the 6-week dosing interval.

The GARNET study is intended to support a Biologics License Application (BLA) submission to the U.S. Food and Drug Administration (FDA) for patients with MSI-H cancers in 2019.

**TESARO Poster Presentations at AACR** (all times local)

**Immuno-oncology**
Monday, April 16, 2018, 8:00 AM to 12:00 PM
*Preliminary safety, efficacy and PK/PD characterization from GARNET, a phase I clinical trial of the anti-PD-1 monoclonal antibody, TSR-042, in patients with recurrent or advanced NSCLC or MSI-H endometrial cancer*
Poster Session, Abstract: CT053, Location: Exhibit Hall A, Poster Section 42, Poster Board 6

Monday, April 16, 2018, 8:00 AM to 12:00 PM
*Checkpoint inhibitor signatures across endometrial cancer histologies*
Poster Session, Abstract: 1687, Location: Exhibit Hall A, Poster Section 31, Poster Board 12

Monday, April 16, 2018, 8:00 AM to 12:00 PM
*Simultaneous measurement and significance of PD-1, LAG-3 and TIM-3 expression in human solid tumors*
Poster Session, Abstract: 1681, Location: Exhibit Hall A, Poster Section 31, Poster Board 6

Monday, April 16, 2018, 1:00 PM to 5:00 PM
*Investigation of the expression profile and functional role of PD-1, TIM-3 and LAG-3 in human tumors*

Poster Session, Abstract: 2722, Location: Exhibit Hall A, Poster Section 32, Poster Board 14

Wednesday, April 18, 2018, 8:00 AM to 12:00 PM
*Characterization of tumor growth and immune microenvironment in humanized NOG-EXL mice implanted with A549, MDA-MB-436 and A375 cells*
Poster Session, Abstract: 5690, Location: Exhibit Hall A, Poster Section 31, Poster Board 26

**About GARNET**
The ongoing Phase I GARNET trial is evaluating TSR-042 as monotherapy in patients with advanced solid tumors. GARNET included a weight-based dose escalation study (Part 1) and a fixed-dose safety study (Part 2A), both of which have been completed. Results of these studies were used to determine the recommended Phase 2 dose (RP2D; 500 mg Q3W for the first 4 cycles then 1000 mg Q6W). The study is now enrolling patients with MSI-H endometrial cancer, MSI-H non-endometrial cancer, MSS endometrial cancer, and NSCLC into four large expansion cohorts.

**About TSR-042**
TSR-042 is an investigational humanized anti-programmed death (PD)-1 monoclonal antibody that binds with high affinity to the PD-1 receptor and effectively blocks its interaction with the ligands PD-L1 and PD-L2. TSR-042 is the only anti-PD-1 therapy administered as monotherapy every 3 weeks for 4 doses then every 6 weeks thereafter. TSR-042 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 devoted to providing transformative therapies to people facing cancer. For more information, visit www.tesarobio.com, and follow us on Twitter and LinkedIn.

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

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

*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 the potential dosing schedule for TSR-042, the timing of expected completion of enrollment of the MSI-H endometrial cohort, and the expected timing of our planned regulatory submission for TSR-042. 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 our products and product candidates, including 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, 2017.*


Primary Logo

Source: TESARO, Inc.