TESARO Announces Data Presentations at the 2019 SGO Annual Meeting on Women's Cancer

March 5, 2019

WALTHAM, Mass., March 05, 2019 (GLOBE NEWSWIRE) -- TESARO, an oncology-focused business within GSK, today announced that data for dostarlimab (anti-PD-1 antibody, formerly TSR-042) and Zejula® (niraparib) will be presented at the 2019 Society of Gynecologic Oncology (SGO) Annual Meeting on Women's Cancer being held March 16-19 in Honolulu, Hawaii.

"At this year's SGO meeting, data will be presented from the GARNET trial of dostarlimab in recurrent endometrial cancer patients, including patients with recurrent MSS endometrial cancer, for which limited treatment options exist today," said Mary Lynne Hedley, Ph.D., President and COO of TESARO. "We are on track to submit a BLA for dostarlimab by the end of the year. Data will also be presented from several studies of Zejula in patients with ovarian cancer, including safety data from the fully enrolled Phase 3 PRIMA study of Zejula as a first-line maintenance therapy for ovarian cancer regardless of *BRCA* status."

Please plan to visit TESARO at Booth #207 for information on the expanded development program for Zejula, dostarlimab and our broader pipeline.

Oral Presentations Information (all times local):

Dostarlimab (TSR-042)

Tuesday, March 19, 2019, 7:45 AM to 9:00 AM
Preliminary safety, efficacy, and pharmacokinetic/pharmacodynamic characterization from GARNET, a phase I/II clinical trial of the anti–PD-1 monoclonal antibody, TSR-042, in patients with recurrent or advanced MSI-H and MSS endometrial cancer (EC)
Oral in the Scientific Plenary VI, Abstract: 33, Location: Kamehameha 3

Zejula® (niraparib)

Saturday, March 16, 2019, 6:45 AM to 7:45 AM
Time without symptoms or toxicity in patients with recurrent ovarian cancer receiving niraparib maintenance treatment versus placebo: A TWIST analysis of the ENGOT-OV16/NOVA trial
Oral in the Scientific Plenary I, Abstract: 1, Location: Kamehameha 3

Saturday, March 16, 2019, 6:45 AM to 7:45 AM
Baseline platelet count and body weight as predictors of early dose modification in the QUADRA trial of niraparib monotherapy for the treatment of heavily pretreated (≥4th line), advanced, recurrent high-grade serous ovarian cancer (OC)
Oral in the Scientific Plenary I, Abstract: 2, Location: Kamehameha 3

Saturday, March 16, 2019, 6:45 AM to 7:45 AM
A prospective evaluation of tolerability of niraparib dosing based upon baseline body weight and platelet count: Blinded pooled interim safety data from the ENGOT-OV26/PRIMA study
Oral in the Scientific Plenary I, Abstract: 3, Location: Kamehameha 3

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) 1/2 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 tumour relative to plasma, delivering greater than 90% durable inhibition of PARP 1/2 and a persistent antitumour 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 prescribing information, including additional important safety information, available at www.zejula.com.

About GARNET
The ongoing Phase I/II GARNET trial is evaluating dostarlimab 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). Part 2B of the study includes four large expansion cohorts: MSI-H endometrial cancer, MSI-H non-endometrial cancer, MSS endometrial cancer, and non-small cell lung cancer (NSCLC).

About dostarlimab
Dostarlimab (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. Dostarlimab is the only anti-PD-1 therapy administered as monotherapy every 3 weeks for 4 doses then every 6 weeks thereafter. Dostarlimab 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 business within GSK, devoted to providing transformative therapies to people facing cancer. For more information, visit www.tesarobio.com, and follow us on Twitter and LinkedIn.

Media Contact:
Kristin Ainsworth
Vice President, Corporate Affairs, Advocacy, PR & Communications
+1.781.786.7007 or kainsworth@tesarobio.com