COPENHAGEN, October 8, 2016 – TESARO, Inc. (NASDAQ: TSRO), an oncology-focused biopharmaceutical company, and ENGOT, the European Network for Gynaecological Oncological Trial groups, today announced the presentation of the niraparib Phase 3 ENGOT-OV16/NOVA clinical trial results at the ESMO 2016 Congress, the congress of the European Society for Medical Oncology (ESMO), by Dr. Mansoor Raza Mirza, M.D., Medical Director of the Nordic Society of Gynecologic Oncology (NSGO) and principal investigator on the ENGOT-OV16/NOVA trial. These data were discussed during the ESMO press briefing in Copenhagen as part of the congress, and were simultaneously published online in the New England Journal of Medicine.1 The results will also be presented by Dr. Mirza later today during Presidential Symposium 1 (Abstract #LBA3_PR) at ESMO.

ENGOT-OV16/NOVA is a double-blind, placebo-controlled, international Phase 3 trial of niraparib that enrolled 553 patients with recurrent ovarian cancer who were in response to their most recent platinum-based chemotherapy. This trial was designed to assess progression free survival (PFS) in a broad population of patients who were assigned to one of two cohorts based upon germline BRCA mutation status. The ENGOT-OV16/NOVA trial successfully achieved its primary endpoint in both cohorts, demonstrating that niraparib treatment significantly prolonged PFS compared to control in patients who were germline BRCA mutation (gBRCAmut) carriers and in patients who were not germline BRCA mutation (non-gBRCAmut) carriers. In addition, within the non-gBRCA cohort, niraparib treatment significantly prolonged PFS compared to control for the prospectively defined patient population with tumors deficient in homologous recombination (HRDpos) as determined by the Myriad myChoice® HRD test. A high proportion of patients in both treatment groups in both cohorts had received three or more prior lines of chemotherapy.

“These landmark results are extremely encouraging for the ovarian cancer community,” said Dr. Mirza. “The effectiveness of platinum-based chemotherapy diminishes over time, and PFS and platinum-free intervals generally become shorter after each round of platinum treatment. In addition, the incidence of infection and risk of neuropathy and hypersensitivity with certain chemotherapy agents rises with subsequent cycles. An oral maintenance treatment that could lengthen the PFS interval between rounds of platinum-based chemotherapy would be very meaningful for patients with ovarian cancer, who often live with a fear of recurrence after ending active treatment.”
“We would like to thank the patients, their families and the caregivers that participated in the ENGOT-OV16/NOVA study, as well as our partners at ENGOT for their diligence in executing this trial,” said Mary Lynne Hedley, Ph.D., President and COO of TESARO. “We believe the results of this Phase 3 study demonstrated a meaningful benefit for women with platinum sensitive, recurrent ovarian cancer.”

**Primary Endpoint Results:**

**Statistically Significant PFS Results in the gBRCAmut Cohort**
Among patients who were germline BRCA mutation carriers, the niraparib arm successfully achieved statistical significance over the control arm for the primary endpoint of PFS, with a hazard ratio of 0.27 (95% CI, 0.173-0.410). The median PFS for patients treated with niraparib was 21.0 months, compared to 5.5 months for control (p<0.0001).

**Statistically Significant PFS Results in the non-gBRCAmut Cohort**
Niraparib showed statistical significance for patients in the non-germline BRCA mutant cohort. The niraparib arm successfully achieved statistical significance over the control arm for the primary endpoint of PFS, with a hazard ratio of 0.45 (95% CI, 0.338-0.607). The median PFS for patients treated with niraparib was 9.3 months, compared to 3.9 months for control (p<0.0001).

**Statistically Significant PFS Results in non-gBRCAmut Cohort for Patients with HRD-Positive Tumors**
For patients who were not germline BRCA mutation carriers but whose tumors were determined to be HRD positive using the Myriad myChoice® HRD test, the niraparib arm successfully achieved statistical significance over the control arm for the primary endpoint of PFS, with a hazard ratio of 0.38 (95% CI, 0.243-0.586). The median PFS for patients with HRD-positive tumors who were treated with niraparib was 12.9 months, compared to 3.8 months for control (p<0.0001).

**Secondary Endpoint Results:**
Secondary endpoint analyses, including chemotherapy-free interval, time to first subsequent treatment, and PFS 2 were all statistically significant and favored niraparib over control for patients in both the gBRCAmut and non-gBRCAmut cohorts. Patient-reported outcome results from validated survey tools indicated that niraparib-treated patients reported no difference from control in measures associated with quality of life. Data for overall survival are immature (HR 0.73; 95% CI, 0.480 to 1.125; p=0.1545), as fewer than 20% of events had occurred at the time of analysis.

**Safety Results:**
The most common (≥10%) treatment-emergent grade 3/4 adverse events in the niraparib arm were thrombocytopenia (33.8%), anemia (25.3%), and neutropenia (19.6%) with treatment discontinuation for these events of 3.3%, 1.4% and 1.9%, respectively. Thrombocytopenia was not associated with grade 3/4 bleeding events. The majority of these hematological laboratory abnormalities occurred within the first three cycles; following dose modifications the incidence
of these lab abnormalities decreased and thrombocytopenia and neutropenia were infrequent beyond cycle 3. The rates of MDS/AML in the niraparib (1.4%) and control (1.1%) arms were similar. There were no deaths among patients during study treatment.

“Despite diagnostic and treatment advances, ovarian cancer remains the deadliest gynecologic cancer, and the need for new therapeutic options that prolong response remains critical,” said David Barley, CEO of the National Ovarian Cancer Coalition. “The results of the NOVA trial are encouraging, and could offer patients and their families a treatment option during the stressful period that follows platinum-based chemotherapy where the majority of patients receive no treatment.”

**Investor Briefing and Webcast**
TESARO will webcast an investor and analyst briefing in Copenhagen on Saturday, October 8 at 7:00 PM local time in Copenhagen in conjunction with the ESMO annual meeting. At this briefing, TESARO management will review the niraparib development program and data presented at ESMO and answer questions from investors and analysts. This event will be webcast live and archived for 30 days, and may be accessed from the TESARO Investor Events and Presentations webpage at [www.tesarobio.com](http://www.tesarobio.com). A reception will begin at 6:30 PM local time for those institutional investors and analysts attending this event in Copenhagen; please RSVP to krausch@tesarobio.com in order to attend.

**About the Phase 3 ENGOT-OV16/NOVA Clinical Trial of Niraparib**
NOVA is a double-blind, placebo-controlled, international Phase 3 trial of niraparib that enrolled 553 patients with recurrent ovarian cancer who were in a response to their most recent platinum-based chemotherapy. Patients were enrolled into one of two independent cohorts based on germline BRCA mutation status. One cohort enrolled patients who were germline BRCA mutation carriers (gBRCAmut), and the second cohort enrolled patients who were not germline BRCA mutation carriers (non-gBRCAmut) and included patients with HRD-positive and HRD-negative tumors. Within each cohort, patients were randomized 2:1 to receive niraparib or placebo and were treated continuously with placebo or 300 milligrams of niraparib, dosed as three 100 milligram tablets once per day, until progression. The primary endpoint of this study was progression-free survival (PFS). Secondary endpoints include patient-reported outcomes, chemotherapy-free interval length, PFS 2, overall survival, and other measures of safety and tolerability. More information about this trial is available at [http://clinicaltrials.gov/show/NCT01847274](http://clinicaltrials.gov/show/NCT01847274).

**About Niraparib**
Niraparib is an oral, once-daily PARP inhibitor that is currently being evaluated in four ongoing pivotal trials. TESARO is building a robust niraparib franchise by assessing activity across multiple tumor types and by evaluating several potential combinations of niraparib with other therapeutics. The ongoing development program for niraparib includes a Phase 3 trial in patients with platinum-sensitive, recurrent ovarian cancer (the NOVA trial); a Phase 3 trial in patients with first-line ovarian cancer (the PRIMA trial); a registrational Phase 2 treatment trial in patients with ovarian cancer (the QUADRA trial); and a Phase 3 trial for the treatment of patients with BRCA-mutant breast cancer (the BRAVO trial). Several combination studies are also underway, including trials of niraparib plus pembrolizumab and bevacizumab. Janssen Biotech
has licensed rights to develop and commercialize niraparib specifically for patients with prostate cancer worldwide, except in Japan.

The U.S. Food and Drug Administration (FDA) has granted Fast Track designation to niraparib for the treatment of patients with recurrent platinum-sensitive ovarian, fallopian tube, or primary peritoneal cancer. TESARO has initiated a rolling submission of a New Drug Application (NDA) for niraparib to the FDA, and intends to complete this submission during the fourth quarter. The Marketing Authorization Application (MAA) for niraparib is planned for submission to the European Medicines Agency (EMA) in the fourth quarter.

Niraparib is an investigational agent and, as such, has not been approved by the U.S. FDA, the European Medicines Agency (EMA), or any other regulatory agencies.

About Ovarian Cancer
Approximately 22,000 women are diagnosed each year with ovarian cancer in the United States, and more than 65,000 women are diagnosed annually in Europe. Ovarian cancer is the fifth most frequent cause of cancer death among women. Despite high response rates to platinum-based chemotherapy in the second-line advanced treatment setting, approximately 85% of patients will experience recurrence within two years. If approved, niraparib may address the difficult “watchful waiting” periods experienced by patients with recurrent ovarian cancer in between cycles of platinum-based chemotherapy.

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.

Investor/Media Contact:
Jennifer Davis
Sr. Director, Corporate Development & Investor Relations
+1.781.325.1116 or jdavis@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 our expectation to complete the rolling NDA submission and submit the MAA for niraparib in the fourth quarter of 2016. Forward-looking statements in this release involve substantial risks and uncertainties that could cause our research and pre-clinical development programs, 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, risks related to our intellectual property, the uncertainties inherent in the execution and completion of clinical trials,
uncertainties surrounding the timing of availability of data from our clinical trials, risks regarding ongoing discussions with and actions by regulatory authorities, patient accrual rates for clinical trials, risks from competitors, and other matters that could affect the timing of availability of data from or initiation of our clinical trials, uncertainties regarding regulatory approvals, uncertainties regarding certain expenditures, risks related to manufacturing and supply, and other matters that could affect the availability or commercial potential of our drug candidates. 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, 2015 and its Quarterly Report on Form 10-Q for the quarter ended June 30, 2016.

Reference:

###