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Tesaro Announces Presentation of Niraparib Phase 3 ENGOT-OV16/NOVA Trial Secondary Endpoint Results During SGO

NATIONAL HARBOR, Md., March 13, 2017 (GLOBE NEWSWIRE) -- TESARO, Inc. (NASDAQ:TSRO), an oncology-focused biopharmaceutical company, today announced the presentation of secondary endpoint results from the Phase 3 ENGOT-OV16/NOVA trial of niraparib at the 2017 Society for Gynecologic Oncology (SGO) Annual Meeting on Women's Cancer, March 12 to 15, 2017 by Dr. Sven Mahner, M.D., Director, Department of Gynecology and Obstetrics, University of Munich.

"The results of several secondary endpoints from the ENGOT-OV16/NOVA trial, including chemotherapy-free interval (CFI), time to second subsequent therapy (TSST), and progression-free survival 2 (PFS-2), demonstrate the positive and durable treatment effect of niraparib in a broad population of patients with ovarian cancer, regardless of germline *BRCA* mutation status," said Mary Lynne Hedley, Ph.D., President and COO of TESARO. "An assessment of progression-free survival in patients who have progressed on treatment received after completing the NOVA study treatment (PFS-2) compared to their first progression while on the NOVA study (PFS) indicates that niraparib does not decrease the benefit of subsequent treatment."

Niraparib is the only PARP inhibitor that has shown a clinically meaningful increase in progression-free survival (PFS) in women with recurrent ovarian cancer, regardless of *BRCA* mutation or biomarker status, in a randomized, prospectively designed Phase 3 clinical trial.

Secondary Endpoint Results:

Niraparib Significantly Improved Chemotherapy-free Interval (CFI)

Among patients who were germline *BRCA* mutation (g*BRCA*mut) carriers, the niraparib arm successfully achieved statistical significance over the control arm for the secondary endpoint of CFI, with a hazard ratio of 0.26 (95% CI, 0.166-0.409). The median CFI for patients treated with niraparib was 22.8 months, compared to 9.4 months for control (p<0.0001).

Among patients without germline *BRCA* mutations (non-g*BRCA*mut), the niraparib arm successfully achieved statistical significance over the control arm for the secondary endpoint of CFI, with a hazard ratio of 0.50 (95% CI, 0.370-0.666). The median CFI for patients treated with niraparib was 12.7 months, compared to 8.6 months for control (p<0.0001).

Niraparib Significantly Improved Time to First Subsequent Treatment (TFST)

Among patients who were germline *BRCA* mutation carriers, the niraparib arm successfully achieved statistical significance over the control arm for the secondary endpoint of TFST, with a hazard ratio of 0.31 (95% CI, 0.205-0.481). The median TFST for patients treated with niraparib was 21.0 months, compared to 8.4 months for control (p<0.0001).

Among patients without germline *BRCA* mutations, the niraparib arm successfully achieved statistical significance over the control arm for the secondary endpoint of TFST, with a hazard ratio of 0.55 (95% CI, 0.412-0.721). The median TFST for patients treated with niraparib was 11.8 months, compared to 7.2 months for control (p<0.0001).

Niraparib Had No Impact on the Efficacy of Next-Line Therapy

For a pooled group of patients who have progressed on subsequent therapy (including patients with germline *BRCA* mutations and without germline *BRCA* mutations), each patient's initial progression-free survival interval was subtracted from the progression-free survival 2 interval, which showed no reduction in benefit of niraparib treatment on the effectiveness of subsequent chemotherapy, with a hazard ratio of 1.02 (95% CI, 0.765-1.349). In the NOVA study, a HR of 1.0 demonstrates that the impact of niraparib on efficacy of the subsequent therapy was clinically indistinguishable from the impact of placebo control on the efficacy of the subsequent therapy.

Progression-free Surivival-2 and Overall Survival are Immature, but Favor Niraparib

PFS-2 data were statistically significant and favored niraparib over control for patients in both the g*BRCA*mut cohort (HR 0.48; 95% CI, 0.242-0.687) and non-g*BRCA*mut cohort (HR 0.69; 95% CI, 0.494-0.964). Given the relatively long PFS patients experienced on niraparib, PFS-2 was immature, with only 30% of events captured for patients in the g*BRCA*mut cohort and only 50% of events captured for patients in the non-g*BRCA*mut cohort. Data for overall survival were also 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.

Phase 3 ENGOT-OV16/NOVA Trial Results

The ENGOT-OV16/NOVA trial is an international Phase 3, double-blind, placebo-controlled study that enrolled 553 patients with recurrent ovarian cancer who had achieved either a partial or complete response (PR or CR) to their most recent

platinum-based chemotherapy. Niraparib significantly increased PFS in patients with and without germline *BRCA* mutations as compared to control, and the magnitude of benefit was similar for patients entering the trial with a PR or a CR. Results also showed that treatment with niraparib reduced the risk of disease progression or death by 73% in patients with germline *BRCA* mutations (HR 0.27) and by 55% in patients without germline *BRCA* mutations (HR 0.45). Niraparib is the only PARP inhibitor that has shown a clinically meaningful increase in progression-free survival (PFS) in women with recurrent ovarian cancer, regardless of *BRCA* mutation or biomarker status, in a randomized, prospectively designed Phase 3 clinical trial.

The most common grade 3/4 adverse reactions to niraparib in the NOVA trial included thrombocytopenia (29%), anemia (25%), neutropenia (20%), and hypertension (9%). The majority of hematologic adverse events were managed via dose modification. Discontinuation of therapy due to thrombocytopenia, neutropenia and anemia occurred in 3.3%, 1.9% and 1.4% of patients, respectively.

About Niraparib
Niraparib is an oral, once-daily PARP inhibitor that is currently being evaluated in three pivotal trials. In pre-clinical studies, niraparib was found to concentrate in the tumor relative to plasma, delivering selective, greater than 90% durable PARP inhibition and a persistent anti-tumor effect.

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 who have received first-line treatment for ovarian cancer (the PRIMA trial), a registrational Phase 2 trial in patients who have received multiple lines of treatment for ovarian cancer (the QUADRA trial), and a Phase 3 trial for the treatment of patients with germline *BRCA*-mutated, metastatic breast cancer (the BRAVO trial). Several combination studies are also underway, including trials of niraparib plus pembrolizumab and niraparib plus bevacizumab. Janssen Biotech has licensed rights to develop and commercialize niraparib specifically for patients with prostate cancer worldwide, except in Japan.

The niraparib New Drug Application (NDA) has been accepted for priority review by the U.S. Food and Drug Administration (FDA) and is supported by data from the ENGOT-OV16/NOVA trial, a double-blind, placebo-controlled, international Phase 3 study that enrolled 553 patients, either with or without a germline *BRCA* mutation, with recurrent ovarian cancer following complete or partial response to their most recent platinum-based chemotherapy. The full results of the ENGOT-OV16/NOVA trial were presented in detail at the European Society for Medical Oncology (ESMO) 2016 Congress in Copenhagen on October 8, 2016 by Dr. Mansoor Raza Mirza, M.D., Medical Director of the Nordic Society of Gynecologic Oncology (NSGO) and principal investigator. These data were simultaneously published in the *New England Journal of Medicine*.

Regulatory applications are under review for niraparib in the U.S. and Europe and TESARO expects to launch niraparib in the U.S. in the first half of 2017 and in Europe by year-end 2017, pending regulatory approvals. Niraparib is an investigational agent and, as such, has not been approved by the FDA, 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. Without an active treatment following chemotherapy, the majority of women who have responded to platinum-based chemotherapy undergo "watchful waiting" — a period without any anti-cancer treatment during which a patient and their healthcare provider will monitor signs of the disease returning. 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 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.

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. 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 expectations with respect to niraparib regulatory submissions and approvals, 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, 2016.

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