TESARO Announces Achievement of ZEJULA Prostate Cancer Development Milestones by Janssen

October 29, 2018

WALTHAM, Mass., Oct. 29, 2018 (GLOBE NEWSWIRE) -- TESARO, Inc. (NASDAQ: TSRO), an oncology-focused biopharmaceutical company, today announced the achievement of development milestones that trigger an $18 million payment from Janssen Biotech Inc. (Janssen). The milestones are related to Janssen's ongoing GALAHAD trial, which is assessing niraparib monotherapy for the treatment of men with metastatic castration-resistant prostate cancer (mCRPC) and DNA-repair anomalies. Data from the trial are anticipated to support global regulatory filings in 2019.

In addition, data from the Phase 1b BEDIVERE trial were recently presented at the European Society of Clinical Oncology (ESMO) and demonstrated the safety and tolerability of combining niraparib with abiraterone acetate + prednisone (AA-P) in men with mCRPC. Data from the BEDIVERE trial will be used to inform the dosing regimen in a future Phase 3 trial that will assess the clinical benefit of niraparib in combination with AA-P in mCRPC patients.

TESARO entered into a global prostate collaboration and license agreement with Janssen in 2016, through which Janssen received rights to develop and commercialize niraparib for patients with prostate cancer worldwide, except Japan. Under the terms of the agreement, TESARO is eligible to receive development, regulatory and commercial milestones, in addition to royalty payments.

About the Janssen GALAHAD Clinical Trial
GALAHAD is an ongoing Phase 2, open-label, single arm trial designed to evaluate the safety and efficacy of niraparib monotherapy (300mg daily) in men with metastatic castration-resistant prostate cancer (mCRPC) and DNA-repair anomalies progressing on/after taxane-based chemotherapy and androgen receptor targeted therapy. Patients are enrolled in the study based on their DNA-repair deficiency status.

About the Janssen BEDIVERE Clinical Trial
BEDIVERE is an ongoing Phase 1b, open-label, dose-selection study with dose expansion designed to evaluate the safety of niraparib in combination with AA-P in men with metastatic castration-resistant prostate cancer (mCRPC) who may or may not have had DNA-repair anomalies.

About ZEJULA® (Niraparib)
Niraparib is marketed in the United States and Europe under trade name ZEJULA®. ZEJULA (niraparib) is a poly(ADP-ribose) polymerase (PARP) 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 tumor relative to plasma, delivering greater than 90% durable inhibition of PARP 1/2 and a persistent antitumor effect.

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.

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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, among others, statements regarding: the expected timing of data from the GALAHAD trial and associated regulatory filings, and the expected initiation of a Phase 3 trial in mCRPC patients. Forward-looking statements in this release such as these involve substantial risks and uncertainties that could cause our research and development programs, future financial and other 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 the uncertainties inherent in the execution and completion of clinical trials, uncertainties surrounding the timing of availability of data from clinical trials, and uncertainties regarding the expected timing or regulatory filings. 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 and Quarterly Report on Form 10-Q for the quarter ended June 30, 2018.

Source: TESARO, Inc.