February 27, 2017

TESARO Receives Positive CHMP Opinion for VARUBY®

WALTHAM, Mass., Feb. 27, 2017 (GLOBE NEWSWIRE) -- TESARO, Inc. (NASDAQ:TSRO), an oncology-focused biopharmaceutical company, today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has rendered a positive opinion for the Company's marketing authorization application (MAA) for VARUBY® (oral rolapitant tablets) for the prevention of delayed nausea and vomiting associated with highly and moderately emetogenic cancer chemotherapy in adults.

The VARUBY MAA submission was supported by data from four controlled studies covering a spectrum of patients receiving emetogenic chemotherapy. One study enrolled patients receiving moderately emetogenic chemotherapy (MEC), and three studies enrolled patients receiving cisplatin-based highly emetogenic chemotherapy (HEC). The top-line results of each of the three Phase 3 studies of rolapitant were presented in detail at the American Society for Clinical Oncology (ASCO) annual meeting in June 2014. Oral rolapitant was approved by the U.S. Food and Drug Administration on September 1, 2015 and is marketed by TESARO in the United States under the brand name VARUBI®.

"Chemotherapy-induced nausea and vomiting (CINV) remains a significant unmet need, with more than half of patients treated with emetogenic chemotherapy experiencing this debilitating side effect for up to five days," said Mary Lynne Hedley, Ph.D., President and COO of TESARO. "The positive CHMP opinion for VARUBY is an important milestone for the Company. VARUBY is positioned to be TESARO's first commercial product in Europe, and we look forward to bringing this important medicine to patients as quickly as possible."

"TESARO has an exciting pipeline of oncology therapeutics, and with the positive CHMP opinion for VARUBY today and our planned product launches in Europe this year, we are globalizing our mission of providing transformative therapies to people bravely facing cancer," said Orlando Oliveira, Senior Vice President and General Manager of TESARO International. "Following today's positive CHMP opinion, and subject to final approval and completion of pricing and reimbursement discussions, TESARO plans to launch VARUBY in Europe beginning in the first half of 2017, on a country-by-country basis. Our international organization now spans 17 European countries and is well prepared to make this treatment available in each country as soon as possible."

About VARUBI® (Rolapitant)

VARUBI is a substance P/neurokinin-1 (NK-1) receptor antagonist that is approved in the United States for use in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. VARUBI is contraindicated in patients receiving thioridazine, a CYP2D6 substrate. The inhibitory effect of a single dose of VARUBI on CYP2D6 lasts at least seven days and may last longer. Avoid use of pimozide; monitor for adverse events if concomitant use with other CYP2D6 substrates with a narrow therapeutic index cannot be avoided. Please see full prescribing information, including additional important safety information, available at www.varubirx.com.

Rolapitant will be marked under the trade name VARUBY in Europe.

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.

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 TESARO's plans to launch two products in Europe in 2017, including VARUBY in the first half of 2017. Forward-looking statements in this release involve substantial risks and uncertainties that could cause our future results, performance, or achievements, including the potential approval

and launch of VARUBY in Europe, to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in drug development and the execution and completion of clinical trials, uncertainties surrounding our ongoing discussions with and potential actions by the EMA, risks related to manufacturing and supply, and other matters that could affect the ultimate approval, availability or commercial potential of VARUBY. 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2016.

Investor/Media Contact:

Jennifer Davis
Vice President, Corporate Affairs & Investor Relations
+1.781.325.1116 or jdavis@tesarobio.com