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TESARO Announces Submission of Investigational New Drug Application for Anti-LAG Antibody TSR-033 to the U.S. FDA

Phase 1 trial of TSR-033 planned to begin in mid-2017

WALTHAM, Mass., May 01, 2017 (GLOBE NEWSWIRE) -- TESARO, Inc. (NASDAQ:TSRO), an oncology-focused biopharmaceutical company, today announced the submission of an Investigational New Drug (IND) Application for TSR-033 to the U.S. Food and Drug Administration. TSR-033 is a monoclonal antibody targeting LAG-3.

"The IND for TSR-033 is the third application from our immuno-oncology franchise to be submitted to the FDA within the past 17 months," said Mary Lynne Hedley, Ph.D., President and COO of TESARO. "Our vision is that immuno-oncology candidates such as TSR-033, TSR-042, our anti-PD-1 antibody, and TSR-022, our anti-TIM-3 antibody, could become a foundation of cancer therapy regimens across a variety of tumor types. A Phase 1 clinical study of TSR-033 is planned to begin in mid-2017."

About TSR-033

TSR-033 is a monoclonal antibody candidate targeting LAG-3 developed as part of 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.

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 our vision that TSR-033, TSR-042, and TSR-022 could become a foundation of cancer therapy regimens across a variety of tumor types and our expectation that a Phase 1 clinical study of TSR-033 will begin in mid-2017. 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, risks associated with FDA clearance of the IND for TSR-033, the uncertainties inherent in the execution and completion of clinical trials, risks associated with our reliance upon third parties for the conduct of clinical trials, uncertainties surrounding our ongoing discussions with and potential actions by regulatory authorities, risks related to manufacturing and supply, risks related to intellectual property, and other matters that could affect the timing of availability of data from or initiation of our planned clinical trials. 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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