October 10, 2016

ZIOPHARM Presents Data Demonstrating Activation of Anti-Tumor Immune Response Using Ad-RTS-hIL-12 in Patients with Advanced Breast Cancer

Results Presented at the European Society for Medical Oncology (ESMO) 2016 Congress

BOSTON, Oct. 10, 2016 (GLOBE NEWSWIRE) -- ZIOPHARM Oncology, Inc. (Nasdaq:ZIOP) announced the presentation of preliminary data from the Company's Phase 1b/2 study of Ad-RTS-hIL-12 + veledimex following standard chemotherapy for the treatment of patients with locally advanced or metastatic breast cancer. The poster presentation, titled "Phase 1b/2 study of intratumoral Ad-RTS-hIL-12+veledimex in patients with chemotherapy-responsive locally advanced or metastatic breast cancer," was presented at the European Society for Medical Oncology (ESMO) 2016 Congress today in Copenhagen, Denmark.

The study, which is being conducted at the Memorial Sloan Kettering Cancer Center in New York, is designed to examine the safety, tolerability and efficacy of Ad-RTS-hIL-12 immunotherapy in up to 40 women with locally advanced or metastatic breast cancer of all subtypes. Ad-RTS-hIL-12 + veledimex is a novel gene therapy which controls local expression of IL-12. The ability to regulate the production of IL-12 by modulating veledimex dosing is designed to improve its therapeutic index with standard of care.

Following entry into the trial, patients go on a chemotherapy holiday and enter an immunotherapy phase of treatment. A single cycle of Ad-RTS-hIL-12, along with the oral activator ligand veledimex, is given during the immunotherapy phase, with the goal of maintaining or improving pre-study response.

As of August 30, 2016, a total of nine patients were available for initial assessment. Results show that Ad-RTS-hIL-12 + 7 days of veledimex consistently elicited production of IL-12 which in turn produced IFNγ. It was notable that the intratumoral influx of CD8+ T cells and IFNγ were present six weeks after completion of veledimex consistent with the ability of Ad-RTS-hIL-12 to favorably impact the tumor environment over the long term. In two patients, Ad-RTS-hIL-12 + veledimex provided a meaningful drug holiday, with durable responses for 18 and 35 weeks. In all patients, disease control rate (DCR) was 44% at Week 6 and 22% at Week 12. Overall response rate (ORR), defined as achieving a partial response (PR) or better, was 11% at Week 12. Most toxicities promptly reversed upon discontinuation of veledimex, including cytokine release syndrome (grade 1-2 CRS), observed in six of nine patients. The higher than expected incidence of CRS was likely related to CYP-3A4 drug interactions with veledimex (80 mg) which resulted in enhanced peak cytokine expression.

"These data provide additional evidence that IL-12 expression and corresponding downstream signaling is activated using Ad-RTS-hIL-12 + veledimex, consistent with results observed in other studies and tumor types," said Francois Lebel, M.D., Executive Vice President, Research and Development, Chief Medical Officer at ZIOPHARM. "Early results from this study are promising, providing further support and validation for our ongoing study of Ad-RTS-hIL-12 in glioblastoma, a program we anticipate moving into a pivotal trial."

ESMO Presentation Details

Title: Phase 1b/2 study of intratumoral Ad-RTS-hIL-12+veledimex in patients with chemotherapy-responsive locally advanced or metastatic breast cancer
Abstract Number: 280P
Date and Time: October 10, 2016, 1:00-2:00p CET
Location: Hall E

About ZIOPHARM Oncology, Inc.:

ZIOPHARM Oncology is a Boston, Massachusetts-based biotechnology company employing novel gene expression, control and cell technologies to deliver safe, effective and scalable cell- and viral-based therapies for the treatment of cancer and graft-versus-host-disease. The Company's immuno-oncology programs, in collaboration with Intrexon Corporation (NYSE:XON) and the MD Anderson Cancer Center, include chimeric antigen receptor T cell (CAR-T) and other adoptive cell-based approaches that use non-viral gene transfer methods for broad scalability. The Company is advancing programs in multiple stages of development together with Intrexon Corporation's RheoSwitch Therapeutic System® technology, a switch to turn on and off, and precisely modulate, gene expression in order to improve therapeutic index. The Company's

pipeline includes a number of cell-based therapeutics in both clinical and preclinical testing which are focused on hematologic and solid tumor malignancies.

Forward-Looking Safe-Harbor Statement:

This press release contains certain forward-looking information about ZIOPHARM Oncology, Inc. that is intended to be covered by the safe harbor for "forward-looking statements" provided by the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts, and in some cases can be identified by terms such as "may," "will," "could," "expects," "plans," "anticipates," and "believes." These statements include, but are not limited to, statements regarding the Company's plans and expectations regarding its securities offerings, fundraising activities and financial strategy, the progress, timing and results of preclinical and clinical trials involving the Company's drug candidates, and the progress of the Company's research and development programs. All of such statements are subject to certain risks and uncertainties, many of which are difficult to predict and generally beyond the control of the Company, that could cause actual results to differ materially from those expressed in, or implied by, the forward-looking statements. These risks and uncertainties include, but are not limited to: our ability to finance our operations and business initiatives and obtain funding for such activities, whether chimeric antigen receptor T cell (CAR T) approaches, Ad-RTS-hIL-12, TCR and NK cell-based therapies, or any of our other therapeutic candidates will advance further in the pre-clinical or clinical trials process and whether and when, if at all, they will receive final approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies and for which indications; whether chimeric antigen receptor T cell (CAR T) approaches, Ad-RTS-hIL-12, TCR and NK cell-based therapies, and our other therapeutic products will be successfully marketed if approved; the strength and enforceability of our intellectual property rights; competition from other pharmaceutical and biotechnology companies; and the other risk factors contained in our periodic and interim SEC reports filed from time to time with the Securities and Exchange Commission, including but not limited to, our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, and our Quarterly Report for the quarter ended June 30, 2016. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof, and we do not undertake any obligation to revise and disseminate forward-looking statements to reflect events or circumstances after the date hereof, or to reflect the occurrence of or non-occurrence of any events.

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