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ZIOPHARM Announces Initiation of Phase 1b/2 Study of Ad-RTS-hIL-12 Gene Therapy in Patients With Locally Advanced or Metastatic Breast Cancer

BOSTON, April 27, 2015 (GLOBE NEWSWIRE) -- ZIOPHARM Oncology, Inc. (Nasdaq:ZIO), a biopharmaceutical company focused on the development and commercialization of new cancer therapies, today announced the initiation of a 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 study will be conducted at the Memorial Sloan Kettering Cancer Center in New York led by principal investigator Heather L. McArthur, M.D., M.P.H., Assistant Attending Physician, Breast Medicine Service, Memorial Sloan Kettering Cancer Center. Ad-RTS-hIL-12 is a novel gene therapy candidate for the controlled expression of IL-12, an important protein for collapsing tumor stroma and stimulating an anti-cancer T cell immune response.

The study is designed to examine the safety, tolerability and efficacy of Ad-RTS-hIL-12 immunotherapy in women with locally advanced or metastatic breast cancer of all subtypes. Up to 40 subjects may be enrolled in the study, including up to 20% (8 subjects) with HER2+ breast cancer. Subjects who are receiving first- or second-line standard therapy and have achieved a partial response or stable disease are eligible. Following entry into the trial, patients will go on a treatment holiday from chemotherapy and enter an immunotherapy phase of treatment. A single cycle of Ad-RTS-hIL-12, along with the oral activator ligand veledimex, will be given during the immunotherapy phase, with the goal of maintaining or improving pre-study response. Continuation of HER2-targeted antibody therapy is permitted during this immunotherapy phase for women with HER2+ disease. The primary study objective is to evaluate the safety and tolerability of Ad-RTS-hIL-12 immunotherapy. Secondary objectives include overall response rate, disease control rate and impact of treatment on tumor and serum immune biomarkers.

"Metastatic breast cancer is generally incurable and treatments are given with palliative intent, but can prolong survival and improve quality of life. We clearly need more effective and safer treatment options," said Clifford A. Hudis, M.D., Chief, Breast Medicine Service, at the Memorial Sloan Kettering Cancer Center. "Immunotherapy has recently been shown to be potentially effective for patients with breast cancer, and IL-12 has demonstrated profound effects on the tumor environment in this disease. Because Ad-RTS-hIL-12 gene therapy allows us to control IL-12 expression using an orally-administered activator ligand, it offers the potential to prolong a chemotherapy- or HER2-targeted antibody-induced response, and perhaps improve survival, with acceptable toxicity."

"Advances in immune-based therapeutic strategies have demonstrated the significant potential of harnessing the immune system as an anticancer mechanism," said Dr. McArthur. "In breast cancer, CD8+ T-cells, immune cells which are activated by IL-12, have been shown to correlate with powerful anti-tumor activity and prolonged survival. We look forward to understanding how this potent immuno-oncology agent may augment anti-cancer activity in patients with earlier stage metastatic breast cancer after treatment with standard therapy."

About ZIOPHARM Oncology, Inc.:

ZIOPHARM Oncology is a Boston, Massachusetts-based biotechnology company employing novel gene expression, control and cell technologies to deliver safer, more effective and scalable cell-based therapies for the treatment of cancer. The Company's synthetic 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 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: whether chimeric antigen receptor T cell (CAR T) approaches, Ad-RTS-IL-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-IL-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, 2014. 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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