May 5, 2015

# ZIOPHARM Announces Initiation of Phase 1 Study of Ad-RTS-IL-12 Gene Therapy in Patients With Brain Cancer

BOSTON, May 5, 2015 (GLOBE NEWSWIRE) -- ZIOPHARM Oncology, Inc. (Nasdaq:ZIOP), a biopharmaceutical company focused on the development and commercialization of new cancer therapies, today announced the initiation of a Phase 1 study of Ad-RTS-hIL-12 + veledimex in patients with recurrent or progressive glioblastoma or Grade III malignant glioma, a form of brain cancer. Ad-RTS-hIL-12 is a novel gene therapy candidate for the controlled expression of IL-12, a critical protein for stimulating an anti-cancer T cell immune response.

The Phase 1 study is designed to examine a gene therapy treatment strategy for high grade gliomas with the goal of generating an anti tumor T cell immune response. Eligible patients will be stratified to one of two groups, according to clinical indication for tumor resection. One group will undergo resection plus injection and the other group will undergo stereotactic injection. Ad-RTS-hIL-12 will be injected locally in the tumor lesion, with IL-12 expression levels tightly regulated by escalating doses of the oral activator ligand veledimex. This strategy makes it feasible to control the gene therapy in vivo and to lower or terminate IL-12 expression in the event of severe or unexpected toxicities. The primary objective of the study is to determine the safety and tolerability of a single intra tumoral Ad-RTS-hIL-12 injection plus escalating oral veledimex doses. Secondary Objectives are to determine the veledimex maximum tolerated dose, the immune responses elicited by Ad-RTS-hIL-12 and veledimex, and investigator assessment of response, including the tumor objective response rate and progression-free survival, and determine overall survival, among other measures.

The study is expected to enroll up to 72 subjects at up to 12 leading treatment centers. Among the centers expected to begin enrollment are the Stanford School of Medicine, Dana Farber/Brigham and Women's, the University of Chicago Pritzker School of Medicine, Cedars-Sinai/the David Geffen School of Medicine at the University of California, Los Angeles, and Northwestern Memorial Hospital.

"Recurrent or progressive glioblastoma and malignant glioma are associated with a particularly aggressive course and dismal prognosis," said Maciej S. Lesniak, MD, MHCM, Professor of Surgery and Neurology, Director, Neurosurgical Oncology, Director, Neuro-Oncology Research, University of Chicago Pritzker School of Medicine. "The current standard of care treatment is based on surgical resection, which is limited by the infiltrative nature of the disease and the lack of clear margins delimitating the tumor. Given the poor overall prognosis and lack of effective treatments, new therapeutic approaches are urgently needed. Ad-RTS-IL-12 has demonstrated very promising preclinical efficacy."

"Evidence that IL-12 is able to trigger innate and adaptive immunity and collapse tumor stroma supports its relevance as an important immunotherapeutic agent," said Nino Chiocca, MD, PhD, Harvey W. Cushing Professor of Neurosurgery, Department of Surgery, Harvard Medical School, Surgical Director, Center for Neuro-oncology, Dana-Farber Cancer Institute, Chairman, Neurosurgery, Brigham And Women's Hospital and Co-Director, Institute for the Neurosciences, Brigham And Women's Hospital. "The preclinical data shows that Ad-RTS-IL-12 gene therapy could be a highly promising novel treatment for GBM."

**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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