



ZIOPHARM Oncology, Inc.

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ZIOPHARM Oncology Initiates Phase 2 Study of Ad-RTS IL-12 and Palifosfamide Combination for Treatment of Advanced Breast Cancer

NEW YORK, March 11, 2013 (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 randomized, open label Phase 2 clinical study of Ad-RTS IL-12 in combination with palifosfamide to treat patients with non-resectable recurrent or metastatic breast cancer.

The two-part, multi-center U.S. study will enroll up to 68 patients with non-resectable, recurrent or metastatic breast cancer who have visible lesions or lesions accessible by injection. The study is designed to assess the safety and efficacy of the drug combination of Ad-RTS IL-12 and palifosfamide. Ad-RTS IL-12 is a targeted and controlled DNA-based therapeutic designed to express interleukin-12 (IL-12), a protein important for an immune response to cancer. Palifosfamide is a potent bi-functional DNA alkylating agent.

Part one of the two-part study will consist of a safety assessment for Ad-RTS IL-12 and palifosfamide, alone or in combination. Part two will consist of an efficacy evaluation of the Ad-RTS IL-12 only arm and the combination arm. The primary endpoint of the study is rate of progression-free survival at 16 weeks. Secondary endpoints include objective response rate, duration of response and evaluation of pharmacodynamic tumor markers.

"Several recent breakthroughs in cancer treatment are based on the hypothesis that the immune system plays a central role in suppressing both cancer's growth and metastasis," said John Nemunaitis, M.D., lead investigator and Executive Medical Director, Mary Crowley Medical Research Center. "For breast cancer, the positive correlation of survival with immune response in the tumor elicited by non-immune treatments has only recently been elucidated, and this understanding hints at the potential for exciting new breakthroughs in this still underserved population. We look forward to participating in this study and to gaining further insight regarding the combined effect of Ad-RTS IL-12, a selectively controlled immunotherapy, and palifosfamide, a potent bi-functional DNA alkylating agent."

Jonathan Lewis, M.D., Ph.D., Chief Executive Officer of ZIOPHARM, added, "This study has exciting potential, both for this difficult-to-treat indication and for our synthetic biology platform, in which Ad-RTS IL-12 is the lead program. Building on preclinical work supporting a synergistic effect between Ad-RTS IL-12 and palifosfamide, and the clinical findings from our ongoing Phase 2 melanoma study, we believe the combination of Ad-RTS IL-12 and palifosfamide has the potential to be quite impactful in breast cancer."

About ZIOPHARM Oncology, Inc.:

ZIOPHARM Oncology is a biopharmaceutical company focused on the development and commercialization of new cancer therapies. The Company's clinical programs include: Palifosfamide (ZIO-201) is a potent bi-functional DNA alkylating agent that has activity in multiple tumors by evading typical resistance pathways. Palifosfamide is in the same class as bendamustine, cyclophosphamide, and ifosfamide. Intravenous palifosfamide is currently being studied in a randomized, double-blinded, placebo-controlled Phase 3 trial (PICASSO 3) for the treatment of first-line metastatic soft tissue sarcoma and is also in a pivotal Phase 3 trial (MATISSE) for first-line metastatic small cell lung cancer. Additionally, the Company is developing an oral capsule form of palifosfamide.

Ad-RTS IL-12 is currently being tested in two Phase 2 studies, the first for the treatment of advanced melanoma, and the second in combination with palifosfamide for the treatment of non-resectable recurrent or metastatic breast cancer. Ad-RTS IL-12 uses synthetic biology to enable controlled, local delivery of therapeutic interleukin-12 (IL-12), a protein important for an immune response to cancer. ZIOPHARM's DNA synthetic biology platform is being developed in partnership with Intrexon Corporation and employs an inducible gene-delivery system that enables controlled, local delivery of genes that produce therapeutic proteins to treat cancer. This is achieved by placing IL-12 under the control of Intrexon's proprietary biological "switch" (the RheoSwitch Therapeutic System[®], RTS[®]) to turn on/off the therapeutic protein expression at the tumor site.

Indibulin (ZIO-301) is a novel, tubulin binding agent that is expected to have several potential benefits, including oral dosing, application in multi-drug resistant tumors, no neuropathy and a tolerable toxicity profile. It is currently being studied in a Phase 1/2 trial in metastatic breast cancer.

Darinaparsin (ZIO-101) is a novel mitochondrial-and hedgehog-targeted agent (organic arsenic) currently in ongoing studies

with Solasia Pharma K.K.

ZIOPHARM's operations are located in Boston, MA, and New York City. Further information about ZIOPHARM may be found at www.ziopharm.com.

Forward-Looking Safe Harbor Statement:

This press release contains certain forward-looking information about ZIOPHARM Oncology 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. Words such as "expect(s)," "feel(s)," "believe(s)," "will," "may," "anticipate(s)" and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements regarding our ability to successfully develop and commercialize our therapeutic products; our ability to expand our long-term business opportunities; financial projections and estimates and their underlying assumptions; and future performance. 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 or projected by, the forward-looking information and statements. These risks and uncertainties include, but are not limited to: whether Palifosfamide, Ad-RTS-IL-12, Darinaparsin, Indibulin, or any of our other therapeutic products will advance further in the 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 Palifosfamide, Ad-RTS-IL-12, Darinaparsin, Indibulin, and our other therapeutic products will be successfully marketed if approved; whether any of our other DNA-based biotherapeutics discovery and development efforts will be successful; our ability to achieve the results contemplated by our collaboration agreements; the strength and enforceability of our intellectual property rights; competition from pharmaceutical and biotechnology companies; the development of and our ability to take advantage of the market for DNA-based biotherapeutics; our ability to raise additional capital to fund our operations on terms acceptable to us; general economic conditions; 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, 2011, and our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2012. 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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