



ZIOPHARM Oncology, Inc.

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ZIOPHARM Oncology Announces Compelling Clinical Activity in Phase 1 Study of Ad-RTS IL-12 in Advanced Melanoma and Dosing of First Patient in Phase 2 Study

NEW YORK, Oct. 25, 2012 (GLOBE NEWSWIRE) -- ZIOPHARM Oncology, Inc. (Nasdaq:ZIOP), a biopharmaceutical company focused on the development and commercialization of new cancer therapies, today announced that compelling clinical activity was seen in its Phase 1 study of Ad-RTS IL-12, a novel DNA-based therapeutic candidate, in advanced melanoma. Based on early activity, and determination of a biologically effective dose, the Company also announced that the study has advanced to Phase 2 in which the first patient has been dosed.

Initiation of the Phase 2 study follows the successful, dose-escalation Phase 1 study in which clinical activity was observed in 5 of 7 (71%) patients dosed at the two highest dose levels. The data also showed a correlation between T-cell immune responses and clinical outcome, with no dose-limiting toxicities reported. A total of 13 patients were enrolled in the Phase 1 study, and were treated with a range of doses of an orally administered activator ligand. Three serious adverse events (SAE) were reported: two related to therapy (pyrexia and cytopenia), and one unrelated (deep vein thrombosis). Unrelated to the study therapy, one patient death was reported due to bacterial sepsis and progression of disease. The Company expects to submit full results of the study for presentation at a major medical meeting.

The Phase 2 multi-center, single-arm, open-label expansion study will enroll up to 15 patients with unresectable Stage III or IV melanoma and further evaluate the safety and efficacy of intratumoral injections of Ad-RTS IL-12 in combination with an oral activator ligand. Data from this study are expected in the first half of 2013.

"ZIOPHARM, working with our DNA therapy platform, is ushering in a paradigm shift in how we treat cancer, one that transforms our ability to deliver therapy, leading to better, safer treatment and ultimately, to cures," said Samuel Broder, M.D., Chairman of Intrexon Therapeutic Opportunities Committee and former Director of the NCI (National Cancer Institute). "We look forward to seeing additional data as ZIOPHARM expands the Ad-RTS IL-12 DNA program into multiple indications, including breast cancer, and to the introduction of the next generation of DNA-based therapeutic candidates for oncology."

"This Phase 1 study demonstrates that IL-12 dosing, delivered and controlled through a pioneering DNA therapeutic strategy, is both tolerable and clinically active," stated Hagop Youssoufian, M.D., President of Research and Development and Chief Medical Officer of ZIOPHARM. "An important early sign of this effect was manifested in lesions not injected with Ad-RTS IL-12, where clinical response was observed, indicating systemic, anti-cancer immune activity. We also saw activity in patients who had been previously exposed to ipilimumab, as well as other forms of immunotherapy, suggesting that Ad-RTS IL-12 may provide benefit for patients with advanced disease."

In connection with the achievement of this milestone, ZIOPHARM announced today that it will issue 3,636,926 shares of the Company's common stock to Intrexon Corporation in accordance with the terms of the Exclusive Channel Partner Agreement (ECP) between the companies entered into in January 2011. All of the shares issued to Intrexon will be unregistered but certain registration rights in accordance with the Registration Rights Agreement entered into by the companies at the time of the ECP.

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 a Phase 2 study. Ad-RTS IL-12 is a novel DNA therapeutic that is delivered to the patient's tumor thereby localizing expression of the therapeutic modality, interleukin-12 (IL-12), a protein important for an immune response to cancer. ZIOPHARM's DNA therapeutics are being developed in partnership with Intrexon Corporation employing a revolutionary synthetic biology platform that permits targeted, controlled production of therapeutic proteins in humans. This is achieved by placing IL-12 under the control of a 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 June 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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