



ZIOPHARM Oncology, Inc.

ZIOPHARM Oncology Files Investigational New Drug Application for Ad-RTS-IL-12, a Novel DNA-Based Oncology Therapeutic Candidate

NEW YORK--(BUSINESS WIRE)-- ZIOPHARM Oncology, Inc. (Nasdaq: ZIOP), a drug development company employing small molecule and synthetic biology approaches to cancer therapy, today announced that it has submitted an Investigational New Drug (IND) application to the U.S. Food & Drug Administration (FDA) to begin clinical study of Ad-RTS-IL-12 (INXN 2001/1001), a novel DNA-based therapeutic candidate. When initiated, the Phase I study will evaluate safety in addition to immunological and biological effects of the therapeutic candidate in patients with melanoma. Ad-RTS-IL12 is the second clinical oncology product candidate from the ZIOPHARM/Intrexon Corporation's exclusive, synthetic biology channel partnership.

Through intratumoral injection, Ad-RTS-IL-12 employs an adenoviral vector (Ad) to deliver directly into the patient's own cells a gene which expresses Interleukin-12 (IL-12), a potent anticancer cytokine. Production of IL-12 within the cell is in turn tightly regulated by the Intrexon RheoSwitch Therapeutic System™ (RTS™), a "gene switch" controlled by an activator ligand taken orally. IL-12 is a naturally occurring regulatory cytokine that has a function central to the initiation and regulation of cellular immune responses.

"Cancer is a disease of DNA and synthetic biology uses genetic tools to offer us entirely new approaches to addressing its challenges," said Mark Thornton, M.D., Ph.D., Executive Vice President and Chief Development Officer of ZIOPHARM. "IL-12, for example, naturally elicits an immune response to cancer, but is too toxic to be given as a recombinant protein. By producing IL-12 in the body with a DNA-based drug, and using our unique technology to switch this production on or off with a pill, we expect to achieve therapeutic levels of IL-12 without being limited by the toxicities typically associated with recombinant therapy. Both Ad-RTS-IL-12 and DC-RTS-IL-12 (INXN 3001/1001), our clinical-stage candidate that employs the patient's transduced dendritic cells to deliver Ad-RTS-IL-12, represent truly novel and pioneering treatment."

Data from two preclinical studies of Ad-RTS-IL-12 in various *in vivo* cancer models will be presented at the 2011 Annual Meeting of the American Society of Gene and Cell Therapy (ASGCT), being held May 18-21 in Seattle, Washington. Data from a Phase Ib trial with DC-RTS-IL-12 will be presented at the 2011 Annual Meeting of the American Society of Clinical Oncology (ASCO) being held June 3-7 in Chicago, Illinois.

About ZIOPHARM Oncology, Inc.:

ZIOPHARM Oncology is a biopharmaceutical company engaged in the development and commercialization of a diverse portfolio of cancer therapeutics. The Company is currently focused on several clinical programs.

Palifosfamide (Zymafos™ or ZI001) is a novel DNA cross-linker in class with bendamustine, ifosfamide, and cyclophosphamide. ZIOPHARM is currently enrolling patients in a randomized, double-blinded, placebo-controlled Phase III trial with palifosfamide administered intravenously for the treatment of metastatic soft tissue sarcoma in the front-line setting. The company is also currently conducting a Phase I intravenous study of palifosfamide in combination with standard of care for addressing small cell lung cancer likely in an adaptive potentially pivotal trial and an oral form of the drug for treatment of solid tumors is currently in the advanced preclinical stage of development.

Darinaparsin (Zinapar™ or ZI001) is a novel mitochondrial-targeted agent (organic arsenic) being developed intravenously for the treatment of relapsed peripheral T-cell lymphoma likely with an adaptive potentially pivotal study expected to begin in late 2011. An oral form is in a Phase I trial in solid tumors.

Indibulin (Zybulin™ or ZI001) is a novel, oral tubulin binding agent that is expected to have several potential benefits including oral dosing, application in multi-drug resistant tumors, no neuropathy and a quite tolerable toxicity profile. It is currently being studied in Phase I in metastatic breast cancer with an expected substitution of a modified dosage form for simpler dosage administration.

ZIOPHARM is also pursuing the development of novel DNA-based therapeutics in the field of cancer pursuant to an exclusive channel partnership with Intrexon Corporation. The partnership includes two existing clinical-stage product candidates, the first of which is in a Phase Ib study and the second is currently the subject of an Investigational New Drug (IND) application filed with the U.S. Food and Drug Administration.

ZIOPHARM's operations are located in Boston, MA and Germantown, MD with an executive office in New York City. Further

information about ZIOPHARM may be found at www.ziopharm.com.

ZIOP-G

About Intrexon Corporation:

Intrexon Corporation is a privately held synthetic biology company that employs modular DNA control systems to enhance capabilities, improve safety and lower cost in human therapeutics, protein production, industrial products, animal sciences and agricultural biotechnology. The company's advanced transgene engineering platform enables Better DNA™ by combining breakthroughs in DNA control systems with corresponding advancements in modular transgene design, assembly and optimization. The company is currently using these advanced capabilities to undertake foremost challenges across the spectrum for biological applications. More information about the company is available at www.DNA.com.

Forward-Looking Safe Harbor Statement:

This press release contains forward-looking statements for ZIOPHARM Oncology, Inc. that involve risks and uncertainties that could cause ZIOPHARM Oncology's actual results to differ materially from the anticipated results and expectations expressed in these forward-looking statements. These statements are based on current expectations, forecasts and assumptions that are subject to risks and uncertainties, which could cause actual outcomes and results to differ materially from these statements. Among other things, there can be no assurance that any of ZIOPHARM Oncology's development efforts relating to its product candidates will be successful, or such product candidates will be successfully commercialized. Other risks that affect forward-looking information contained in this press release include the possibility of being unable to obtain regulatory approval of ZIOPHARM Oncology's product candidates, the risk that the results of clinical trials may not support ZIOPHARM Oncology's claims, the risk that pre-clinical or clinical trials will not proceed on schedules that are consistent with ZIOPHARM Oncology's current expectations or at all, risks related to ZIOPHARM Oncology's ability to protect its intellectual property and its reliance on third parties to develop its product candidates, risks related to the sufficiency of existing capital reserves to fund continued operations for a particular amount of time and uncertainties regarding ZIOPHARM Oncology's ability to obtain additional financing to support its operations thereafter, as well as other risks regarding ZIOPHARM Oncology that are discussed under the heading "Risk Factors" in ZIOPHARM Oncology's filings with the United States Securities and Exchange Commission. Forward-looking statements can be identified by the use of words such as "may," "will," "intend," "should," "could," "can," "would," "expect," "believe," "estimate," "predict," "potential," "plan," "is designed to," "target" and similar expressions. ZIOPHARM Oncology assumes no obligation to update these forward-looking statements, except as required by law.

ZIOPHARM Oncology, Inc.
Tyler Cook, 617-259-1982
tcook@ziopharm.com

or
Media:
Argot Partners
David Pitts, 212-600-1902
david@argotpartners.com

Source: ZIOPHARM Oncology, Inc.

News Provided by Acquire Media