



ZIOPHARM Oncology, Inc.

ZIOPHARM Oncology Announces Acceptance of Investigational New Drug Application for ZIN ATI-001 (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, announced today that the U.S. Food & Drug Administration (FDA) has accepted the Company's investigational new drug (IND) application to begin clinical study of ZIN ATI-001, a novel DNA-based therapeutic candidate also known as Ad-RTS-IL-12 + AL (INXN 2001/1001), in oncology. When initiated, the Phase I study will evaluate safety in addition to immunological and biological effects of the therapeutic candidate in patients with melanoma. ZIN ATI-001 is the second clinical oncology product candidate from the ZIOPHARM-Intrexon Corporation exclusive synthetic biology channel partnership.

ZIN ATI-001 employs an adenoviral vector to deliver, directly into the patient's own cells, a gene which expresses Interleukin-12 (IL-12), a potent, naturally occurring anticancer cytokine central to the initiation and regulation of cellular immune responses. Production of IL-12 within cells is then tightly regulated by the Intrexon RheoSwitch Therapeutic System™ (RTS™), a "gene switch" controlled by an orally administered activator ligand (AL). Preclinical studies have shown that the immunological mechanism of action of ZIN ATI-001 is similar to that of ZIN-CTI-001 (DC-RTS-IL-12 + AL), ZIOPHARM's most advanced DNA-based product candidate, currently in Phase Ib. Positive clinical data of ZIN-CTI-001, the first-ever to demonstrate small molecule-controlled production of an anticancer protein in humans, were recently presented at the 2011 Annual Meeting of the American Society of Clinical Oncology.

"The rapid acceptance of this IND underscores ZIOPHARM's strengths as our exclusive partner for the development of DNA-based therapeutics in oncology," stated RJ Kirk, Intrexon's Chairman and CEO, and a Director of the ZIOPHARM Board of Directors. "ZIN ATI-001, which offers an effective, yet simpler approach to introducing IL-12 therapy, is the first of many products we expect to introduce into the clinic as partners over the next two years. ZIOPHARM's understanding of the development spectrum, from preclinical work through large outcome studies, ensures that the great promise of this technology is delivered quickly and intelligently."

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 addressing small cell lung cancer 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 a two-stage 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/II in metastatic breast cancer.

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, entering Phase I study.

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.

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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 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's 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.

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Source: ZIOPHARM Oncology, Inc.

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