ZIOPHARM Oncology, Inc.

ZIOPHARM Oncology Presents Preclinical Data for Darinaparsin Effect on Hedgehog Signaling Pathway in Prostate Cancer at AACR-NCI-EORTC Meeting

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 results from preclinical studies of darinaparsin (Zinapar® or ZIO-101), a novel organic arsenic, in prostate cancer were presented at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, taking place November 12-16 in San Francisco. In addition to Company authors, the studies included authors Joseph R. Bertino M.D. and Nitu Bansal Ph.D. from UMDNJ-The Cancer Institute of New Jersey.

The studies were designed to evaluate the effect of darinaparsin on the Hedgehog signaling pathway in prostate cancer. Aberrant hedgehog signaling has been implicated in a number of cancers due to its association with the transformation of adult stem cells into cancer stem cells. Data from the studies demonstrate that darinaparsin is a potent inhibitor of DU145 prostate cells, which inhibited prostate spheroid growth (IC_{50}:2uM) and prostate stem cell colony formation. Western analysis showed that darinaparsin decreased levels of the transcription factor Gli2, a downstream effector of the activated Hedgehog pathway which is elevated in certain cancers. Further, combination studies with taxotere, a U.S. Food and Drug Administration-approved drug for the treatment of patients with advanced prostate cancer, showed synergistic cell destruction at high fixed doses of the drugs.

"We know from past research that arsenic trioxide inhibits growth in certain tumors through its activity against the Hedgehog pathway," commented Joseph Bertino, M.D., Associate Director and Chief Scientific Officer of the Cancer Institute of New Jersey, University Professor of Medicine and Pharmacology at UMDNJ-Robert Wood Johnson, former President of AACR and ASCO, and a member of ZIOPHARM's Medical Advisory Board. "Due to inorganic arsenic trioxide's severe cardiotoxicity and neurotoxicity profile, darinaparsin, an organic arsenic, was thought to be a far better treatment candidate and these studies encourage additional preclinical and clinical study, as a single agent and in combination."

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's small molecule programs include:

Palifosfamide (Zymafos® or ZIO-201) is a novel DNA cross-linker in class with bendamustine, ifosfamide, and cyclophosphamide and is currently in a randomized, double-blinded, placebo-controlled Phase 3 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 1 study of palifosfamide in combination with standard of care for addressing small cell lung cancer; an oral form of palifosfamide continues in preclinical study.

Darinaparsin (Zinapar® or ZIO-101) is a novel mitochondrial-targeted agent (organic arsenic) currently in a solid tumor Phase 1 study with oral administration and has been developed intravenously for the treatment of relapsed peripheral T-cell lymphoma.

Indibulin (Zybulin™ or ZIO-301) 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 1/2 in metastatic breast cancer.

ZIOPHARM is also pursuing the development of novel DNA-based therapeutics in the field of cancer pursuant to a partnering arrangement with Intrexon Corporation. The partnership includes two existing clinical-stage product candidates, both of which are currently in Phase 1.

ZIOPHARM's principal operations are located in Boston, MA with an executive office in New York City and a small satellite office in Germantown, MD. Further information about ZIOPHARM may be found at www.ziopharm.com.

ZIOP-G

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, 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, Darinaparsin, Indibulin, and our other therapeutic products will be successfully marketed if approved; whether our 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 including but not limited to our Annual Report on Form 10-K for the fiscal year ended December 31, 2010, our Quarterly Report on Form 10-Q for the quarter ended September 30, 2011, and our Current Reports on Form 8-K filed from time to time with the Securities and Exchange Commission. 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.

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.