



ZIOPHARM Commences Treatment of First Patients in Two Separate Phase I/II Combination Studies of Both Indibulin and Palifosfamide

NEW YORK, Feb 04, 2008 (BUSINESS WIRE) -- ZIOPHARM Oncology, Inc. (NASDAQ: ZIOP), announced today that dosing of the first patient took place in two separate new studies, including:

-- A Phase I/II combination study evaluating oral indibulin (ZIO-301) combined with oral Tarceva® (erlotinib) in the treatment of patients with solid tumors, and

-- A Phase I/II study of palifosfamide (ZIO-201) used in combination with Adriamycin® (doxorubicin) in the treatment of patients with sarcoma.

The Phase I/II study evaluating indibulin combined with erlotinib is supported by preclinical studies that have demonstrated potent synergistic activity between indibulin and erlotinib. Indibulin is a novel synthetic anti-mitotic agent that binds to tubulin, destabilizes microtubule polymerization, arrests tumor cell growth at the G2/M phase and inhibits cell mobility and metastasis. Erlotinib is approved in lung cancer and blocks EGF signal transduction T-kinase activation.

The Phase I/II study of palifosfamide used in combination with doxorubicin in the treatment of patients with sarcoma is supported by preclinical studies that have demonstrated potent synergistic activity when combining the two agents. ZIOPHARM is developing several proprietary stabilized forms of palifosfamide (isofosforamide mustard or IPM), the cancer targeting component of ifosfamide, and a standard of care for treating sarcoma. Both palifosfamide and doxorubicin interfere with the repair and replication of DNA in cancer cells. This Phase I/II combination study will serve as lead in to the randomized Phase III pivotal trial of palifosfamide expected to begin in the second half of 2008.

The Company also announced today that the United States Adopted Names Council (USAN) and World Health Organization (WHO) International Nonproprietary Names (INN) Expert Committee have approved palifosfamide as the non-proprietary name for isofosforamide mustard (IPM), the active pharmaceutical ingredient in ZIO-201.

"These two studies exemplify our strategy to maintain a data driven focus in the clinical development of our three lead compounds," commented Brian Schwartz, M.D., Chief Medical Officer at ZIOPHARM Oncology. "The rationale for our development plan is based on encouraging clinical and preclinical data evaluating the use of indibulin and palifosfamide and we look forward to the data from these two combination trials."

For more details on these trials please see www.clinicaltrials.gov.

About Indibulin

Indibulin is a novel synthetic anti-mitotic agent that binds to tubulin, destabilizes microtubule polymerization, arrests tumor cell growth at the G2/M phase and inhibits cell mobility and metastasis. Microtubules are well-established targets for anti-cancer drug development and tubulin-binding drugs such as taxanes and vinca alkaloids are currently widely used to treat cancer. Indibulin is orally available, lacks neurotoxicity, and has efficacy in taxane refractory preclinical models.

About Palifosfamide

Palifosfamide (isofosforamide mustard or IPM), the active moiety of ifosfamide (IFOS), is a bi-functional alkylator that causes irreparable inter-strand DNA cross-linking resulting in cell death. Palifosfamide is equal to or more active than IFOS in diverse cancer models. Unlike IFOS, which is a pro-drug, palifosfamide is directly active against cancer cells. Also, unlike IFOS, palifosfamide is not metabolized to acrolein or chloroacetaldehyde which cause bladder or central nervous system toxicities. Palifosfamide has completed a Phase II study in sarcoma suggesting activity.

About ZIOPHARM Oncology, Inc.

ZIOPHARM Oncology, Inc. is a biopharmaceutical company engaged in the development and commercialization of a diverse, risk-sensitive portfolio of in-licensed cancer drugs to address unmet medical needs. The Company applies new insights from molecular and cancer biology to understand the efficacy and safety limitations of approved and developmental cancer therapies and identifies proprietary and related molecules for better patient treatment. For more information, visit www.ziopharm.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 the Company'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 the Company'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 the Company's product candidates, the risk that the results of clinical trials may not support the Company's claims, and risks related to the Company's ability to protect its intellectual property and its reliance on third parties to develop its product candidates. The Company assumes no obligation to update these forward-looking statements, except as required by law.

SOURCE: ZIOPHARM Oncology, Inc.

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