



ZiOPHARM Presents Positive Indibulin Translational and Dose Scheduling Data at ASCO

ORLANDO, Fla., May 30, 2009 (BUSINESS WIRE) -- ZiOPHARM Oncology, Inc. (Nasdaq: ZIOP) announced today that it presented positive data from both a Phase Ib clinical trial and preclinical dosing studies of orally administered indibulin (ZybulinTM or ZIO-301), the Company's novel tubulin binding agent, at the 45th Annual American Society of Clinical Oncology (ASCO) meeting held in Orlando, FL, May 29th to June 2nd.

In the Phase Ib study, oral indibulin was administered with oral capecitabine (XelodaTM) in patients with advanced solid tumors. Trial results presented are for 7 patients who had received a median of three prior therapies. All 7 patients were evaluable for safety, and 4 for efficacy. Three patients had stable disease for a minimum of 6 cycles with 1 patient ongoing in their 11th cycle of treatment. There were no dose limiting toxicities and therefore no maximum tolerated dose was established. Adverse events included hand-and-foot syndrome (capecitabine), fatigue, vomiting, loss of appetite and headaches, and were easily managed. There was no reported neurotoxicity, consistent with other Phase I and preclinical data with indibulin. There was early activity seen in breast, colon, bladder and prostate cancers with this sub-optimal dose level and schedule, which is encouraging with regard to further study using mathematically-optimized dose scheduling, the subject of the preclinical data also presented.

The preclinical results were derived from mathematical modeling applying Norton-Simon models in breast cancer xenografts. The work was conducted by the Company under the direction of Dr. Larry Norton (Harmon Hill). Formal analyses revealed that the major effect of therapy occurs in five days of exposure, which is not manifest on gross inspection until one week thereafter. Therefore an intermittent schedule based on five days of drug administration preserves full activity while minimizing the possibility of toxicity. A Phase I/II study in breast cancer using this highly novel scheduling strategy is in development under the direction of two leading breast cancer specialists, Dr. Clifford Hudis in the United States and Dr. Jose Baselga in Spain.

"Indibulin is not only an interesting drug because it is active against taxane-resistant cells without the neurotoxicity seen with all the other tubulin binding agents, but also because mathematical modeling has revealed a novel dose-schedule that promises to maximize efficacy and minimize toxicity in the clinic. Also, it is oral, so it is potentially of value to the entire world's population", commented Dr. Larry Norton, senior author on this presentation.

To view the presentation please visit:

http://www.ziopharm.com/docs/Indibulin_Poster_ASCO_2009.pdf

About ZiOPHARM Oncology, Inc.:

ZiOPHARM Oncology is a biopharmaceutical company engaged in the development and commercialization of a diverse portfolio of cancer drugs. The Company is currently focused on three clinical programs.

Palifosfamide (ZymafosTM or ZIO-201) references a novel composition (tris formulation) that comprises the functional active metabolite of ifosfamide, a standard of care for treating sarcoma, testicular and other cancers. Palifosfamide delivers only the cancer fighting component of ifosfamide. It is expected to overcome the resistance of ifosfamide and cyclophosphamide in certain cancers. It does not have the toxic metabolites of ifosfamide that cause the debilitating side effects of "fuzzy brain" (encephalopathy) and severe bladder inflammation. Intravenous (IV) palifosfamide is currently in a Phase II randomized trial to treat soft tissue sarcoma. An oral form of palifosfamide has been developed preclinically.

Indibulin (ZybulinTM or ZIO-301) is a novel, oral tubulin binding agent that targets both mitosis and cancer cell migration. Indibulin is expected to have several potential benefits, including oral dosing, application in multi-drug resistant tumors, no neuropathy and minimal overall toxicity. Indibulin has shown early activity in Phase I study as a single agent in many types of solid tumors. Indibulin is also completing Phase I trials in combination with Tarceva(R) and Xeloda(R). Oral indibulin preclinical "dose density" and "metronomic" dose administration studies with our consultant Dr. Larry Norton have progressed to the point of translation with the intention of further pursuit in clinical study.

Darinaparsin (ZinaparTM or ZIO-101) is a novel organic arsenic being developed for the treatment of various hematologic and solid cancers. Preclinical and Phase I and II results to date demonstrate that darinaparsin is much less toxic than other forms of arsenic. Intravenous darinaparsin continues to be studied in a Phase II hematology trial with favorable treatment activity in certain lymphomas and in Phase I study with oral administration. Darinaparsin has been well tolerated in all trials to date.

ZIOPHARM's operations are located in Boston, MA with an executive office in New York. Further information about ZIOPHARM may be found at www.ziopharm.com.

ZIOP-G

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, risks related to the Company'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 the Company's ability to obtain additional financing to support its operations thereafter. The Company assumes no obligation to update these forward-looking statements, except as required by law.

SOURCE: ZIOPHARM Oncology, Inc.

ZIOPHARM Oncology, Inc.

Tyler Cook, 617-259-1982

tcook@ziopharm.com

or

International Investor Relations Inc.

Dennis Dobson, 203-258-0159

dsdobson@optonline.net

Copyright Business Wire 2009