ZIOPHARM Presents Positive Darinaparsin Clinical Data at ASCO's Prestigious Clinical Science Symposium

Phase II Results Possible Basis for FDA DialogueRegarding Registration Trial

ORLANDO, Fla., Jun 01, 2009 (BUSINESS WIRE) -- ZIOPHARM Oncology, Inc. (Nasdaq: ZIOP) announced today that it presented positive data from both Phase II intravenous (IV) and Phase I oral studies of darinaparsin (Zinapar^{TM} or ZIO-101), the novel organic arsenic molecule, as part of the prestigious Clinical Cancer Symposia at the 45th Annual American Society of Clinical Oncology (ASCO) meeting held in Orlando, FL, May 29th to June 2nd.

The study results were presented at the Clinical Science Symposium, New Agents for Lymphoma, by Izidore S. Lossos, M.D, Chief of the Lymphoma Program, and Professor of Medicine at the University of Miami Miller School Of Medicine. Darinaparsin was one of three new drugs selected at this high profile ASCO session.

"This drug is active in highly-refractory lymphoma patients and well tolerated," commented Dr. Lossos, lead investigator for the Phase II trial. "Interestingly a lot of patients I and others have treated with this drug report feeling the best they have felt since first getting lymphoma, having been on many different treatments. The oral data are also promising and darinaparsin could well be effective in treating other cancers as well."

The Phase II intravenous (IV) study is fully enrolled with 29 heavily pretreated lymphoma patients. Of 19 evaluable patients, initial findings are 7 objective responses, for an overall response rate of 37 percent, with 3 complete responses (CRs) and 4 partial responses (PRs). Four additional patients had prolonged stable disease (SD). There are 5 peripheral T-cell lymphoma (PTCL) patients included in the 19 patients and in this group there were 3 objective responses, for an overall response rate of 60 percent, of which there were 2 CRs and 1 PR. Of the 4 patients with stable disease, 1 patient had PTCL. Darinaparsin was very well tolerated with neutropenic fever as a severe adverse event in 1 patient.

On the advice of multiple experts, the Company intends, on complete review of the final data, to open dialogue with the U.S. Food and Drug Administration with a view of entering into a formal registration trial, likely for peripheral T-cell lymphoma where, even with other agents under evaluation, there remains a very high unmet medical need.

The two Phase I oral dose escalation studies included patients with all types of cancers. Darinaparsin was dosed with various schedules. The study included 36 patients. The study has not yet reached MTD. Of 27 evaluable patients, 1 had a partial response (head and neck cancer) and 15 had prolonged stable disease, including head and neck, lymphoma, colon, and pancreatic cancers. Oral darinaparsin was well tolerated with atrial fibrillation, congestive heart failure and dyspnea as severe adverse events.

Treatment with darinaparsin has not evidenced any QT prolongation in either the IV or oral studies. QT prolongation has been problematic with inorganic arsenic and is a "black box" side effect warning in the labeling. The Company continues dialogue regarding partnering and other initiatives regarding the further clinical development of darinaparsin.

To view the presentation please visit:

http://www.ziopharm.com/docs/Darinaparsin_2009_ASCO_Symposium_Presentation.ppt

About ZIOPHARM Oncology, Inc.:

ZIOPHARM Oncologyis 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 (Zymafos^{TM} 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 (Zybulin™ 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 (Zinapar™ 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.

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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 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.

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