



ZIOPHARM Presents Positive Data from Phase I Study of Palifosfamide in Combination with Doxorubicin at ASCO

-- Continued Safety and Activity Strongly Support Ongoing Phase II Randomized Trial --

ORLANDO, Fla., May 31, 2009 (BUSINESS WIRE) -- ZIOPHARM Oncology, Inc. (Nasdaq: ZIOP) announced today that it presented final data from a Phase I study of palifosfamide (ZymafosTM) in combination with doxorubicin at the 45th Annual American Society of Clinical Oncology (ASCO) meeting held in Orlando, FL, May 29th to June 2nd.

The Phase I trial of palifosfamide in combination with doxorubicin was fully enrolled with 13 patients, predominantly with soft tissue sarcoma and non-small cell lung cancer, and who had received a median of two prior therapies. Of 12 evaluable patients, there were 3 partial responses. Of the 8 patients with soft tissue sarcoma (STS) 75 percent had stable disease or better, with 2 having partial responses and 4 having prolonged stable disease. The median progression free survival (PFS) was 19 weeks.

The combination has proven to be easily administered and was well tolerated with no dose-limiting toxicities during a total of 73 cycles of treatment. Importantly, there were no reported events of encephalopathy, hemorrhagic cystitis or renal toxicity often associated with some current treatments for STS. Adverse events were primarily hematologic, including neutropenia and thrombocytopenia, and were managed easily. The pharmacokinetic evaluation in this trial indicates that palifosfamide exposure is comparable to that seen in murine models that resulted in marked synergy with doxorubicin.

The Company is now enrolling into a Phase II randomized controlled trial comparing palifosfamide plus doxorubicin vs. doxorubicin in the front- and second-line treatment setting of STS. This is a multicenter, multinational trial in the United States and Europe. The objective of the randomized Phase II trial is to validate certain hypotheses that would form the basis for a registration trial to be initiated as early as the first half of next year.

"These highly favorable Phase I data of palifosfamide in combination with doxorubicin established the foundation for the now ongoing Phase II randomized trial in the front and second-line setting", commented Sant Chawla, MD, co-principal investigator. "Data has previously been reported on the activity of palifosfamide as a single agent in advanced sarcoma as well as the established synergy of palifosfamide with doxorubicin preclinically. With so few treatment options, I look forward to ZIOPHARM initiating the final phase of the drug development program that could establish the first new front-line sarcoma therapy in decades and as well to advancing into the clinic an oral form for much expanded patient access."

To view the presentation please visit: http://www.ziopharm.com/docs/Palifosfamide_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.

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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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