



ZiOPHARM Announces Positive Palifosfamide Sarcoma Randomized Phase II Interim Data: Trial Enrollment Stopped Early

--Full Interim Data Presentation at CTOS--

NEW YORK, Oct 14, 2009 (BUSINESS WIRE) -- ZiOPHARM Oncology, Inc. (Nasdaq: ZIOP) announced today positive top line interim data from the multicenter randomized Phase II trial of palifosfamide (ZymafosTM, ZIO-201) treating patients with unresectable or metastatic soft tissue sarcoma. The analysis evaluated 62 patients treated as of the end of September, with 58 being analyzed. As a result of reaching a key efficacy milestone and following safety and efficacy data review by the Data Committee, sarcoma experts, and the Company's Medical Advisory Board, the decision was reached formally to stop enrollment yesterday in the trial. The Company will report the interim data in full at the upcoming Connective Tissue Oncology Society (CTOS) Annual Meeting on November 5th and plans to initiate a registration trial following regulatory review of the palifosfamide program to date.

The Randomized Phase II trial treats patients with unresectable or metastatic soft tissue sarcoma in the front- and second-line setting. Patients are randomized either to doxorubicin (the current only FDA approved agent in sarcoma) or to palifosfamide in combination with doxorubicin. A total of 58 patients have been evaluated for PFS (progression-free survival) with 19 documented PFS events (doxorubicin alone = 13 events; palifosfamide + doxorubicin = 6 events) based on a three month median follow-up time. With this analysis based on all randomized and eligible patients, the hazard ratio is 0.67 favoring palifosfamide + doxorubicin (two-sided Wilcoxon-Gehan p-value = 0.042); the pre-defined milestone was to reach one-sided p=0.1.

The interim safety data indicate that the addition of palifosfamide does not add to the toxicity of single agent doxorubicin. The most frequently reported side effects in both arms of the study include neutropenia and fatigue, hypokalemia, nausea, anemia, leucopenia, and alopecia. Palifosfamide is usually easily administered as an out-patient treatment, and generally well-tolerated.

"The hypothesis of the randomized Phase II trial design for this very difficult to treat cancer population has been validated and the interim results are promising and supportive of a pivotal trial," said Robert Maki, MD, PhD, co-leader of the adult sarcoma program at Memorial Sloan-Kettering Cancer Center, and current President of CTOS (Connective Tissue Oncology Society), a multidisciplinary sarcoma specialty group.

"This will hopefully continue to progress forward step by step and result in a new treatment option for patients with a high unmet need" said Murray Brennan, MD, Chairman Emeritus of Surgery at Memorial Sloan-Kettering Cancer Center, renowned sarcoma expert and Lead Director at ZiOPHARM.

More detailed data will be reported at CTOS. Subsequently, the Company will be formalizing a final registration trial plan for review by the appropriate regulatory authorities.

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 is the functional active metabolite of ifosfamide, a standard of care for treating sarcoma, lymphoma, testicular, and other cancers. Palifosfamide delivers only the cancer fighting component of ifosfamide. It is expected to overcome the resistance seen with ifosfamide and cyclophosphamide, two of the most commonly used alkylating drugs used to treat certain cancers. Palifosfamide does not have the toxic metabolites of ifosfamide that cause the debilitating side effects of "fuzzy brain" (encephalopathy) and severe bladder inflammation. Intravenous palifosfamide is currently in a randomized Phase II trial, the subject of this press release, to treat unresectable or metastatic soft tissue sarcoma in the front- and second-line setting, a study expected to establish the basis for a registration trial as early as the first half of 2010. An oral form of palifosfamide has been developed preclinically to the investigational new drug application stage.

Darinaparsin (ZinaparTM or ZIO-101) is a novel organic arsenic being developed for the treatment of various hematologic and solid cancers. Preclinical and clinical studies to date have demonstrated that darinaparsin is considerably less toxic than

inorganic arsenic, particularly with regard to cardiac toxicity. Phase I and Phase II testing of the intravenous form of darinaparsin in solid tumors and hematological cancers has been completed or is nearing completion. The Company has reported clinical activity and, importantly, a safety profile from these studies as predicted by preclinical results. Favorable results from the trial with IV-administered darinaparsin in lymphoma, particularly peripheral T-cell lymphoma ("PTCL"), were reported at the American Society of Clinical Oncology ("ASCO") in May. Supported by these data, the Company expects to advance into a registration trial in peripheral T-cell lymphoma as early as the first half of 2010. Also as reported at ASCO, in ongoing Phase I trials the oral form is active and well tolerated.

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. In multiple Phase I trials in cancer patients, oral indibulin has been administered both as a single agent and in combination with favorable activity and a promising safety profile that does not include the neurotoxicity seen with all of the other classes of tubulin binding agents. Most recently, results of oral indibulin in combination with oral capecitabine (Xeloda^(R)) were presented at this year's American Society of Clinical Oncology (ASCO) along with the preclinical findings of a novel dosing schedule conducted under the direction of Dr. Larry Norton. The Company expects to initiate a Phase I/II study of oral indibulin in breast cancer patients employing this dosing schedule established preclinically. Once the maximum tolerated dose is established in the Phase I portion of the trial, Phase II will proceed with an expanded population.

ZIOPHARM's operations are located in Boston, MA with an executive office in New York City. 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 final trial data may not support interim analysis and that the results of clinical trials in general may not support the Company's claims, risks related to the Company's ability to protect its intellectual property, risks related to 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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