ZIOPHARM Presents Positive Palifosfamide Sarcoma Randomized Phase II Interim Data at Annual Meeting of the Connective Tissue Oncology Society

-- Palifosfamide prolongs progression-free survival by at least 50% --

NEW YORK, Nov 06, 2009 (BUSINESS WIRE) -- ZIOPHARM Oncology, Inc. (Nasdaq: ZIOP) presented today at the 15th Annual Connective Tissue Oncology Society (CTOS) Meeting, positive interim data from the multicenter randomized Phase II trial of palifosfamide (Zymafos™, ZIO-201) treating patients with unresectable or metastatic soft tissue sarcoma. As previously announced, having achieved the study-specified efficacy milestone following planned safety and efficacy review by the Data Committee, a panel of international sarcoma experts, and the Company's Medical Advisory Board, it was determined that the data are compelling and sufficient to proceed to a pivotal study in support of product registration and to conclude enrollment in the trial.

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 only currently FDA-approved agent in sarcoma) or to palifosfamide in combination with doxorubicin. As of the October 5th cut-off date, there were 67 patients randomized to the trial, with 65 treated and 61 eligible for analysis. The 61 patients were evaluated for progression-free survival (PFS) with 20 documented PFS events (doxorubicin alone = 14 events; palifosfamide + doxorubicin = 6 events). With this analysis of all randomized and eligible patients, the hazard ratio is 0.63 favoring palifosfamide + doxorubicin (two-sided Wilcoxon-Gehan p-value = 0.026), statistically supporting that palifosfamide prolongs PFS by at least 50%.

The median PFS for doxorubicin is 4.4 months, the median PFS for palifosfamide + doxorubicin has not yet been reached; the 1st quartile PFS was 1.5 months for doxorubicin vs. 3.5 months for palifosfamide + doxorubicin (PFS more than doubled at this level). PFS is a biologically important end point in sarcoma, and has been well demonstrated to be a relevant measurement of the effect of treatment on outcome.

The arms of the trial were very well-balanced by predetermined stratification in terms of 1) Age (greater-than or equal to 65 years and < 65 yrs) and 2) Pre-selected histopathological subtypes (leiomyosarcoma, synovial sarcoma and "other"). In addition, and consequently, this also resulted in balance between front- and second-line patients.

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 easily administered as an out-patient treatment, and generally well-tolerated.

"These interim results are very promising, indicating a potentially new drug to help control this life-threatening disease with acceptable safety and quality of life," commented George Demetri, MD, Director of the Center for Sarcoma and Bone Oncology and the Ludwig Center at the Dana-Farber Cancer Institute and Harvard Medical School, and a member of ZIOPHARM's Medical Advisory Board, whose experience includes having served as lead investigator in the clinical trials leading to the approval of Gleevec™ and Sutent ™ to treat GIST, a form of soft tissue sarcoma.

"These data are not only encouraging for sarcoma but hopefully palifosfamide may also work in treating other cancers. This is particularly interesting if the oral form is successful in the clinic," added Lawrence Einhorn, MD, Distinguished Professor at the Simon Cancer Center of Indiana University Medical Center, Lance Armstrong Foundation Chair in Oncology, former President of ASCO and also a member of ZIOPHARM's Medical Advisory Board, whose experience includes having served as the principal investigator in the development of ifosfamide in curing testicular cancer.

The Company is in the process of finalizing a registration trial plan in soft tissue sarcoma for review by the appropriate U.S. and international regulatory authorities.

The presentation is viewable at:

http://www.ziopharm.com/docs/ZIOPHARM_CTOS_Nov09.pdf

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™ 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 (Zinapar™ 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 (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**.** 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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