ZIOPHARM Reports Third Quarter Financial Results and Updated Clinical Progress

NEW YORK, Nov 11, 2009 (BUSINESS WIRE) -- ZIOPHARM Oncology, Inc. (Nasdaq: ZIOP), a biopharmaceutical company that is seeking to develop and commercialize a diverse, risk sensitive portfolio of in-licensed cancer drugs addressing unmet medical needs, today reported its financial results for the quarter ended September 30, 2009 and provided an update on the Company's clinical programs.

The Company reported a net loss for the third quarter 2009 of $2.9 million, or $(0.13) per share, compared with a net loss for the third quarter of 2008 of $5.5 million, or $(0.26) per share. The significant decrease in operating expenses is attributable to a continuing focus of resources as well as tight management of operating expenses. For the third quarter of 2009, as compared to 2008, Research and Development expenses declined $2.6 million while General and Administrative expenses declined by $0.4 million. Net cash used in operations was $2.1 million in the third quarter of 2009 as compared with $5.9 million during the comparable 2008 period. The decrease in net cash used in operations was primarily attributable to a decrease in net loss of $2.7 million. Net cash used in operations for the nine months ended September 30, 2009 and 2008 was $8.9 million and $19.7 million, respectively. Again, the decrease in net cash used in operations was primarily attributable to a decrease in the net loss of $12.0 million. The Company ended the September 2009 quarter with cash of approximately $7.1 million which is expected to support operations into the second quarter of 2010.

During the third quarter, the company completed an offering of its common stock and warrants resulting in net proceeds of approximately $4.6 million after paying offering expenses of $0.5 million.

The Company's clinical programs have progressed well. The palifosfamide (Zymafos™, ZIO-201) randomized Phase II trial in metastatic or unresectable soft tissue sarcoma 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. The company is in dialogue with the U.S. Food and Drug Administration (FDA) on the design and implementation of a registration trial, a study the Company expects could initiate as early as the first half of 2010. The Company is also in dialogue with FDA on the intravenous Phase II darinaparsin (Zinapar™ or ZIO-101) study results in lymphoma with the intent of conducting a registration trial in peripheral T-cell lymphoma, also as early as the first half of 2010. The oral darinaparsin Phase I trials continue enrollment in order to establish the best dose and schedule. Oral indibulin (Zybulin™ or ZIO-301) is scheduled to enter into a Phase I/II study in breast cancer patients using the Norton-dosing schedule developed preclinically with Dr. Larry Norton and initiating in early 2010 with the teams of Dr. Clifford Hudis (Memorial Sloan-Kettering Cancer Center) in the United States and Dr. Jose Baselga (Vall d'Hebron University Hospital) in Spain.

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 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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