



ZIOPHARM Commences Randomized Phase II Study of Palifosfamide in Soft Tissue Sarcoma

NEW YORK, Sep 05, 2008 (BUSINESS WIRE) -- ZIOPHARM Oncology, Inc. (NASDAQ: ZIOP), announced today that the first patient has been dosed in its international Phase II randomized controlled trial of palifosfamide (ZIO-201) in patients with soft-tissue sarcoma (STS): This is a Phase II multi-center, parallel group, randomized study of palifosfamide plus doxorubicin versus doxorubicin in subjects with unresectable or metastatic Soft-tissue Sarcoma (PICASSO). Approximately 100 evaluable subjects are expected to be enrolled in this multi-center trial, which is being conducted at sites in the U.S. and Europe by several key opinion leaders in sarcoma.

This Phase II trial will evaluate the clinical benefit of palifosfamide administered with doxorubicin compared with single-agent doxorubicin in subjects diagnosed with unresectable or metastatic STS in the front- or second-line treatment setting. The primary endpoint is assessment of the difference in progression-free survival between subjects in the two arms of the trial.

Sant P. Chawla, M.D., Director, Sarcoma Oncology Center, Santa Monica, and one of the lead investigators of the study noted, "I am delighted to announce the dosing of the first patient in this key combination trial for palifosfamide in front- and second-line patients following very promising results in previous trials in sarcoma in the refractory setting. By conducting a randomized controlled Phase II trial where the primary endpoint is progression-free survival, ZIOPHARM has optimized its chances of yielding positive results by aiding in the design and thereby mitigating risk for a Phase III pivotal trial to follow."

In May 2008, ZIOPHARM received Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for palifosfamide in the treatment of STS. For more details about this trial, please see www.clinicaltrials.gov.

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 the development of three clinical programs for multiple indications. Palifosfamide (ZIO-201) is a novel molecule that is the functional active metabolite of ifosfamide, a standard of care for treating sarcoma, testicular cancer and other cancers. Palifosfamide delivers only the cancer fighting component of ifosfamide. It overcomes the resistance of ifosfamide and cyclophosphamide in certain cancers. It does not have the toxic metabolites that cause the debilitating side effects of "fuzzy brain" (encephalopathy) and severe bladder inflammation. Indibulin (ZIO-301) is a novel, oral tubulin binding agent that targets both mitosis and cancer cell migration. Indibulin has several potential benefits, including oral dosing, application in multi-drug resistant tumors, no neuropathy and minimal overall toxicity. Indibulin has shown early activity in many types of solid tumors. Darinaparsin (ZIO-101) is a novel organic arsenic being developed for the treatment of various hematologic and solid cancers. Studies demonstrate that darinaparsin is less toxic and more active in treating cancer than FDA-approved inorganic arsenic. 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, and risks related to the Company's ability to protect its intellectual property and its reliance on third parties to develop its product candidates. The Company assumes no obligation to update these forward-looking statements, except as required by law.

SOURCE: ZIOPHARM Oncology, Inc.

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Suzanne McKenna, 646-214-0703
smckenna@ziopharm.com

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