



ZIOPHARM Receives FDA Orphan Drug Designation for Darinaparsin in the Treatment of Peripheral T-cell Lymphoma

NEW YORK, Sep 23, 2010 (BUSINESS WIRE) -- ZIOPHARM Oncology, Inc. (Nasdaq: ZIOP) announced today that the United States Food & Drug Administration (FDA) has granted Orphan Drug Designation to darinaparsin (Zinapar(TM) or ZIO-101) for the treatment of peripheral T-cell Lymphoma (PTCL). The United States Orphan Drug Act of 1983 was created to provide incentives for companies to develop and market treatments for diseases or conditions affecting fewer than 200,000 people in the United States. The Orphan Drug designation provides eligibility for a seven-year period of market exclusivity in the United States after product approval, an accelerated review process, accelerated approval where appropriate, grant funding, tax benefits and an exemption from user fees.

"Peripheral T-cell lymphomas represent a distinct subgroup of aggressive lymphomas that have been ignored in most lymphoma studies, creating a population whose treatment needs remain largely unaddressed in the front line setting," said James Armitage, MD, Professor of Internal Medicine, Division of Hematology and Oncology, University of Nebraska Medical Center. "Darinaparsin has demonstrated early signs of activity and tolerability in this population, with a mechanism of action that differentiates it from other existing therapeutic options."

ZIOPHARM reported favorable results from a Phase II trial with IV-administered darinaparsin in lymphoma, particularly PTCL, at the 2009 Annual Meeting of the American Society of Clinical Oncology. The Company expects to begin enrolling patients imminently in a Phase I study of darinaparsin in combination with CHOP (Cyclophosphamide, Doxorubicin, Vincristine, and Prednisone), the current standard of care for front line PTCL, to confirm the tolerability of the combination. On the advice of leading hematology experts and subject to the outcome of this Phase I study and further dialogue with the U.S. Food and Drug Administration, the Company expects to move forward with a registration study of the darinaparsin and CHOP combination for the front-line treatment of PTCL in late 2011. There are currently no FDA-approved therapies for the front-line treatment of advanced PTCL, a setting where the National Comprehensive Cancer Network (NCCN) guidelines recommend the use of experimental drugs.

About PTCL

Peripheral T-cell Lymphoma represents a subgroup of aggressive lymphomas that develop from T-cells in different stages of maturity. According to the Lymphoma Research Foundation, PTCL accounts for approximately 10-15% of the estimated 66,000 new cases of non-Hodgkin's lymphoma diagnosed each year in the United States. PTCL generally affects people over the age of 60 and is diagnosed in more men than women.

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 (Zymafos(TM) or ZIO-201) references a novel composition (tris formulation) that comprises 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 DNA-alkylating drugs used to treat cancers. ZIOPHARM is currently enrolling patients in a randomized, double-blinded, placebo-controlled Phase III trial of intravenous palifosfamide used in the treatment of metastatic soft tissue sarcoma in the front-line setting.

Darinaparsin (ZinaparTM or ZIO-101) is a novel mitochondrial-targeted agent (organic arsenic) being developed for the treatment of various hematologic and solid cancers.

Indibulin (Zybulin(TM) or ZIO-301) is a novel, oral tubulin binding agent that targets both mitosis and cancer cell migration. In addition, indibulin is expected to have several potential benefits, including oral dosing, application in multi-drug resistant tumors, no neuropathy and minimal overall toxicity.

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.

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, the risk that pre-clinical or clinical trials will proceed on schedules that are consistent with the Company's current expectations or at all, 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, as well as other risks regarding the Company that are discussed under the heading "Risk Factors" in the Company's filings with the United States Securities and Exchange Commission. Forward-looking statements can be identified by the use of words such as "may," "will," "intend," "should," "could," "can," "would," "expect," "believe," "estimate," "predict," "potential," "plan," "is designed to," "target" and similar expressions. The Company assumes no obligation to update these forward-looking statements, except as required by law.

SOURCE: ZIOPHARM Oncology, Inc.

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