



ZIOPHARM Presents ZIO-201 Phase I Data at CTOS

Data Support Expanded Clinical Development Program

VENICE, ITALY, Nov 03, 2006 (BUSINESS WIRE) -- ZIOPHARM Oncology, Inc. (NASDAQ: ZIOP) announced today the presentation of updated clinical data on ZIO-201 at the Connective Tissue Oncology Society (CTOS) meeting in Venice. Related new preclinical data for ZIO-201 was the subject of an earlier presentation at CTOS. ZIO-201 is a proprietary form of the therapeutic active metabolite of ifosfamide (IFOS), a drug that is the standard of care in the treatment of sarcoma and is widely used in the treatment of lymphoma and pediatric cancers. IFOS is associated with severe toxicity to the bladder and the central nervous system because of the presence of two other metabolites - acrolein and chloroacetaldehyde. These toxicities can be particularly troubling, especially in the treatment of pediatric cancers.

The safety and dose-ranging phase I studies utilized ZIO-201 administered daily for three consecutive days each four weeks (1 cycle) and were conducted at the University of Texas M. D. Anderson Cancer Center in Houston, the Karmanos Cancer Center in Detroit and Premier Oncology in Santa Monica. The results demonstrated evidence of clinical activity in sarcoma (2/11 patients including at least one who had failed IFOS therapy) and mesothelioma (1 patient with extended stable disease). The maximum tolerated dose (MTD) of ZIO-201 on this schedule was 400 mg/me²/d. There was little bone marrow toxicity and no hemorrhagic cystitis (bladder toxicity) or CNS toxicity. The dose limiting toxicity was characterized by electrolyte imbalances. This MTD is comparable to IFOS doses of greater than 25 g/me² and this dose achieves serum levels that are 25-fold higher than doses that kill 50% of human sarcoma cell lines.

"These phase I results with ZIO-201 are encouraging," commented Dr. Brian Schwartz, Chief Medical Officer at ZIOPHARM. "Avoiding the more serious toxicities associated with the administration of ifosfamide at doses that are much higher than the equivalent ifosfamide dose is what we were hoping to see. We are presently continuing the phase I trial with a single monthly administration of ZIO-201, a regimen that is strongly supported by the preclinical data presented yesterday at CTOS. The phase II trial in sarcoma with the 3-day regimen continues. We are also planning for a pediatric phase I/II trial, exploring the possibility of administering intrathecally for metastatic brain cancer, and moving forward with an oral form."

About ZIO-201

ZIO-201 (isophosphoramidate mustard-lysine; IPM-Lys), the active moiety of IFOS, is a bi-functional alkylator that causes irreparable inter-strand DNA cross-linking resulting in cell death. ZIO-201 is as or more active than IFOS in diverse cancer models. Unlike IFOS which is a pro-drug, ZIO-201 is directly active against cancer cells. Also, unlike IFOS, ZIO-201 is not metabolized to acrolein or chloroacetaldehyde which cause bladder or central nervous system toxicities. ZIO-201 is in phase I and I/II trials in diverse cancers exploring maximum tolerated dose at alternate schedules. Clinical activity (stable disease) in patients with advanced cancers (including those resistant to IFOS) has been seen.

About ZIOPHARM Oncology, Inc.

ZIOPHARM Oncology, Inc. is a biopharmaceutical company engaged in the development and commercialization of a diverse, risk-sensitive portfolio of in-licensed cancer drugs to address unmet medical needs. The Company applies new insights from molecular and cancer biology to understand the efficacy and safety limitations of approved and developmental cancer therapies and identifies proprietary and related molecules for better patient treatment. For more information, visit 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, 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.

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SOURCE: ZIOPHARM Oncology, Inc.

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