



ZIO-301 (Indibulin) Interim Phase I Data Presented at ASCO

Early Evidence of Clinical Activity Coupled with No Observable Neurotoxicity

NEW YORK, Jun 03, 2007 (BUSINESS WIRE) -- ZIOPHARM Oncology, Inc. (NASDAQ: ZIOP), announced today the presentation of interim Phase I data for indibulin (ZIO-301) at the 2007 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago. The poster entitled "Phase I and pharmacological study of orally administered indibulin in advanced solid tumors" was presented by RL Oostendorp, M.D., Department of Medical Oncology, The Netherlands Cancer Institute, Amsterdam. Indibulin is a novel, oral synthetic anti-mitotic agent related to but with a different mechanism than other tubulin-binding drugs that include the widely used taxanes and the vinca alkaloids.

To date and as reported, 18 patients received a liquid formulation of indibulin in doses up to 80 mg daily and a subsequent 21 patients have received a capsule formulation in doses up to the current 900 mg daily. Thus far, stable disease was achieved in 6 patients including 2 patients with colorectal cancer, 2 with salivary gland tumors, one with non-small cell lung cancer and one with prostate cancer. There are no dose limiting toxicities and dose escalation continues with the capsule formulation. Importantly, there has been no neurotoxicity reported, a common and problematic adverse event usually associated with tubulin-binding agents. An additional Phase I study with a continuous dosing schedule will be initiated in the U.S. shortly.

The primary objective of this open-label, dose-escalating study is to determine the maximum tolerated dose (MTD) of indibulin administered daily for 14 days every 3 weeks in patients with solid tumors until toxicity, disease progression, or 4 cycles are completed. In addition, the study will determine dose-limiting toxicities and evaluate early therapeutic effects.

"Our interest in a Phase I with indibulin started with preclinical data that highlighted oral administration and a sound scientific basis for a hypothesized absence of neurotoxicity," commented Prof. Jan Schellens of the Netherlands Cancer Institute and the Principal Investigator for the ongoing Phase I trial. "As we continue to explore drug activity, dosing schedules, and dose-limiting toxicities, we are hopeful that the lack of neurotoxicity to date will be maintained."

About ZIO-301

ZIO-301 (indibulin) is a novel synthetic anti-mitotic agent that binds to tubulin, destabilizes microtubule polymerization, and arrests tumor cell growth at the G2/M phase. Microtubules are well-established targets for anti-cancer drug development and tubulin-binding drugs such as taxanes and vinca alkaloids are currently widely used to treat cancer. Indibulin is in a Phase I dose-ranging and safety study in Europe. The Company expects to begin Phase I/II trials in the U.S. soon.

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.

SOURCE: ZIOPHARM Oncology, Inc.

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