



Cyclacel Begins Phase I Pharmacologic Study Of Oral Sapacitabine In Patients With Advanced Leukemias

SHORT HILLS, NJ, JUNE 15, 2006 – Cyclacel Pharmaceuticals, Inc. (Nasdaq: CYCC) announced today that the company has initiated a Phase I clinical trial of sapacitabine (CYC682), an orally available nucleoside analogue, in patients with advanced leukemias or myelodysplastic syndromes (MDS). This study follows three Phase I trials in solid tumors or lymphomas involving over 120 patients which evaluated safety and pharmacokinetics of a variety of dosing schedules for future Phase II studies and combination studies with other anti-cancer agents.

The study is led by Dr. Hagop Kantarjian, Chairman of the Department of Leukemia at The University of Texas M. D. Anderson Cancer Center (UTMDACC) in Houston. The study's primary objective is to determine the maximum tolerated dose of sapacitabine in patients with advanced leukemias or MDS. The study's secondary objectives are to characterize the pharmacodynamic effects of sapacitabine in tumor cells, evaluate the relationship between pharmacokinetics and pharmacodynamics, and correlate the pharmacodynamic effects of sapacitabine with anti-cancer activity. The pharmacologic part of the study is led by Dr. William Plunkett, Chief of Cellular and Molecular Pharmacology at UTMDACC. The trial will involve approximately 30 patients.

Sapacitabine appears to act through a dual mechanism that is unique among nucleoside analogues. It interferes with DNA synthesis by causing single-strand DNA breaks and induces arrest of the cell division cycle at G2 phase. Both sapacitabine and its major metabolite, CNDAC, have demonstrated potent anti-tumor activity in preclinical studies. In a liver metastatic mouse model, sapacitabine was shown to be superior to gemcitabine (Gemzar®; Lilly) or 5-FU, two widely used nucleoside analogues, in delaying the onset and growth of liver metastasis.

“Nucleoside analogues, such as ara-C and fludarabine, play an important role in the treatment of leukemias,” said Dr. Kantarjian, principal investigator of the trial. “We are interested in evaluating sapacitabine because of its unique mechanisms of action and the possibility that it may be an active drug in leukemias that can be orally administered.”

“Our laboratory has extensive experience in evaluating cellular pharmacology of nucleoside analogues. This trial provides an opportunity to assess the cellular pharmacology of this novel nucleoside analogue, which is an important step toward providing guidance for optimizing dose and schedule for future trials,” said Dr. Plunkett, a collaborating investigator in the trial.

“This study is part of a broad Phase I program for sapacitabine based on its preclinical activity against a wide range of tumor types,” said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. “The results from this and previous trials will provide a strong foundation for designing Phase II studies and combination studies with other anti-cancer agents. The sapacitabine program is part of Cyclacel's strategy to develop a portfolio of cell cycle inhibitors. Cyclacel's other development programs include seliciclib, a CDK (cyclin dependent kinase) inhibitor in Phase II clinical trials for non-small cell lung cancer, and CYC 116, an aurora kinase inhibitor in late preclinical development.”

About Cyclacel Pharmaceuticals, Inc.

Cyclacel is a clinical-stage biopharmaceutical company dedicated to the discovery, development and commercialization of novel, mechanism-targeted drugs to treat human cancers and other serious disorders. The Company is currently evaluating seliciclib (CYC202), an orally-available cyclin dependent kinase inhibitor, in Phase II clinical trials for the treatment of lung cancer. Sapacitabine (CYC682) is an orally-available, cell cycle modulating nucleoside analog in Phase I clinical trials for the treatment of cancer. CYC116 is an orally-available, Aurora kinase inhibitor in IND-directed preclinical development. Several additional programs are at an earlier stage.

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Risk Factors

This news release contains certain forward-looking statements that involve risks and uncertainties that could cause actual results to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. Such forward-looking statements include statements regarding, among other things, the efficacy, safety, and intended utilization of Cyclacel's product candidates, the conduct and results of future clinical trials, plans regarding regulatory filings, future research and clinical trials and plans regarding partnering activities. Factors that may cause actual results to differ materially include the risk that product candidates that appeared promising in early research and clinical trials do not demonstrate safety and/or efficacy in larger-scale or later clinical trials, the risk that Cyclacel will not obtain approval to market its products, the risks associated with reliance on outside financing to meet capital requirements, and the risks associated with

reliance on collaborative partners for further clinical trials, development and commercialization of product candidates. You are urged to consider statements that include the words "may," "will," "would," "could," "should," "believes," "estimates," "projects," "potential," "expects," "plans," "anticipates," "intends," "continues," "forecast," "designed," "goal," or the negative of those words or other comparable words to be uncertain and forward-looking. These factors and others are more fully discussed under "Risk Factors" in the registration statement on Form S-4 (File No. 333-131225) and in the other reports of Cyclacel filed with the SEC.

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