Cyclacel reports Phase I sapacitabine data in patients with advanced leukemias and myelodysplastic syndromes at 2007 ASCO

BERKELEY HEIGHTS, NJ, June 2, 2007 – Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP) reported interim results from a Phase I clinical trial of sapacitabine (CYC682), a novel orally available nucleoside analog, in patients with advanced leukemias or myelodysplastic syndromes (MDS). The data demonstrated that sapacitabine had a favorable safety profile and promising anti-leukemic activity in patients with relapsed and refractory acute myelogenous leukemia (AML) and MDS. The study is ongoing at the University of Texas M.D. Anderson Cancer Center and is led by Dr. Hagop Kantarjian, Professor of Medicine and Chairman of the Leukemia Department and Dr. William Plunkett, Professor and Chief, Section of Molecular and Cellular Oncology, Department of Experimental Therapeutics. The results were presented in a poster at the 43rd annual meeting of the American Society of Clinical Oncology (ASCO) in Chicago, June 1-5, 2007. Based on the results of this study, Cyclacel plans to expand its Phase II clinical program for sapacitabine in hematological cancers.

Thirty-five patients were treated twice daily for 7 consecutive days every 21 days at doses between 75 and 375 mg per day. The maximum tolerated dose (MTD) was 375 mg twice daily and the recommended Phase II dose was determined to be 325 mg twice daily. The best responses were complete remissions (CR) or complete remissions without platelet recovery (CRp) in 4 patients. In addition, 11 patients had more than a 50% decrease in bone marrow blasts including 7 with blast reduction to 5% or less. Dose-limiting toxicity was gastrointestinal including abdominal pain, diarrhea, small bowel obstruction and neutropenic colitis. One patient treated at the MTD died of complications from neutropenic colitis. Non-hematological toxicities were mostly mild to moderate. An additional five patients were treated by a 3-day schedule at doses of 375 mg and 425 mg. This part of the study is ongoing.

“The interim results of this study are impressive in terms of the observed anti-leukemic activity and good tolerability of sapacitabine. I believe these promising early data warrant further studies of sapacitabine in leukemias and MDS,” commented Dr. Kantarjian, the study’s principal investigator.

“The promising anti-leukemic activity observed in this study suggests that sapacitabine may bring clinical benefit to patients with AML and MDS, both of which are areas of unmet medical need,” commented Dr. Judy Chiao, Vice President of Clinical Development and Regulatory Affairs of Cyclacel.

“We are very encouraged by the results of this trial and sapacitabine’s emerging clinical profile,” said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. “These results, along with data from our solid tumor studies, suggest that sapacitabine oral capsules may be active in both hematological and solid tumors. If further data are confirmatory this would be an exciting development in terms of sapacitabine’s commercial potential as anticancer drugs are rarely active in both oncology and hematology.”

The reported 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.

Study Details

Design
The primary objective of the study is to determine the maximum tolerated dose (MTD) of sapacitabine administered twice daily for 7 consecutive days every 21 days or 3 consecutive days per week for 2 weeks every 21 days. Of the 40 treated patients, 35 received the drug by the 7-day schedule and 5 received the drug by the 3-day schedule. Among 35 patients treated on the 7-day schedule, 23 patients were over 60 years of age and most had AML (n=30) and MDS (n=4).

Results
The MTD was reached at 375 mg twice daily on the 7-day schedule and the recommended Phase II dose was determined to be 325 mg twice daily. Dose-limiting toxicity on the 7-day schedule was gastrointestinal which included abdominal pain, diarrhea, small bowel obstruction and neutropenic colitis. One patient treated at the MTD died of complications from neutropenic colitis. Non-hematological toxicities were mostly mild to moderate. The best response from the 7-day schedule was complete remission without platelet recovery in 2 patients with refractory AML (n=2), complete remission in 1 patient with refractory AML leukemia cutis (n=1), and completion remission in 1 patient with refractory MDS (n=1). In addition, 11 patients (AML, n=9; MDS, n=2) had more than 50% decrease in bone marrow blasts including 7 patients who had a reduction in bone marrow blasts to 5% or less.

Abstract #7063

About Sapacitabine
Sapacitabine appears to act through a dual mechanism. It interferes with DNA synthesis by causing single-strand DNA breaks and also induces arrest of cell cycle progression at G2/M-Phase. Both sapacitabine and CNDAC, its major metabolite or a substance into which the drugs converts after ingestion by patients, have demonstrated potent anti-tumor activity in preclinical studies. In addition, in a mouse model of liver metastasis, sapacitabine was shown to be superior in terms of delaying the onset and growth of liver metastasis to either gemcitabine (Gemzar®; Lilly) or 5-FU, two widely used nucleoside analogs. Gemcitabine is indicated for the palliative treatment of breast, lung, pancreatic and ovarian cancer, but it has not been reported to be active in leukemias or MDS.

A Phase II study of sapacitabine in patients with advanced cutaneous T cell lymphoma started in the first half of 2007. A second Phase II trial in hematological cancers is planned to begin later this year along with a third Phase II trial in patients with non-small cell lung cancer.

Sapacitabine is part of a deep pipeline of small molecule drugs designed to target and stop uncontrolled cell division. Cyclacel's other development programs include seliciclib, a CDK (cyclin dependent kinase) inhibitor in Phase IIb clinical trials for non-small cell lung cancer, and CYC116, an aurora kinase inhibitor in IND-directed development.

About Cyclacel Pharmaceuticals, Inc.
Cyclacel is a biopharmaceutical company dedicated to the discovery, development and commercialization of novel, mechanism-targeted drugs to treat human cancers and other serious disorders. Two Cyclacel drugs are in Phase II trials: sapacitabine (CYC682), an orally-available, cell cycle modulating nucleoside analog, for the treatment of cutaneous T-cell lymphoma (CTCL) and seliciclib (CYC202), an orally-available CDK (cyclin dependent kinase) inhibitor, for the treatment of lung cancer. Sapacitabine is also in Phase I trials in patients with hematological malignancies. CYC116, an orally-available, Aurora kinase and VEGFR2 inhibitor, is at the IND stage. Several additional programs are at an earlier stage.

Please visit http://www.cyclacel.com/cyc/investors/news/pressreleases for additional information. Note: The Cyclacel logo and Cyclacel® are trademarks of Cyclacel Pharmaceuticals, Inc.

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 Forms S-3 (File No. 333-134945) and S-4 (File No. 333-131225) and in the other reports of Cyclacel filed with the SEC.

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