Cyclacel reports interim Phase I data for sapacitabine in patients with advanced leukemias or myelodysplastic syndromes

Short Hills, NJ, November 28, 2006 - Cyclacel Pharmaceuticals, Inc. (Nasdaq: CYCC; Nasdaq: CYCCP) announced today interim results from a Phase I pharmacologic trial of sapacitabine (CYC682), a novel orally-available nucleoside analog, in patients with advanced leukemias or myelodysplastic syndromes (MDS). The Phase I study is being conducted by Dr. Hagop Kantarjian, Professor of Medicine and Chairman of the Leukemia Department at M.D. Anderson Cancer Center (UTMDACC) in Houston, Texas.

The study's primary objective is to determine the maximum tolerated dose (MTD) of sapacitabine administered twice daily (b.i.d.) by mouth for seven consecutive days, every 21 days. As of November 2006, 26 patients were enrolled and 25 patients have received at least one dose of sapacitabine. Preliminary interim data are available on 22 patients, of which nine had de novo acute myelogenous leukemia (AML de novo); seven had AML preceded by MDS; three had MDS-refractory anemia with excess blasts (RAEB); and one each had treatment-related AML, acute lymphocytic leukemia (ALL) and chronic lymphocytic leukemia (CLL). The median age is 62 ranging from 39 to 91. Twenty-one patients received prior chemotherapy and one elderly patient (aged 91) did not receive any prior chemotherapy. The median number of prior chemotherapy regimens is two, ranging from one to four. Fifteen patients were previously treated with Ara-C-containing regimens (nine with AML de novo and six with AML preceded by MDS). Six patients were previously treated with decitabine (three with MDS-RAEB, one with AML de novo, one with AML preceded by MDS, and one with treatment-related AML).

One patient treated at the dose level of 275 mg b.i.d. experienced a dose limiting toxicity (DLT) consisting of Grade 3 diarrhea and Grade 3 neutropenic colitis, which resolved after cessation of dosing and medical treatment. No DLTs were reported in the remaining five patients treated at 275 mg b.i.d. Dose escalation continues and the MTD has not been reached at the dose level of 325 mg b.i.d., which is approximately four times the recommended Phase II dose for solid tumor patients.

To date, the best response to sapacitabine was reduction in bone marrow blast counts to 5% or less, which was observed in seven patients (three with AML de novo, two with AML preceded by MDS, and two with MDS-RAEB). In addition, two AML patients with leukemia cutis had significant shrinkage of leukemic infiltrates in their skin.

"These early study results suggest that sapacitabine has anti-leukemic activity against AML refractory to Ara-C and MDS-RAEB refractory to decitabine, both of which are areas of unmet medical need that have yet to be addressed," commented Dr. Judy Chiao, Vice President of Clinical Development and Regulatory Affairs of Cyclacel.

"This is an exciting development with regard to the potential commercial profile of sapacitabine. We will evaluate these results along with those from three previous studies of sapacitabine in solid tumors to define a Phase II program that is expected to commence in 2007," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "The indication of sapacitabine activity in hematological cancers that are no longer responsive to the nucleoside analogs Ara-C and decitabine suggests that the anti-tumor activity of sapacitabine may be independent of the responsiveness of tumors to other nucleoside analogs."

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.

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 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 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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