Cyclacel expands Phase 2 sapacitabine trial in elderly AML to include patients with MDS

-- First MDS patient enrolled under the amended protocol --

BERKELEY HEIGHTS, NJ, September 12, 2008 – Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP) announced that it has advanced sapacitabine into Phase 2 development as a second-line treatment for myelodysplastic syndromes (MDS). The MDS study is designed as a protocol amendment expanding the ongoing Phase 2 trial of sapacitabine in elderly patients with acute myeloid leukemia (AML) to include a cohort of patients with MDS. MDS are a group of hematologic cancers in which the bone marrow becomes unable to produce a sufficient number of healthy blood cells. Patients with MDS often progress to AML.

"We have enrolled our first MDS patient under this expanded Phase 2 protocol," said Dr Judy Chiao, M.D., Vice President, Clinical Development and Regulatory Affairs of Cyclacel. "An unmet medical need exists for patients with MDS who progress after hypomethylating agents, such as azacitidine or decitabine. In a Phase 1 study in patients with advanced leukemias or MDS sapacitabine demonstrated encouraging activity in MDS patients. Among four MDS patients with aggressive disease that had progressed following azacitidine or decitabine treatment, one achieved complete remission and two achieved a decrease in bone marrow blast count to 5% or less. If similar activity is observed in this Phase 2 study, sapacitabine could emerge as an important treatment for this life-threatening disease."

Cyclacel is currently enrolling patients in an open-label, multicenter, randomized Phase 2 trial of oral sapacitabine in elderly patients with AML who are previously untreated or in first relapse. Based on encouraging safety and efficacy data from the elderly AML patients, Cyclacel has amended the protocol to include a cohort of MDS patients who have been previously treated with hypomethylating agents. Following the protocol amendment the trial will enroll a total of approximately 120 patients in two separate strata, AML and MDS, with approximately 60 patients in each stratum.

"Sapacitabine has previously demonstrated activity in MDS as well as both forms of AML: AML de novo and AML preceded by MDS," commented Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "Expanding our ongoing AML study to include an MDS stratum is a rapid and cost effective strategy to obtain Phase 2 data in an important second indication. We believe that this study design enhances the commercial prospects of sapacitabine as it expands the drug's potential market."

As with the original Phase 2 study in elderly patients with AML, the primary objective of the MDS stratum is to evaluate the one-year survival rate of three dosing schedules of sapacitabine. Secondary objectives are to assess the number of patients who have achieved a complete remission (CR), complete remission without blood count recovery (CRi), hematological improvement and their corresponding durations, transfusion requirements, number of hospitalization days and safety. The study uses a selection design with the objective of identifying a dosing schedule which produces a better one year survival rate for each stratum in the event that all three dosing schedules are active.

For more information on this study, please visit www.clinicaltrials.gov.

About sapacitabine

Sapacitabine acts through a dual mechanism, interfering with DNA synthesis by causing single-strand DNA breaks and inducing arrest of cell cycle progression mainly at G2/M-Phase. Both sapacitabine and CNDAC, its major metabolite, have demonstrated potent anti-tumor activity in preclinical studies. Sapacitabine to date has been given as a single agent to approximately 170 patients with both hematologic malignancies and solid tumors in four Phase 1 studies. In an earlier reported Phase 1 trial two treatment schedules of sapacitabine were evaluated in 47 pretreated patients with advanced leukemias or MDS. Six patients achieved complete remission or complete remission without platelet count recovery and a further 15 achieved non-detectable levels of leukemic blast cells in their bone marrow. In addition to the Phase 2 study in elderly AML and MDS patients, sapacitabine is being studied in a currently ongoing Phase 2 study in patients with advanced cutaneous T cell lymphoma.

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. Three orally-available Cyclacel drugs are in clinical development. Sapacitabine (CYC682), a cell cycle modulating nucleoside analog, is in Phase 2 studies for the treatment of acute myeloid leukemia in the elderly, myelodysplastic syndromes and cutaneous T-cell lymphoma. Seliciclib (CYC202 or R-roscovitine), a CDK (cyclin dependent kinase) inhibitor, is in Phase 2 for the treatment of lung cancer and nasopharyngeal

cancer and in Phase 1 in combination with Tarceva®. CYC116, an Aurora kinase and VEGFR2 inhibitor, is in Phase 1 in patients with solid tumors. Several additional programs are at an earlier stage. Cyclacel's ALIGN Pharmaceuticals subsidiary markets directly in the U.S. Xclair® Cream for radiation dermatitis, Numoisyn™ Liquid and Numoisyn™ Lozenges for xerostomia. Cyclacel's strategy is to build a diversified biopharmaceutical business focused in hematology, oncology and other therapeutic areas based on a portfolio of commercial products and a development pipeline of novel drug candidates.

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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 Annual Report on Form 10-K for the year ended December 31, 2007, as supplemented by the interim quarterly reports, filed with the SEC.

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