Cyclacel initates phase 2 sapacitabine trial in elderly AML patients

BERKELEY HEIGHTS, NJ, December 31, 2007 – Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP) today announced the opening of an open-label, multicenter, randomized Phase 2 clinical trial of oral sapacitabine in elderly patients with acute myeloid leukemia (AML) who are previously untreated or in first relapse. This study follows the encouraging anti-leukemic activity observed in a Phase 1 trial of oral sapacitabine in patients with advanced leukemias or myelodysplastic syndromes (MDS) in which previously treated patients with AML or MDS achieved complete remission (CR) or complete remission without platelet count recovery.

“The opening of this study marks the expansion of the Phase 2 program of sapacitabine,” said Dr. Judy Chiao, Vice President of Clinical Development and Regulatory Affairs of Cyclacel. “Sapacitabine is also undergoing Phase 2 evaluation in patients with advanced cutaneous T-cell lymphoma and has been given as a single agent to approximately 170 patients in four Phase 1 studies.”

The Phase 2 study is led by Hagop Kantarjian, M.D., chair of the Department of Leukemia at The University of Texas M. D. Anderson Cancer Center in Houston, Texas. The primary objective of this study is to evaluate the 1-year survival rate of three dosing schedules of sapacitabine in elderly patients with previously untreated or first relapsed AML. Secondary objectives are to assess the number of patients who have achieved a CR or CR without blood count recovery (CRi), duration of CR or CRi, transfusion requirements, number of hospitalized days and safety.

The study uses a selection design with the objective of identifying a dosing schedule which produces a better 1-year survival rate in the event that all three dosing schedules are active. The trial will enroll a total of approximately 60 patients or approximately 20 patients in each arm. The study uses a Bayesian continuous monitoring rule to stop accrual in one or more arms of the study in the event that a dosing schedule does not appear to have a sufficient number of responses.

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

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 mainly 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, ovarian and pancreatic cancer, but it has not been reported to be active in leukemias or MDS.

The Phase II study opened today follows three Phase 1 trials in solid tumors or lymphomas involving over 120 patients which evaluated safety and pharmacokinetics of a variety of dosing schedules for future Phase 2 studies and combination studies with other anti-cancer agents. A fourth Phase 1 trial evaluated two treatment schedules of sapacitabine in 47 patients with advanced leukemias or myelodysplastic syndromes (MDS) in which previously treated patients with AML or MDS achieved complete remission (CR) or complete remission without platelet count recovery. In addition to the Phase 2 study in elderly AML patients, a further Phase 2 study of sapacitabine is currently ongoing in patients with advanced cutaneous T cell lymphoma.

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) 2 inhibitor in two randomized Phase 2 clinical trials for non-small cell lung cancer and nasopharyngeal cancer, and CYC116, an Aurora kinase and VEGFR2 inhibitor in Phase 1 development in patients with solid tumors.

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. Cyclacel’s ALIGN Pharmaceuticals subsidiary markets directly in the U.S. Xclair® Cream for radiation dermatitis, Numoisyn® Liquid and Numoisyn® Lozenges for xerostomia. Three Cyclacel drugs are in clinical development. Sapacitabine (CYC682), an orally-available, cell cycle modulating nucleoside analog, is in two randomized Phase 2 studies for the treatment of cutaneous T-cell lymphoma (CTCL) and elderly acute myeloid leukemia (AML) and in Phase 1 in patients with hematologic malignancies. Seliciclib (CYC202), an orally-available CDK

(cyclin dependent kinase) inhibitor, is in two randomized Phase 2 studies for the treatment of lung cancer and nasopharyngeal cancer. CYC116, an orally-available, Aurora kinase and VEGFR2 inhibitor, is in Phase 1 development in patients with solid tumors. Several additional programs are at an earlier stage. Cyclacel's strategy is to build a diversified biopharmaceutical business focused in oncology, hematology and other therapeutic areas based on a portfolio of commercial products and a development pipeline of novel drug candidates.

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. Numoisyn® and Xclair® are trademarks of Sinclair Pharma plc.

Forward-Looking Statements & 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, 2006, as supplemented by the interim quarterly reports, filed with the SEC.

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