Cyclacel Pharmaceuticals advances oral sapacitabine pivotal trial plan in hematological malignancies

BERKELEY HEIGHTS, NJ – February 6, 2009 – Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP) announced today progress with a pivotal trial plan for sapacitabine, its oral nucleoside analogue, for the treatment of hematological malignancies. The announcement follows the company's recent meeting with the U.S. Food and Drug Administration (FDA).

The pivotal trial plan consists of treating in an open-label, single arm study approximately 100 patients with acute myeloid leukemia (AML) or myelodysplastic syndromes (MDS) on a dosing regimen to be selected from the currently ongoing randomized Phase 2 study of oral sapacitabine in elderly patients. The company anticipates that it will start enrolling patients in such a pivotal study within 2009. Efficacy and safety in a total of approximately 200 patients with leukemias or MDS will be required to provide information for the label in a future submission of a New Drug Application (NDA).

"We are gratified by the advice offered by the FDA on our proposed plan. Results of this pivotal study, if positive, may serve as the basis of an NDA filing and may support expanded investigation of sapacitabine in additional indications," said Spiro Rombotis, Cyclacel's President and CEO. "We will require additional meetings and dialogue with FDA before any NDA filing. Available data from our ongoing Phase 2 studies of sapacitabine include complete remissions at all doses tested with good tolerability, support previously-reported Phase 1 findings and suggest that this agent may address a substantial, unmet medical need in older patients with AML and MDS. We thank our clinical investigators, their staff and patients for helping us reach this important milestone."

Sapacitabine is currently being studied 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 with the objective of evaluating three dosing schedules. Based on encouraging efficacy and safety data from the elderly AML patients, Cyclacel amended the protocol in 2008 to include a cohort of MDS patients who have been previously treated with hypomethylating agents. Following the protocol amendment the Phase 2 trial is anticipated to enroll a total of approximately 120 patients in two separate strata, AML and MDS, with approximately 60 patients in each stratum.

Cyclacel expects to report interim data from ongoing Phase 2 studies at upcoming major scientific meetings.

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. Data from a Phase 1 dose-escalation trial of sapacitabine were presented in December 2007 at the American Society of Hematology annual meeting. Two treatment schedules of sapacitabine were assessed in 47 evaluable, 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 currently ongoing Phase 2 studies in patients with advanced cutaneous T cell lymphoma and non-small cell lung cancer.

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, cutaneous T-cell lymphoma and lung cancer. Seliciclib (CYC202 or R-roscovitine), a CDK (cyclin dependent kinase) inhibitor, is in Phase 2 for the treatment of lung cancer and nasopharyngeal cancer. CYC116, an Aurora kinase and VEGFR2 inhibitor, is in Phase 1 in patients with solid tumors. 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.

Please visit www.cyclacel.com for additional information. Note: The Cyclacel logo and Cyclacel® are trademarks of Cyclacel Pharmaceuticals, Inc. Numoisyn® and Xclair® are trademarks of Sinclair Pharma plc.

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.

Contacts for Cyclacel:

Cyclacel Pharmaceuticals, Inc.
Corey Sohmer
(908) 517-7330

WeissComm Partners
Aline Schimmel
(312) 646-6295

College Hill, Life Sciences
Sue Charles & Justine Lamond
+44 (20) 7866 7857