



## **Cyclacel begins Phase 2 study of oral sapacitabine in patients with previously treated non-small cell lung cancer**

**BERKELEY HEIGHTS, NJ – January 13, 2009** – Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP) announced today that the company has begun treating patients in a Phase 2, open label, single arm, multicenter clinical trial of sapacitabine (CYC682) in patients with non-small cell lung cancer (NSCLC) who have had one prior chemotherapy. This study builds on the observation of prolonged stable disease of four months or longer experienced by heavily pretreated NSCLC patients involved in two Phase 1 studies of sapacitabine. The multicenter Phase 2 trial is led by Philip D. Bonomi, M.D., the Alice Pirie Wirtz Professor of Medical Oncology at the Rush University Medical Center, Chicago.

“Nucleoside analogs, such as gemcitabine, have significant activity in NSCLC” said Dr. Bonomi. “We are interested in evaluating sapacitabine because of its unique mechanisms of action, indication of activity in Phase 1 studies and the possibility that it may be an active drug in NSCLC that can be administered by the oral route”.

The primary objective of the study is to evaluate the rate of response and stable disease in patients with previously treated NSCLC. Secondary objectives are to assess progression-free survival, duration of response, duration of stable disease, one year survival, overall survival and safety. The study will enroll approximately 60 patients and has a lead-in phase for dose escalation with the objective of defining a recommended dose followed by a second stage in which patients will be treated at the recommended dose. Study completion is planned to occur approximately six months after the last patient is enrolled.

“The opening of this study marks the expansion of the Phase 2 program of sapacitabine into solid tumors,” said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. “We believe that sapacitabine has the potential to emerge as a novel, orally-administered treatment for patients with both hematologic malignancies and solid tumors. During this quarter Cyclacel will meet with the US FDA to discuss registration pathways for sapacitabine as a treatment for acute myeloid leukemia (AML) or myelodysplastic syndromes (MDS) in elderly patients.”

### **About sapacitabine**

Cyclacel is now evaluating sapacitabine, an orally available nucleoside analog, in three Phase 2 trials in both hematological and solid tumors. 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 has been given as a single agent to approximately 170 patients with both hematologic malignancies and solid tumors in four Phase 1 studies. In Phase 1 trials reported earlier sapacitabine was evaluated in 47 pretreated patients with advanced leukemias or MDS and 123 heavily-pretreated patients with various solid tumors. In the hematological malignancy trial six patients achieved complete remission or complete remission without platelet count recovery and a further 15 had a significant decrease in bone marrow blasts including 7 with blast reduction to 5% or less. In the solid tumor studies, 20 patients experienced prolonged stable disease and remained on study for four months or longer, five with NSCLC, one with small cell lung cancer, four with colorectal, two with bladder, two with gastrointestinal stromal tumors, two with ovarian, one with breast, one with renal, one with parotid and one with an unknown primary tumor. Sapacitabine is also being studied in a currently ongoing Phase 2 trial 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, 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. 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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