Cyclacel begins pivotal Phase 3 “SEAMLESS” trial of sapacitabine as front-line treatment for AML under a SPA

Cyclacel to host conference call at 4:30 pm ET on Tuesday, January 18, 2011 to discuss study design

Berkeley Heights, NJ, January 11, 2011 - Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP; “Cyclacel” or the “Company”), today announced that it has opened enrollment of the SEAMLESS pivotal Phase 3 trial for the Company’s sapacitabine oral capsules as a front-line treatment of elderly patients aged 70 years or older with newly diagnosed acute myeloid leukemia (AML) who are not candidates for intensive induction chemotherapy. The study is being conducted under a Special Protocol Assessment (SPA) agreement that Cyclacel reached with the U.S. Food and Drug Administration (FDA). SEAMLESS builds on promising 1-year survival observed in elderly patients aged 70 years or older with newly diagnosed AML or AML in first relapse enrolled in a Phase 2 study of single agent sapacitabine.

“The opening of the SEAMLESS study for patient enrollment marks an important milestone for Cyclacel as this is the first pivotal Phase 3 trial ever conducted by the Company,” said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. “If it reaches the market, sapacitabine will become an important treatment option for many elderly patients who are suffering from this life-threatening disease. We also look forward to interim data from the Phase 2 study of sapacitabine in Non-Small Cell Lung Cancer (NSCLC). Sapacitabine may be one of few cancer drugs with activity against both hematological malignancies and solid tumors.”

The SEAMLESS study is chaired by Hagop M. Kantarjian, M.D., Chairman and Professor, Department of Leukemia, The University of Texas MD Anderson Cancer Center, Houston, Texas. SEAMLESS is a multicenter, randomized, Phase 3 study comparing three treatment arms. In Arm A sapacitabine is administered in alternating cycles with decitabine, in Arm B sapacitabine is administered alone and in Arm C decitabine is administered alone. The primary efficacy endpoint is overall survival. The study is designed to demonstrate an improvement in overall survival of either of two pairwise comparisons: (1) Arm A versus Arm C or (2) Arm B versus Arm C. Approximately 150 patients per arm or a total of 450 patients from approximately 50 centers will be enrolled. SEAMLESS will be monitored by a Data Safety Monitoring Board (DSMB). A prespecified interim analysis for futility will be performed and reviewed by the DSMB.

“We chose decitabine as an active control arm as it is one of the treatment options recommended by the National Comprehensive Cancer Network’s Clinical Practice Guidelines. We are pleased to learn that this active control arm is acceptable to AML investigators.” said Judy Chiao, M.D., Vice President of Clinical Development and Regulatory Affairs of Cyclacel. “AML in the elderly is a life-threatening disease with high unmet medical need. Patients with AML aged 70 years or older have a poor prognosis, as the majority of these patients are not candidates for intensive induction chemotherapy because of poor tolerability to such therapy and a high risk of relapse because of the lack of effective consolidation and maintenance therapy. If the SEAMLESS study is successful, sapacitabine may significantly improve the outcome of this devastating disease in elderly patients.”

The treatment regimen of sapacitabine administered in alternating cycles with decitabine has been found to be safe and efficacious in an on-going pilot study conducted at The University of Texas MD Anderson Cancer Center. In addition, SEAMLESS has a lead-in stage to further confirm the safety and efficacy of the alternating treatment regimen in the multicenter setting.

The FDA has designated sapacitabine as an orphan drug for the treatment of both AML and myelodysplastic syndromes (MDS).

Conference call and Webcast Information:

Cyclacel management will review the SEAMLESS trial design on a conference call scheduled for January 18, 2011 at 4:30 p.m. Eastern. Conference call and webcast details are as follows:

US/Canada call: (877) 493-9121/ international call: (973) 582-2750
US/Canada archive: (800) 642-1687 / international archive: (706) 645-9291
Code for live and archived conference call is 36660893.

Webcast: For the live and archived webcast, please visit the Corporate Presentations page on the Cyclacel website at www.cyclacel.com. The webcast will be archived for 90 days and the audio replay for 7 days.

About Acute Myeloid Leukemia (AML)

AML is a cancer of the blood cells that progresses rapidly and if not treated, could be fatal in a few months. AML is generally a disease of older people and is uncommon before the age of 40. The average age of a patient with AML is about 67 years. There are more than 12,300 new cases of AML, of which about half are elderly, and nearly 9,000 deaths caused by this cancer each year in the United States. A recently published review of The University of Texas MD Anderson Cancer Center's historical experience with front-line intensive induction chemotherapy for elderly AML patients aged 70 years or older demonstrated that while 45% of patients achieved a complete remission, median overall survival was only 4.6 months and 36% of patients died within the first 8 weeks of treatment, underscoring the unmet need in this patient setting (Kantarjian, H, et al, Blood, DOI 10.1182/blood-2010-03-276485).

About Special Protocol Assessment (SPA)

A Special Protocol Assessment is a binding written agreement with the FDA that the sponsor's proposed trial protocol design, clinical endpoints and statistical analyses are acceptable to support regulatory approval. Final marketing approval depends on efficacy results, adverse event profile and an evaluation of the benefit/risk of a treatment as demonstrated in the trial. For further information regarding the SPA process, please visit the FDA website, www.fda.gov.

About sapacitabine

Sapacitabine (CYC682), an orally-available nucleoside analogue, is currently being evaluated in a Phase 3 trial in elderly AML under a SPA agreement with the U.S. Food and Drug Administration and Phase 2 trials in patients with hematological malignancies 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-Phase. Both sapacitabine and CNDAC, its major metabolite, have demonstrated potent anti-tumor activity in preclinical studies. Over 200 patients have received sapacitabine in Phase 2 studies in AML, MDS, cutaneous T cell lymphoma (CTCL) and NSCLC. Sapacitabine has been administered to approximately 170 patients in five Phase 1 studies with both hematological malignancies and solid tumors. In December 2009 at the 51st Annual Meeting of the American Society of Hematology (ASH), Cyclacel reported data from a randomized Phase 2 study including promising 1-year survival in elderly patients with AML aged 70 years or older. Sapacitabine is part of Cyclacel's pipeline of small molecule drugs designed to target and stop uncontrolled cell division.

About Cyclacel Pharmaceuticals, Inc.

Cyclacel is a biopharmaceutical company developing oral therapies that target the various phases of cell cycle control for the treatment of cancer and other serious diseases. Sapacitabine (CYC682), a cell cycle modulating nucleoside analog, is in Phase 3 development for the treatment of acute myeloid leukemia in the elderly under a Special Protocol Assessment agreement with the U.S. Food and Drug Administration, and is in Phase 2 studies for myelodysplastic syndromes and lung cancer. Seliciclib (CYC202 or R-roscovitine), a CDK (cyclin dependent kinase) inhibitor, is in Phase 2 studies for the treatment of lung cancer and nasopharyngeal cancer and in a Phase 1 trial in combination with sapacitabine. 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 and oncology based on a portfolio of commercial products and a development pipeline of novel drug candidates. Please visit www.cyclacel.com for additional information.

Forward-looking Statements

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. For a further list and description of the risks and uncertainties the Company faces, please refer to our most recent Annual Report on Form 10-K and other periodic and current filings that have been filed with the Securities and Exchange Commission and are available at www.sec.gov. Such forward-looking statements are current only as of the date they are made, and we assume no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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