Interim results from Cyclacel clinical study highlight safety and efficacy of sequential administration of sapacitabine and decitabine in elderly patients with AML

- Pilot Phase 1/2 Data Presented at the American Society of Clinical Oncology (ASCO) Annual Meeting -

Berkeley Heights, NJ, June 6, 2011 – Cyclacel Pharmaceuticals, Inc. NASDAQ: CYCC, NASDAQ: CYCCP; Cyclacel or the Company), announced interim results from an ongoing, multicenter, Phase 1/2 clinical trial examining the safety and effectiveness of oral sapacitabine, the Company's lead product candidate, administered sequentially with decitabine. Thirty-day mortality from all causes was 4.5%; 60-day mortality from all causes was 9.5%. The overall response rate was 34.8%. The data were reported during a poster session at the 2011 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, Illinois.

"Based on the interim results reported at ASCO, the sequential administration of sapacitabine and decitabine appears safe and active in elderly patients with newly diagnosed AML," said Hagop Kantarjian, M.D., Chairman & Professor, Department of Leukemia, The University of Texas MD Anderson Cancer Center and principal investigator for the study. "Intensive chemotherapy does not benefit most older patients (aged 70 years or older) with acute myeloid leukemia. Median survival by intensive therapy is only 4.6 months and is associated with a 4-week death rate of 26% and an 8-week death rate of 36%. These facts underscore the need for a better treatment regimen for this patient population."

The treatment regimen under evaluation in this pilot study is being used as one of the arms in SEAMLESS, the registration-directed, Phase 3 study of sapacitabine in elderly patients with newly diagnosed acute myeloid leukemia (AML) who are not candidates for or have refused induction chemotherapy. SEAMLESS is being conducted under a Special Protocol Assessment agreement that Cyclacel reached with the US Food and Drug Administration.

Pilot Study Design

Up to 24 patients with previously untreated AML will be enrolled in the Phase 1/2 study. They must be aged 70 years or older and not be candidates for or have refused intensive induction chemotherapy. Patients who received hypomethylating agents for prior myelodysplastic syndromes or myeloproliferative diseases are excluded. Patients received intravenous decitabine administered as 20 mg/m^2 per day for five consecutive days of a 4-week cycle (odd cycles) and received sapacitabine administered as 300 mg orally twice per day for three days per week for two weeks of a 4-week cycle (even cycles). The regimen would be considered tolerable if dose-limiting toxicity occurred in less than 33% of patients. The primary efficacy endpoint is overall response rate (comprised of complete remission, complete remission with incomplete platelet recovery, partial response and major hematological improvement). The regimen will be considered active if the overall response rate is equal or higher than 30%.

Results

Thirty-day mortality from all causes was 4.5%. Sixty-day mortality from all causes was 9.5%. The overall response rate was 34.8%. An additional 26.1% of patients stayed on study for more than 4 cycles with a decrease in bone marrow blast counts despite not meeting criteria of response. Approximately 60.9% of patients received 4 or more cycles of the regimen.

As reported at ASCO, no dose-limiting toxicities were observed in 21 patients treated with the regimen who have had at least 60 days of follow-up. The median age in the group is 76 years (range 72-88). Common adverse events regardless of cause included anemia, anorexia, dehydration, diarrhea, dyspnea, edema, hypocalcemia, nausea, febrile neutropenia, neutropenia, pneumonia, thrombocytopenia, and weakness, which were mostly moderate in intensity.

Abstract Citation

http://abstract.asco.org/AbstView_102_81934.html

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. Nearly 9,000 deaths are 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 AML patients aged 70 years or older demonstrated that while 45% achieved a complete remission, median overall survival was only 4.6 months and was associated with a 4-week death rate of 26% and a 8-week death rate of 36% (Kantarjian, H, et al, Blood, DOI 10.1182/blood-2010-03-276485).

About sapacitabine

Sapacitabine (CYC682), an orally-available nucleoside analogue, is currently being evaluated in a registration-directed, Phase 3 trial in elderly AML 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 and 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, trials may have difficulty enrolling, Cyclacel may 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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View the poster at ASCO 2011 (221KB)