Updated 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 Hematology (ASH) Annual Meeting

BERKELEY HEIGHTS, N.J., Dec. 12, 2011 (GLOBE NEWSWIRE) -- Cyclacel Pharmaceuticals, Inc. (Nasdaq:CYCC) (Nasdaq:CYCCP); (Cyclacel or the Company), announced today updated results from an ongoing, multicenter, Phase 1/2 clinical trial examining the safety and efficacy of oral sapacitabine, the Company's lead product candidate, administered sequentially with decitabine. The study enrolled 25 patients aged 70 years or older, 76% of which were aged 75 years or older. Thirty-day mortality from all causes was 4% and 60-day mortality from all causes 12%. The overall response rate was 40%. Median overall survival is 231 days and 44% of patients are still alive. The data were reported during a poster session at the 2011 American Society of Hematology (ASH) Annual Meeting in San Diego, California.

"The sequential administration of sapacitabine and decitabine is 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 chemotherapy 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 (SPA) agreement that Cyclacel reached with the U.S. Food and Drug Administration (FDA).

Pilot Study Design

Approximately 24 patients with previously untreated AML will be enrolled in the Phase 1/2 study. The patients 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 will receive intravenous decitabine administered as 20 mg/m^2 per day for five consecutive days of a 4-week cycle (odd cycles) and 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 will 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 to or higher than 30%.

Results

Thirty-day mortality from all causes was 4%. Sixty-day mortality from all causes was 12%. The overall response rate was 40%. An additional 20% of patients stayed on study for 5 or more cycles with a decrease in bone marrow blast counts despite not meeting criteria of response. Approximately 60% of patients received 5 or more cycles of the regimen. Median overall survival is 231 days and 11 patients (44%) are still alive.

No dose-limiting toxicities were observed in 25 patients. The median age in the group is 76 years (range 72-90). Nineteen patients are 75 years or older (76%). Common adverse events regardless of cause included anemia, asthenia, decreased appetite, diarrhea, constipation, dyspnea, limb edema, hypocalcemia, nausea, febrile neutropenia, neutropenia, lung infection, and thrombocytopenia, which were mostly moderate in intensity.

Abstract Citation

The abstract can be accessed through the ASH website, http://www.hematology.org/Meetings/Annual-Meeting/3734.aspx. The abstract title is provided below.

"Phase 1/ 2 Study of Sapacitabine and Decitabine Administered Sequentially in Elderly Patients with Newly Diagnosed AML"

Date/Time: Monday, December 12, 2011, 10:00 AM - 8:00 PM Pacific

Abstract Number: 3630

Hall GH (San Diego Convention Center)

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 patients with newly diagnosed acute myeloid leukemia (AML), Phase 2 trials in patients with hematological malignancies, including myelodysplastic syndromes (MDS), cutaneous T-cell lymphoma (CTCL), chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL), and non-small cell lung cancer (NSCLC) and in a Phase 1 trial in combination with seliciclib in patients with advanced solid tumors. Sapacitabine acts through a novel DNA single-strand breaking mechanism, leading to production of DNA double strand breaks (DSBs) and/or checkpoint activation. Unrepaired DSBs cause cell death. Repair of sapacitabine-induced DSBs is dependent on the homologous recombination DNA repair (HRR) pathway. Both sapacitabine and CNDAC, its major metabolite, have demonstrated potent anti-tumor activity in preclinical studies.

Over 350 patients have received sapacitabine in Phase 2 studies in AML, MDS, CTCL and NSCLC. Sapacitabine has been administered to approximately 170 patients in five Phase 1 studies with both hematological malignancies and solid tumors. In June 2009 at the Annual Meeting of the American Society of Hematology (ASH), Cyclacel reported data from a randomized Phase 2 single agent study of sapacitabine including promising 1-year survival in elderly patients with AML aged 70 years or older. In June 2011 at the Annual Meeting of the American Society of Clinical Oncology (ASCO), Cyclacel reported data from a pilot Phase 1/2 study including promising response rate, low 4-week and 8-week mortality in elderly patients with AML aged 70 years or older receiving sapacitabine alternating with decitabine. The FDA and the European Medicines Agency have designated sapacitabine as an orphan drug for the treatment of both AML and MDS. 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), an orally-available, cell cycle modulating, nucleoside analogue, is in a Phase 3 trial being conducted under a SPA with the U.S. FDA for the front-line treatment of acute myeloid leukemia in the elderly and Phase 2 studies for myelodysplastic syndromes, lung cancer and chronic lymphocytic leukemia. Seliciclib (CYC202 or R-roscovitine), an orally-available, 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.

CONTACT: Cyclacel Pharmaceuticals, Inc.

Investors/Media:

Corey Sohmer

(908) 517-7330

csohmer@cyclacel.com