Cyclacel Announces Data Safety Monitoring Board Recommendation to Continue the SEAMLESS Phase 3 Trial of Sapacitabine

Lead-in Portion of the Phase 3 Study Meets Prespecified Criteria Agreed in a SPA With FDA

BERKELEY HEIGHTS, N.J., Oct. 13, 2011 (GLOBE NEWSWIRE) -- Cyclacel Pharmaceuticals, Inc. (Nasdaq:CYCC) (Nasdaq:CYCCP) (Cyclacel or the Company), today announced that the independent Data Safety Monitoring Board (DSMB) of SEAMLESS, the Phase 3, randomized, registration-directed study of sapacitabine in elderly patients with acute myeloid leukemia (AML), recommended that the study should enter the randomized stage as planned. The DSMB reviewed available data from a total of 46 patients receiving oral sapacitabine capsules, the Company's lead product candidate, administered in alternating cycles with decitabine. The DSMB noted that no safety or efficacy concerns were identified. The DSMB review was mandated in the Special Protocol Assessment (SPA) agreement that Cyclacel entered into with the U.S. Food and Drug Administration (FDA) with regard to the SEAMLESS study protocol.

"The DSMB's recommendation to continue our SEAMLESS Phase 3 study of sapacitabine in patients aged 70 years or older who are not candidates for or have refused intensive induction chemotherapy confirms that the treatment regimen of administering sapacitabine in alternating cycles with decitabine is safe and tolerable in the multicenter setting," said Judy H. Chiao, M.D., Vice President, Clinical Development and Regulatory Affairs of Cyclacel. "The objective of the randomized stage of the study is to establish the role of sapacitabine in the front-line treatment of AML in this population with a high unmet medical need," continued Dr. Chiao.

Of the 46 patients reviewed by the DSMB, 21 were enrolled in the lead-in stage of SEAMLESS and 25 in an earlier pilot Phase 1/2 study using an identical treatment regimen. Interim data from the Phase 1/2 study were presented at the American Society of Clinical Oncology (ASCO) Annual Meeting in June 2011.

Lead-In Stage Topline Results

In accordance with the study protocol, 21 patients with previously untreated AML aged 70 years or older who were not candidates for or have refused intensive induction chemotherapy were enrolled. Patients who received hypomethylating agents for prior myelodysplastic syndromes or myeloproliferative diseases were excluded. Patients received intravenous decitabine at 20 mg/m^2 per day for five consecutive days of a 4-week cycle (odd cycles) and sequentially sapacitabine at 300 mg orally twice per day for three days per week for two weeks of a 4-week cycle (even cycles).

The regimen is considered tolerable as the rate of dose-limiting toxicity was 9.5% and the 8-week mortality rate was 14.3%. The prespecified criteria as per protocolwere: dose-limiting toxicity in less than 33% of patients and an 8-week mortality rate of less than 37%. Eight-week mortality, or death rate, was defined as death due to any cause occurring within 60 days after the date of patient registration into the study.

Pilot Phase 1/2 Study Topline Results

Updated data from 25 patients treated with the identical regimen and at least 60 days of follow-up showed no dose-limiting toxicities and 8-week mortality rate of 12.0%. The updated study results will be presented at a forthcoming major medical conference.

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, excluding patients with favorable karyotypes, 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 front-line elderly acute myeloid leukemia (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 300 patients have received sapacitabine in Phase 2 studies in AML, myelodysplastic syndromes (MDS), cutaneous T cell lymphoma (CTCL) and non-small cell lung cancer (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 study 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 8-week mortality in elderly patients with AML aged 70 years or older receiving sapacitabine alternating with decitabine. The U.S. 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 Phase 3 development 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.

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