December 10, 2012

Cyclacel Presents Updated Survival Data From the Pilot Study and Lead-In Phase of Seamless Phase 3 Study at the 2012 ASH Annual Meeting

Median Overall Survival is 238 days, or Approximately 8 Months, and 1-Year Survival is 35% With an Overall Response Rate of 41% in Elderly Patients With Newly Diagnosed AML

BERKELEY HEIGHTS, N.J., Dec. 10, 2012 (GLOBE NEWSWIRE) -- Cyclacel Pharmaceuticals, Inc. (Nasdaq:CYCC) (Nasdaq:CYCCP) (Cyclacel or the Company), a biopharmaceutical company developing oral therapies that target the various phases of cell cycle control for the treatment of cancer and other serious disorders, announced updated survival data from the pilot study and lead-in phase of SEAMLESS, the Company's randomized, Phase 3, registration-directed study of oral sapacitabine capsules in elderly patients aged 70 years or older with newly diagnosed acute myeloid leukemia (AML) who are not candidates for, or have refused, induction chemotherapy. The data were reported at a poster presentation at the 54th Annual Meeting of the American Society of Hematology (ASH) in Atlanta, Georgia.

"The updated survival data of the sequential administration of sapacitabine and decitabine is promising and provides support for the ongoing SEAMLESS Phase 3 study 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 chair of the SEAMLESS study. "Intensive chemotherapy does not benefit most AML patients aged 70 years or older. 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%. We urgently need better treatment regimens for this patient population."

Pooled Topline Results of the Pilot Phase 1/2 Study and Lead-In Stage of SEAMLESS

Forty-six patients were treated with alternating cycles of sapacitabine and decitabine, which is the treatment regimen in the experimental arm of SEAMLESS. Median age is 77 years (range 70-90). Thirty-three patients (72%) are 75 years or older. Median overall survival is 238 days, or approximately 8 months. The number of patients still alive at 3 months was 38 (83%), at 6 months 30 (65%), at 12 months 16 (35%) and at 18 months 12 (26%). Sixteen patients (35%) survived 1 year or longer. Among 33 patients who are 75 years or older, median overall survival is 263 days, or approximately 9 months, and 1-year survival is 36%. Nineteen patients (41%) responded with 10 complete responses (CRs), 4 partial responses (PRs) and 5 major hematological improvements (HIs). Median time to response is 2 cycles, i.e., one cycle of decitabine and one cycle of sapacitabine (range 1-10). Twenty-seven patients (59%) received 5 or more cycles of treatment. Two dose-limiting toxicities (DLT) were observed (lung infection/sepsis, typhlitis). Thirty-day mortality from all causes was 4%. Sixty-day mortality from all causes was 13% with one death from typhlitis considered to be possibly related to decitabine by investigator assessment. The sequential combination of decitabine and sapacitabine is safe and active.

SEAMLESS Study Design

Sapacitabine (CYC682), an orally-available nucleoside analogue, is currently being studied in SEAMLESS, an ongoing, Phase 3, registration-directed trial in elderly patients aged 70 years or older with newly diagnosed 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). Patients who received hypomethylating agents for prior myelodysplastic syndromes or myeloproliferative diseases are excluded from SEAMLESS. Patients in the control arm of SEAMLESS will receive decitabine alone, while in the experimental arm of SEAMLESS, patients will receive intravenous decitabine at 20 mg/m2 per day for five consecutive days of a 4-week cycle (odd cycles) alternating with sapacitabine at 300 mg orally twice per day for three days per week for two weeks of a 4-week cycle (even cycles). The primary efficacy endpoint is overall survival. A prespecified interim analysis for futility will be performed and reviewed by the Data Safety Monitoring Board.

Publication details

54th Annual Meeting of the American Society of Hematology (ASH)

Abstract:	2630
Title:	*Pooled analysis of elderly patients with newly diagnosed AML treated with sapacitabine and decitabine administered in alternating cycles*

Date/Time:	Sunday, December 9, 2012, 6:00 PM — 8:00 PM Eastern Time
	Hall B1-B2, Level 1, Building B (Georgia World Congress Center)
Session:	615. Acute Myeloid Leukemia — Therapy, excluding Transplantation: Poster II

The abstract is available online through the annual meeting section of the American Society of Hematology's website at http://www.hematology.org/Meetings/Annual-Meeting/.

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 aged 70 years or older. Nearly 9,000 deaths are caused by this cancer each year in the United States. A 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 studied in an ongoing, Phase 3, registration-directed trial in elderly patients aged 70 years or older with newly diagnosed AML who are not candidates for or have refused induction chemotherapy. Sapacitabine is also the subject of Phase 2 trials in patients with hematological malignancies, including AML, myelodysplastic syndromes (MDS), cutaneous T-cell lymphoma (CTCL), chronic lymphocytic leukemia and small lymphocytic lymphoma, and non-small cell lung cancer (NSCLC), and 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 500 patients have received sapacitabine in Phase 2 studies in AML, MDS, CTCL and NSCLC and Phase 1 studies in hematological malignancies and solid tumors. Results 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, were published in *The Lancet Oncology* in November 2012. At the 2011 ASH Annual Meeting, Cyclacel reported data from a pilot Phase 1/2 study including promising response rate, overall survival and 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. The Company's most advanced oral product candidate, sapacitabine, is the subject of SEAMLESS, a Phase 3 trial being conducted under an SPA with the FDA as front-line treatment of acute myeloid leukemia (AML) in the elderly and Phase 2 studies for AML, myelodysplastic syndromes (MDS), chronic lymphocytic leukemia (CLL) and solid tumors including breast, lung, ovarian and pancreatic cancer. Cyclacel's pipeline includes seliciclib, a CDK inhibitor, in Phase 2 for lung and nasopharyngeal cancer and in Phase 1 in combination with sapacitabine; and CYC065, a second generation CDK inhibitor, in IND-directed development. Cyclacel's strategy is to build a diversified biopharmaceutical business focused in hematology and oncology based on 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 product candidates, 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 other filings we file 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: Investors/Media:

Corey Sohmer

(908) 517-7330

csohmer@cyclacel.com