

## Cyclacel to Report New Sapacitabine Clinical Data at the American Society of Clinical Oncology Annual Meeting

BERKELEY HEIGHTS, N.J., May 17, 2012 (GLOBE NEWSWIRE) -- Cyclacel Pharmaceuticals, Inc. (Nasdaq:CYCC) (Nasdaq:CYCCP) (Cyclacel or the Company), announced today that new clinical data for oral sapacitabine capsules, the Company's lead product candidate, will be presented as posters during the 2012 American Society of Clinical Oncology (ASCO) Annual Meeting being held June 1-5, 2012, in Chicago, Illinois.

The abstracts can be accessed through the ASCO website, <u>www.asco.org</u>. Abstract titles are provided below. Please note that according to ASCO policy, all data are embargoed until the time of the beginning of the presentation.

"A randomized phase 2 study of sapacitabine in MDS refractory to hypomethylating agents"

Date/Time: Friday June 1, 2012, 4:30 PM — 5:30 PM Central time

Location: S406 (Poster Board 12)

Abstract Number: 6520

"Phase I study of sequential sapacitabine and seliciclib in patients with advanced solid tumors"

Date/Time: Monday, June 4 2012, 8:00 AM — 12:00 PM Central time

Location: S Hall A2 (Poster Board 14C)

Abstract Number: 3053

## About sapacitabine

Sapacitabine (CYC682), an orally-available nucleoside analogue, is in the SEAMLESS, 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), a Phase 1 trial in combination with seliciclib in patients with advanced solid tumors and an investigator-led, Phase 2/3 study comparing sapacitabine to low dose cytarabine as front-line treatment of elderly patients with AML or high risk MDS unfit for intensive chemotherapy. 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 and over 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 oral capsules is in the SEAMLESS Phase 3 trial being conducted under an SPA with the FDA as front-line treatment of acute myeloid leukemia (AML) in the elderly, Phase 2 studies for AML, myelodysplastic syndromes (MDS), solid tumors including lung cancer, chronic lymphocytic leukemia and an investigator-led, Phase 2/3 study comparing sapacitabine to low dose cytarabine as front-line treatment of elderly patients with AML or high risk MDS unfit for intensive chemotherapy. Cyclacel's pipeline includes seliciclib oral capsules 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 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.

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