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

- DSMB Recommends Study Should Continue as Planned Without Any Modifications -

BERKELEY HEIGHTS, N.J., Nov. 25, 2013 (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 today announced that the independent Data and Safety Monitoring Board (DSMB) for the Company's Phase 3 SEAMLESS study in acute myeloid leukemia (AML) has completed its third planned safety review and recommended that the study should continue as planned without any modifications. The DSMB reviewed available data from 212 randomized patients and noted that no safety or efficacy concerns were identified. The DSMB will conduct additional periodic reviews of each 100 patients and will also perform a futility assessment once half the required events have been observed.

"We are encouraged by the DSMB's recommendation after the latest safety review of available data from US sites participating in the SEAMLESS study. We are presently expanding the study into Europe and expect to at least double the number of sites before completing enrollment," said Judy H. Chiao, M.D., Vice President, Clinical Development and Regulatory Affairs of Cyclacel. "We look forward to reporting further updates from SEAMLESS and, separately, primary endpoint data of our Phase 2 study of sapacitabine in older patients with myelodysplastic syndromes (MDS) after treatment failure of hypomethylating agents at the ASH conference in early December."

SEAMLESS is a Phase 3, randomized, registration-directed study of oral sapacitabine capsules in elderly patients with AML who are unfit or have refused intensive chemotherapy. The primary endpoint is overall survival. SEAMLESS is being conducted under a Special Protocol Assessment (SPA) agreement with the US Food and Drug Administration (FDA).

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, Cyclacel's most advanced product candidate, is the subject of SEAMLESS, a Phase 3 trial being conducted under an SPA with the FDA as front-line treatment for acute myeloid leukemia (AML) in the elderly, and other studies for myelodysplastic syndromes (MDS), chronic lymphocytic leukemia (CLL) and solid tumors including breast, lung, ovarian and pancreatic cancer and in particular those carrying gBRCA mutations. 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 the Company's most recent Annual Report on Form 10-K and other periodic and other filings Cyclacel files 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 Cyclacel assumes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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