October 9, 2014

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., Oct. 9, 2014 (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 fourth planned safety review and recommended that the study should continue as planned without any modifications. The DSMB reviewed available data from 317 randomized patients with at least 60 days of follow-up and noted that no safety or efficacy concerns were identified.

"This is the fourth consecutive review for which the DSMB recommended that the SEAMLESS study should continue as planned," said Judy H. Chiao, M.D., Vice President, Clinical Development and Regulatory Affairs of Cyclacel. "We are encouraged by the DSMB's recommendation based on their review of available data from US and European sites participating in SEAMLESS. We now have over 100 US and European sites open and expect completion of enrollment to occur in the next few months. In addition to SEAMLESS, we are conducting feasibility assessment of our Phase 2b randomized study of sapacitabine in older patients with myelodysplastic syndromes (MDS) after treatment failure of hypomethylating agents."

SEAMLESS is a Phase 3, randomized, registration-directed study of oral sapacitabine capsules in elderly (70 years or older) patients with AML who are unfit for or have refused intensive chemotherapy. The primary endpoint is overall survival. SEAMLESS is being conducted under a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA). The DSMB will perform an interim analysis for futility once half of the required events have been observed.

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.

CONTACT: Cyclacel Pharmaceuticals, Inc.

Company: Paul McBarron, (908) 517-7330, pmcbarron@cyclacel.com

Investor Relations: Russo Partners LLC, Robert Flamm,

(212) 845-4226, robert.flamm@russopartnersllc.com