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Cyclacel's CYC065 CDK Inhibitor Demonstrates Therapeutic Potential in Acute Leukemias With Mixed Lineage Leukemia (MLL) Rearrangements

In Vitro and in Vivo Preclinical Data Presented at the SOHO 2014 Meeting Show Selectivity and Activity of CYC065

BERKELEY HEIGHTS, N.J., Sept. 18, 2014 (GLOBE NEWSWIRE) -- Cyclacel Pharmaceuticals, Inc. (Nasdaq:CYCC) (Nasdaq:CYCCP) ("Cyclacel" or the "Company"), today announced the presentation of preclinical data demonstrating the therapeutic potential of CYC065, Cyclacel's second-generation cyclin dependent kinase (CDK) inhibitor, to treat acute leukemias, and in particular those with rearrangements in the mixed lineage leukemia (MLL) gene. The data showed that *in vitro* all human acute myelogenous leukemia (AML) and acute lymphocytic leukemia (ALL) cell lines with MLL rearrangements (MLLr) tested were sensitive to CYC065 and that the drug inhibited MLL-driven gene expression. Potent anticancer activity of CYC065 was demonstrated *in vivo* in AML xenograft models resulting in over 90% inhibition of tumor growth. The data were presented at the 2014 Society of Hematologic Oncology (SOHO) meeting taking place September 17-20, 2014 in Houston, Texas.

"CDK inhibition is emerging as an important therapeutic approach in a number of tumor types," said Spiro Rombotis, Cyclacel's President and Chief Executive Officer. "MLL rearrangements identified in AML or ALL patients are associated with a poor prognosis. CYC065 works by targeting CDK enzymes which are key components of MLLr cell survival and resistance to chemotherapy. We are encouraged by the data reported, as they provide evidence that CYC065 has promising anticancer activity, especially in AML or ALL with MLL rearrangements, and that it can counter drug resistance mechanisms. CYC065 has completed IND-directed drug development and we look forward to advancing it into clinical trials."

The study (Poster no. 209) evaluated the anticancer activity of CYC065 in *in vitro* assays of human AML and ALL cell lines with normal and mutated MLL gene status, CYC065's mechanism of action and determinants of cellular sensitivity. CYC065 induced rapid apoptosis and inhibited MLL-driven transcription of genes involved in leukemia stem cell biology. Cell line sensitivity correlated with the levels of proteins from the Bcl-2 family, which regulate apoptosis, and combining CYC065 with Bcl-2 inhibitors was synergistic in all tested leukemia lines. CYC065's potent anti-cancer activity was confirmed in AML xenograft models in which tumor growth inhibition ranging from 90 to 97 percent was achieved at well-tolerated dose levels.

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 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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