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Mechanistic Rationale for CYC065, Cyclacel's CDK2/9 Inhibitor, in Targeted Solid Tumors and Hematological Malignancies Presented at AACR-NCI-EORTC International Conference

CYC065 Predicted to be Effective in Leukemia and Triple Negative Breast Cancer

BERKELEY HEIGHTS, N.J., Nov. 09, 2015 (GLOBE NEWSWIRE) -- Cyclacel Pharmaceuticals, Inc. (Nasdaq:CYCC) (Nasdaq:CYCCP) ("Cyclacel" or the "Company"), today announced the presentation of preclinical data demonstrating the mechanistic rationale for the development of CYC065 in targeted solid tumors and leukemias. CYC065 is a highly-selective, second-generation cyclin dependent kinase (CDK) inhibitor targeting CDK2- and CDK9-dependent tumors. The data were presented at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, taking place November 5-9, 2015, in Boston.

"Through our understanding of the mechanism of action of CYC065 we have identified CDK2- and CDK9-dependent tumors against which CYC065 is predicted to have activity," said Spiro Rombotis, Cyclacel's President and Chief Executive Officer. "These cancer types include hematological cancers, such as MLL-rearranged (MLLr) leukemias, MYC-driven lymphomas or solid tumors, and also cancers in which Cyclin E amplification is observed, such as drug resistant and poor prognosis breast and uterine cancers. In addition, we have identified approved and investigational anticancer agents, including our own sapacitabine, which exhibit a synergistic effect when combined with CYC065. A first-in-human, Phase 1 clinical trial with CYC065 has commenced and we look forward to reporting data from this study."

Data presented at AACR-NCI-EORTC (Poster no. B182) demonstrated the mechanistic rationale for clinical development of CYC065 in oncology. Relevant solid tumor and hematologic malignancies were identified, including those with amplification or overexpression of Cyclin E (the partner of CDK2), those driven by CDK9-dependent oncogenic and leukemogenic pathways, such as acute leukemias driven by MLLr and MYC overexpressing tumors. Clinically relevant synergistic combinations were identified and the mechanism of action of CYC065 as a single agent elucidated. The anticancer activity of CYC065 was evaluated in *in vitro* assays of human acute myelogenous leukemia (AML) and triple negative breast cancer (TNBC) cell lines to demonstrate the pro-apoptotic mechanism of CYC065 and determinants of cellular sensitivity. CYC065 induced rapid apoptosis by inhibition of expression of CDK9-dependent oncogenic transcripts, including *MCL-1* and *MYC*. CYC065's potent anticancer activity was confirmed in AML xenograft animal models.

CYC065 was highly synergistic in combination with Bcl-2 inhibitors, such as venetoclax (ABT-199/GDC-0199), in both AML and acute lymphoblastic leukemias. CYC065 was also synergistic in combination with Cyclacel's sapacitabine in breast cancer cell lines, as was the case with seliciclib, Cyclacel's first generation CDK2/9 inhibitor.

An oral regimen of seliciclib and sapacitabine is being evaluated in an on-going Phase 1 study of patients with Homologous Recombination (HR) repair-deficient breast, ovarian and pancreatic cancers, including BRCA positive tumors. CYC065 is in a first-in-human, Phase 1 clinical trial.

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, which has completed enrollment and is being conducted under an SPA with the FDA as front-line treatment for acute myeloid leukemia (AML) in the elderly, and other indications including myelodysplastic syndromes (MDS). Cyclacel's pipeline includes an oral regimen of seliciclib in combination with sapacitabine in a Phase 1 study of patients with Homologous Recombination (HR) repair-deficient breast, ovarian and pancreatic cancers, including BRCA positive tumors, and CYC065, a novel CDK2/9 inhibitor in a Phase 1 study of patients with solid tumors with potential utility in both hematological malignancies and solid tumors. 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 more 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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