



December 14, 2015

## **Molecular Basis For Development of Cyclacel's CYC065 CDK2/9 Inhibitor In Triple-Negative Breast Cancer Presented At San Antonio Breast Cancer Symposium**

**Berkeley Heights, NJ, December 14, 2015** - Cyclacel Pharmaceuticals, Inc. (Nasdaq:CYCC) (Nasdaq:CYCCP) ("Cyclacel" or the "Company"), today announced the presentation of preclinical data demonstrating the molecular basis for the development of CYC065 in triple negative breast cancer (TNBC), and in particular basal-like TNBC. CYC065 is a highly-selective, second-generation cyclin dependent kinase (CDK) inhibitor targeting CDK2/9 dependent tumors. The data were presented at the San Antonio Breast Cancer Symposium (SABCS), taking place December 8-12, 2015.

"We have recently reported that CYC065 can target malignancies driven by CDK2/9 dependent oncogenic and leukemogenic pathways such as MLL-rearranged leukemias and tumors overexpressing MYC", said Spiro Rombotis, Cyclacel's President and Chief Executive Officer. "The data presented at SABCS show CYC065 could be active in breast cancer patients with a poor prognosis and that its mechanism induces breast cancer cell death by apoptosis. In addition, we have identified approved and investigational anticancer agents, including our own sapacitabine, which combine effectively 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 SABCS (Program Number: P5-03-10, <https://www.sabcs.org/Program/Poster-Sessions/Poster-Session-5>) demonstrated in particular the mechanistic rationale for clinical development of CYC065 in basal-like TNBC, a cancer with poor prognosis frequently associated with BRCA1 mutations. Molecular characteristics of TNBC include amplification or overexpression of Cyclin E, the partner protein of CDK2, and MYC. CYC065 directs a pro-apoptotic mechanism in breast cancer cell lines, which includes transcriptional down regulation of key pro-survival and oncogenic regulators, including MCL-1 and MYC.

CYC065 was shown to rapidly induce cell death in breast cancer cell lines, while transiently inducing G1 cell cycle arrest in non-malignant breast lines. CYC065's potent anticancer activity has been confirmed in breast cancer xenograft animal models. CYC065 effectively combined with Cyclacel's sapacitabine in breast cancer cell lines, as was the case with seliciclib, Cyclacel's first generation CDK2/9 inhibitor, when combined with sapacitabine.

An oral regimen of seliciclib and sapacitabine is being evaluated in an on-going Phase 1 all-comer study of patients with various advanced cancers. In previously reported initial data from this study, durable partial responses have been observed in breast, ovarian and pancreatic cancer patients with germline mutations in Homologous Recombination (HR) repair genes, specifically BRCA1 or BRCA2.

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](http://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](http://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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