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Cyclacel Reviews 2015 Achievements and Announces Key Business Objectives for 2016

Company to Presents at the Biotech Showcase(TM) 2016 Conference

BERKELEY HEIGHTS, N.J., Jan. 11, 2016 (GLOBE NEWSWIRE) -- Cyclacel Pharmaceuticals, Inc. (Nasdaq:CYCC) (Nasdaq:CYCCP) (Cyclacel or the Company) today reviewed 2015 achievements and provided an outline of the Company's key business objectives for 2016. These will be highlighted at the Company's presentation during the Biotech Showcase™ 2016 Conference at 9:30 a.m. PST, Monday, January 11, 2016, at the Parc 55 Wyndham Hotel - Union Square at 55 Cyril Magnin Street in San Francisco.

"During 2015, we continued to follow-up patients in SEAMLESS, our Phase 3 clinical trial evaluating sapacitabine in the front-line treatment setting of elderly patients with acute myeloid leukemia, or AML," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "Approximately 7% of prespecified events remain to be observed before we can unblind the randomization code and report top-line results. We anticipate this happening by the end of the first half of 2016. At that point, we will analyze available data and determine submissibility to regulatory authorities. We also continued to follow patients in our Phase 1 trial of sapacitabine and seliciclib in patients with advanced solid tumors. Based on observations to date, we are extending the trial into a selected population of patients with breast cancer who are positive for BRCA mutations. Finally, we advanced CYC065, our second-generation CDK2/9 inhibitor, into a Phase 1, first-in-human study. Based on our preclinical data, we have determined the mechanistic rationale for the clinical development of CYC065 in certain hematological and solid tumor indications. We believe that 2016 may prove to be an important year for Cyclacel and we look forward to keeping you apprised of developments as the year unfolds."

2015 Achievements

Drug Development

Sapacitabine in SEAMLESS, pivotal Phase 3 study as first-line treatment in elderly patients with AML:

- Continued follow-up and treatment of patients of this fully enrolled study.
- 7% of events remain before reporting topline results and mature data analysis.
- Submitted to the European Medicines Agency (EMA) a Paediatric Investigation Plan application for sapacitabine.

Sapacitabine and seliciclib in Phase 1 study in patients with advanced solid tumors

- Continued to follow patients treated with the all-oral combination of the CDK2/9 inhibitor seliciclib and sapacitabine in a Phase 1 trial in patients with advanced solid tumors. A breast cancer patient with BRCA mutations has been administered more than 70 cycles of the combination and continues on treatment.

Cyclin Dependent Kinase (CDK) Inhibitor Programs

- Dosed the first patients in a Phase 1 trial of CYC065, the Company's second-generation CDK2/9 inhibitor, to evaluate the safety, tolerability and pharmacokinetic profile of CYC065 in solid tumor and lymphoma patients.
- Presented preclinical data on the molecular rationale and therapeutic potential in both hematologic and solid tumors of CYC065 at several medical conferences including the American Association for Cancer Research (AACR) Annual Meeting 2015, the Society of Hematologic Oncology (SOHO) 2015 Annual Meeting, the AACR-NCI-EORTC International Conference and the San Antonio Breast Cancer Symposium (SABCS). The data show that:
  - CYC065 may reverse drug resistance associated with addiction of cancer cells to cyclin E, the partner protein of CDK2.
  - CYC065 may also inhibit CDK9-dependent oncogenic and leukemogenic pathways, including malignancies driven by certain oncogene and MLL rearrangements. MLL gene status and levels of Bcl-2 family proteins correlated with sensitivity of AML cell lines to CYC065.
  - CYC065's anticancer activity presents an opportunity for patient stratification and combinations with anti-leukemic agents.
  - CYC065 was also effective against uterine cancer cells including those resistant to chemotherapy and was especially potent in uterine cancer cells in which cyclin E was amplified or overexpressed.
  - CYC065 could be active in triple-negative breast cancer.
- First patients dosed in a Phase 2 investigator-sponsored trial (IST) evaluating seliciclib in patients with Cushing's disease.
- Presented preclinical data at the 4th Neuroblastoma Symposium in Newcastle Upon Tyne, UK demonstrating that CYC065 prolongs survival in *MYCN*-addicted neuroblastoma models.

Corporate Developments

- Raised gross proceeds of $10 million from a public offering of common stock.
- Entered into a Controlled Equity Offering℠ Sales Agreement with Cantor Fitzgerald & Co., as sales agent ("Cantor"), under which the Company may, from time to time, sell shares of its common stock having an aggregate offering price of up to $8.35 million through Cantor.
- Entered into a license and supply agreement with ManRos Therapeutics regarding the development of oral seliciclib for the treatment of cystic fibrosis.

2016 Key Upcoming Business Objectives
Sapacitabine in SEAMLESS:

- Continue follow-up of patients until the requisite number of events occur, which is anticipated by the end of the first half of 2016.
- Report top-line results.
- Following analysis of the mature data set determine submissibility to regulatory authorities for marketing approval.
- Progress a Paediatric Investigation Plan for sapacitabine with the European Medicines Agency.

Sapacitabine in myelodysplastic syndromes (MDS):

- Initiate a Phase 1/2 trial of sapacitabine in combination with other agents to determine safety and tolerability.
- Plan a Phase 2 randomized controlled trial (RCT) of sapacitabine in combination with other agents following review of all relevant clinical data with mature follow-up.

Sapacitabine and seliciclib in Phase 1 study in patients with advanced solid tumors:

- Initiate expansion of the Phase 1 study in a breast cancer patient population enriched for BRCA mutations.
- Report updated Phase 1 data.

Cyclin Dependent Kinase (CDK) Inhibitor Programs

- Report top-line results of the CYC065 Phase 1 trial in solid tumor and lymphoma patients.
- Report data from seliciclib ISTs when available.

For the live and archived webcast of the Company's presentation at the Biotech Showcase™ 2016 San Francisco conference, please visit the Corporate Presentations page on the Cyclacel website at www.cyclacel.com. The webcast will be archived for 90 days and the audio replay for seven days.

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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