January 9, 2018

Cyclacel Reviews 2017 Achievements and Announces Key Business Objectives for 2018

Company to Present at the Biotech ShowcaseTM 2018 Conference

BERKELEY HEIGHTS, N.J., Jan. 09, 2018 (GLOBE NEWSWIRE) -- Cyclacel Pharmaceuticals, Inc. (Nasdaq:CYCC) (Nasdaq:CYCCP) (Cyclacel or the Company) reviewed its 2017 achievements and provided an outline of the Company's key business objectives for 2018. These will be highlighted at the Company's presentation during the Biotech Showcase™ 2018 Conference at 2:30 p.m. PST, Tuesday, January 9, 2018, at the Hilton San Francisco Union Square in San Francisco.

"During 2017, we selected a recommended Phase 2 dose (RP2D), for our CYC065 CDK inhibitor, and advanced our clinical programs in selected patient populations relevant to the drugs' mechanism," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "In an ongoing, Phase 1 study, CYC065 demonstrated durable target engagement and biomarker suppression at well tolerated doses in 11 out of 13 patients treated at the RP2D. Initial anticancer activity was observed in five patients. In 2018, we plan to initiate a translational clinical study to evaluate CYC065 in combination with venetoclax in chronic lymphocytic leukemia, or CLL; design clinical studies for CYC065 alone and with standard of care in solid tumors, including certain pediatric cancers. Data from the Phase 3 SEAMLESS study of sapacitabine were recently presented at the American Society of Hematology, or ASH, Annual Meeting. The presentation included additional data emerging from a comprehensive analysis of prespecified subgroups, e.g. low peripheral white blood cell count, which will form the basis of the Company's consultations with regulatory authorities. Following our July offering, we project cash resources to fund currently planned programs through the end of 2019. We look forward to reporting our progress in 2018."

2017 Achievements

Drug Development

Transcriptional Regulation Program: CYC065 CDK inhibitor

- In part 1 of the ongoing, first-in-human, single agent, ascending dose, Phase 1 study, prolonged reduction of Mcl-1 was observed in 11 out of 13 evaluable patients treated at the RP2D following a single dose of CYC065, which was generally well tolerated. Preliminary anticancer activity was observed in 5 patients, of which 4 were treated at the RP2D and 3 of which were reported by investigators to have molecular features of their cancers associated with CYC065's mechanism of action, including overexpression or amplification of Mcl-1, MYC and/or cyclin E. The trial is being conducted at the Dana Farber Cancer Institute in Boston. Part 2 of the Phase 1 translational study will evaluate additional dosing schedules in patients with advanced solid tumors, in particular those with amplification of cyclin E, Mcl-1 or MYC, including subsets of high grade serous ovarian and uterine cancers. Biospecimens will be collected for assessment of biomarkers related to CYC065's mechanism of action.
- Discussions with principal investigators and/or cooperative groups progressed with the objective of evaluating CYC065 in both pediatric and adult patients. One such study, to be conducted as an investigator sponsored trial, will evaluate the drug in patients with leukemias, including AML, and in particular those with mixed lineage leukemia rearrangements, or MLL-r. In parallel, the Company is discussing with investigators the potential evaluation of CYC065 in patients with neuroblastoma, a mostly pediatric life-threatening malignancy, frequently associated with MYC amplification.
- Preclinical data presented and published on the molecular rationale and therapeutic potential of CYC065, a CDK2/9 inhibitor:
  - In an article published in the *Journal of National Cancer Institute* (JNCI), preclinical data demonstrated that both CYC065 and CCT68127, Cyclacel's preclinical stage CDK2/9 inhibitor, demonstrated prominent antitumor activity against lung cancer through anaphase catastrophe, a novel, cancer specific mechanism of action. CYC065 was found to be effective against lung cancer cell lines including those with KRAS mutations.
  - At the American Association for Cancer Research (AACR) Annual Meeting 2017, independent investigators presented preclinical data demonstrating therapeutic potential of CYC065 as a targeted anti-cancer agent. The data show that CYC065 substantially inhibited growth, triggered apoptosis, and induced anaphase catastrophe in murine and human lung cancer cells with known high metastatic potential. This was in marked contrast to effects in immortalized pulmonary epithelial murine and human cells. CYC065 markedly inhibited migration and invasion of lung cancer cells and affected distinctive pathways involved in DNA damage response, apoptosis, cell cycle regulation and cell migration.

DNA Damage Response (DDR) Program

- Enrollment has been completed in an extension of the Phase 1 study evaluating the combination regimen of sapacitabine and seliciclib, our first generation CDK inhibitor, in an enriched population of approximately 20 patients with BRCA positive advanced breast cancer.
- Part 3 of this study has been opened for enrolment with the objective of testing a revised dosing schedule in additional patients, including BRCA positive, ovarian and pancreatic cancer patients.

SEAMLESS Phase 3 Study

- Data from the SEAMLESS study of sapacitabine in acute myeloid leukemia, or AML, were the subject of an oral presentation at the 59th ASH Annual Meeting in Atlanta, Georgia, on December 11, 2017.
- The presentation included additional data from a comprehensive analysis of the SEAMLESS dataset with the objective of characterizing the prespecified subgroups of patients, e.g. those with low peripheral white blood cell count, who appeared to have clinically relevant benefit from the investigational treatment regimen.
- As previously reported, in the intent-to-treat population, the investigational arm of the SEAMLESS study did not reach statistically significant improvement in OS versus an active control. However, improvement in OS was observed in a stratified subgroup of patients with low baseline peripheral white blood cell count. The subgroup comprised approximately two-thirds of the study's population.
- Following analysis of the full SEAMLESS data set and database lock, the Company is developing submission materials to support consultations with European and US authorities with the objective of determining potential regulatory pathways.

PLK1 Inhibitor; CYC140

- Presented at the American Academy of Cancer Research (AACR) Annual Meeting 2017, preclinical data outlining the potential therapeutic utility of CYC140, a novel polo-like kinase (PLK) 1 inhibitor, alone and in synergistic drug combinations, for the treatment of esophageal cancer and acute leukemia.

Corporate Developments

- Raised net proceeds of approximately $13.7 million from an underwritten public offering.

2018 Key Upcoming Business Objectives

- Initiate CYC065 Phase 1b in relapsed/refractory CLL in combination with venetoclax, a Bcl-2 inhibitor
- Update CYC065 Phase 1 data in solid tumors
- Update mature data from the part 1 extension sapacitabine/seliciclib DDR study in the BRCA +ve breast cancer cohort
- Complete part 3 in the sapacitabine/seliciclib DDR study in patients with BRCA +ve cancers, including ovarian and pancreatic
- Submit CYC140 (PLK1 inhibitor) IND application
- Conduct regulatory authority meetings regarding the SEAMLESS study of sapacitabine in AML

For the live and archived webcast of the Company's presentation at the Biotech Showcase™ 2018 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 Pharmaceuticals is a clinical-stage biopharmaceutical company using cell cycle, transcriptional regulation and DNA damage response biology to develop innovative, targeted medicines for cancer and other proliferative diseases. Cyclacel's transcriptional regulation program is evaluating CYC065, a CDK inhibitor, in patients with advanced cancers. The DNA damage response program is evaluating a sequential regimen of sapacitabine and seliciclib, a CDK inhibitor, in patients with BRCA positive, advanced solid cancers. Cyclacel's strategy is to build a diversified biopharmaceutical business focused in hematology and oncology based on a pipeline of novel drug candidates. For additional information, please visit www.cyclacel.com.

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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