Cyclacel Pharmaceuticals Reviews 2018 Achievements and Announces Key Business Objectives for 2019

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BERKELEY HEIGHTS, N.J., Jan. 07, 2019 (GLOBE NEWSWIRE) -- Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP; "Cyclacel" or the "Company"), a biopharmaceutical company developing innovative medicines based on cancer cell biology, today provided a business update reviewing 2018 achievements and providing an outline of the Company's key business objectives for 2019. Cyclacel's clinical and business strategy will be highlighted at a presentation during the 2019 Biotech Showcase Conference on Tuesday, January 8, 2019 from 9:30 a.m. – 10:00 a.m. PST in the Yosemite C Suite at the Hilton San Francisco Union Square.

"In 2018, we presented our targeted oncology strategy with the objective of delivering important data readouts in the next twelve months," said Spiro Rombotis, President and Chief Executive Officer. "At the heart of our business strategy is targeting cancer patients with overexpression of resistance pathways, including Mcl-1, and inherited mutations in DNA damage pathways, including BRCA. Mcl-1, in particular, received wide attention during 2018 medical conferences. We believe CYC065 is the first investigational drug to have consistently demonstrated durable suppression of Mcl-1 in clinical trials at tolerable dosing. Our collaboration with MD Anderson Cancer Center to evaluate three Cyclacel compounds in up to 170 patients is an important development allowing us to advance our programs in a P&L sparing manner. With estimated capital on hand until mid-2020 we look forward to reporting data from our ongoing clinical studies and realizing shareholder value from our targeted drug pipeline."

2018 Achievements

Transcriptional Regulation Program: CYC065 CDK inhibitor

- Initiated a Phase 1 clinical trial evaluating CYC065, a CDK2/9 inhibitor, in combination with venetoclax in patients with relapsed/refractory CLL. The strong biological rationale of dual Mcl-1 and Bcl-2 suppression was presented at the 2018 AACR in a poster titled "Strategic combination of the cyclin-dependent kinase inhibitor CYC065 with venetoclax to target anti-apoptotic proteins in chronic lymphocytic leukemia." The data showed an enhanced effect of the combination of CYC065 and venetoclax in CLL tumor samples, including demonstrating activity in 17p deleted samples which were resistant to either agent alone.

- Reported data from the Phase 1 part 1 clinical study of CYC065 monotherapy in advanced solid tumors at an oral presentation at the 2018 AACR. Prolonged reduction of Mcl-1 expression was observed in 11 out of 13 patients treated at the recommended Phase 2 dose following a single dose of CYC065. Cyclacel continues to enroll patients in part 2 of the study evaluating an increased dosing frequency of CYC065 monotherapy for 2 days per week over 2 weeks of a three-week cycle, versus the once every 21 days schedule evaluated in part 1. Part 2 will also look to evaluate the activity of CYC065 in Mcl-1, MYC or cyclin E amplified cancers relevant to CYC065's mechanism of action.

DNA Damage Response (DDR) Program

- Dosed the first patient in the Phase 1b/2 investigator-sponsored combination study of sapacitabine in combination with olaparib, an approved PARP inhibitor, in BRCA positive patients with breast cancer. Dual targeting of the DNA damage response pathway with the addition of sapacitabine to olaparib may enhance the efficacy of the current standard of care for such patients.

- Continued patient enrollment in part 3 of the Phase 1 study evaluating a revised dosing schedule of sequential sapacitabine and seliciclib, Cyclacel's first-generation CDK inhibitor, in BRCA positive patients with advanced breast, ovarian and pancreatic cancer.

SEAMLESS Phase 3 Clinical Trial

- Received consistent guidance from three European regulatory authorities with whom the company met to discuss a potential approval pathway for sapacitabine. The discussions followed submission of statistical and exploratory analyses demonstrating sapacitabine's potential clinical benefit in a subgroup of patients with AML in the SEAMLESS Phase 3 study. The Company believes that the subgroup results have defined a patient population for whom the sapacitabine regimen may represent an improvement over low intensity treatment by decitabine alone.

CYC140 PLK1 Inhibitor

- Completed IND review and initiated patient enrollment for a Phase I first-in-human study evaluating CYC140 in patients with advanced leukemias. CYC140 is an orally-available, small molecule, selective polo-like-kinase 1 (PLK1) inhibitor that has demonstrated potent and selective target inhibition and high activity in xenograft models of human cancers.

Corporate Developments

- Entered into a collaboration with The University of Texas MD Anderson Cancer Center to evaluate three Cyclacel medicines in patients with hematological malignancies. MD Anderson will evaluate CYC065, CYC140 and sapacitabine either as single agents or in combination with approved drugs, in up to 170 enrolled patients across four clinical trials.
- Added Robert J. Spiegel, M.D. to the Company's Board of Directors. Dr. Spiegel brings over 30 years of R&D and operational experience in the biopharmaceutical industry as well as advisory experience to venture capital and private equity funds.

Key Business Objectives for 2019

- Report initial data readout from the CYC065 plus venetoclax combination Phase 1 study in leukemias
- Report initial data readout from the CYC140 Phase 1 First-in-Human study
- Report initial data readout from the IST-sponsored Phase 1b/2 trial of sapacitabine and olaparib combination in BRCA positive patients with breast cancer
- Complete enrollment in part 3 of the Phase 1 study of sequential sapacitabine and seliciclib in BRCA positive, breast, ovarian and pancreatic cancer patients
- Determine regulatory pathway and submissibility of sapacitabine in elderly AML
- Evaluate bioequivalence of oral CYC065 formulation to intravenously administered CYC065

About Cyclacel Pharmaceuticals, Inc.

Cyclacel Pharmaceuticals is a clinical-stage biopharmaceutical company using its expertise in cell cycle, transcriptional regulation and DNA damage response biology in cancer cells to develop innovative medicines. The transcriptional regulation program is evaluating CYC065, a CDK inhibitor, in patients with advanced solid cancers and in combination with venetoclax in patients with advanced hematological malignancies. The DNA damage response program is evaluating a combination of sapacitabine and seliciclib, a CDK inhibitor, in BRCA positive patients with advanced solid cancers and sapacitabine and olaparib, a PARP inhibitor, in BRCA positive patients with breast cancer. CYC140, a PLK inhibitor, is in a Phase 1 first-in-human study in patients with advanced leukemias. 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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