Cyclacel Pharmaceuticals Reviews 2019 Achievements and Announces Key Business Objectives for 2020

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– Anticancer Activity of CYC065 Monotherapy in Patients with MCL1 Amplified Solid Tumors and CYC065-venetoclax combination in AML/MDS and CLL dose escalation studies –

BERKELEY HEIGHTS, N.J., Jan. 13, 2020 (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 2019 achievements and outlining the Company's key business objectives for 2020. Cyclacel's clinical and business strategy will be highlighted at a presentation during Biotech Showcase™ 2020 on Monday, January 13, 2019 at 9:30 a.m. PT in the Yosemite A Suite (Ballroom level) at the Hilton San Francisco Union Square.

"During 2019 we have been excited to observe evidence of anticancer activity with CYC065, our CDK2/9 inhibitor, in patients with both solid and liquid cancers," said Spiro Rombotis, President and Chief Executive Officer. "We have previously reported that CYC065 durably suppresses MCL1 in cancer patients. Based on recent data we believe that CYC065 is a leader amongst MCL1 suppressing compounds in development. For example, a heavily pretreated patient with MCL1 amplified endometrial cancer achieved a partial response (PR) on CYC065 monotherapy and reduction in her tumor volume has now reached 63%. During 2020 we plan to advance clinical investigation of our lead program CYC065 both as monotherapy and in combinations. Our innovative clinical stage pipeline, comprising of CYC065 together with sapacitabine and CYC140, our PLK1 inhibitor, is a central element of our strategy of addressing cancer resistance."

Initial data from Cyclacel's ongoing clinical evaluation of a combination regimen of CYC065 and venetoclax in patients with advanced leukemias (AML/MDs and CLL) were reported at a recent medical conference. Preliminary evidence from these dose escalation studies suggests that the combination is active and well tolerated. The rationale behind these studies is to investigate a 'dual hit' strategy of simultaneously suppressing MCL1 and BCL2 proteins.

In 2020 Cyclacel will advance its precision medicine strategy by reporting data from ongoing studies addressing high value indications. With estimated capital on hand to the end of the first quarter of 2021 the Company's ultimate goal is to realize shareholder value from its targeted drug pipeline.

2019 Achievements

- Reported anticancer activity in part 2 of 065-01, the Phase 1 study of CYC065 as a single agent, including a patient with MCL1 amplified endometrial cancer who achieved a radiographically confirmed partial response (PR) after 4 cycles of treatment at 213mg;
- Opened part 3 of 065-01 evaluating an oral form of CYC065 in patients with advanced solid tumors;
- Presented the designs of three ongoing studies at the 61st American Society of Hematology Annual Meeting: CYC065 in combination with venetoclax in patients with relapsed or refractory AML/MDS or in patients with CLL and sapacitabine in combination with venetoclax in patients with relapsed or refractory AML/MDS;
- Enrolled eight patients with relapsed or refractory AML/MDS in the 065-03 Phase 1 dose escalation study evaluating CYC065 in combination with venetoclax. A poster presentation at the 61st American Society of Hematology Annual Meeting showed that the combination is active and well tolerated. Preclinical data confirmed synergy of CYC065 and venetoclax, suggesting that the suppression of both BCL2 and MCL1 may be more beneficial than inhibiting either protein alone;
- Opened two new sites in the 065-02 study of CYC065 in combination with venetoclax in patients with relapsed/refractory CLL;
- Enrolled five patients in part 2 of the 682-11 Phase 1/2 study evaluating an oral regimen of sapacitabine in combination with venetoclax in patients with relapsed or refractory AML/MDS. Sapacitabine is a nucleoside analogue that is active in AML and MDS relapsed or refractory to prior therapy such as cytarabine or hypomethylating agents. Combining sapacitabine with venetoclax may offer an effective, oral treatment regimen for patients who have failed front-line therapy;
- Enrolled three patients in a Phase 1, first-in-human study evaluating CYC140 in patients with advanced leukemias. CYC140 is a 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;
- Presented data at the 2019 AACR Annual Meeting from the Company's DNA damage response program with an oral regimen of sequential sapacitabine and seliciclib, a CDK2/9 inhibitor, from an expansion cohort in patients with BRCA mutant metastatic breast cancer demonstrating safety and a clinical benefit rate of 30%;
- Enrolled five patients in a Phase 1b/2 investigator sponsored study (IST) with an oral regimen of concomitant sapacitabine and olaparib in patients with BRCA mutant breast cancer. Dual targeting of the DNA damage response pathway with sapacitabine and the PARP inhibitor olaparib may improve on currently available options for such patients; and
- Raised net proceeds of approximately $4.1 million from a Common Stock Sales Agreement with H.C. Wainwright.

Key Business Objectives for 2020

- Report updated Phase 1 safety, pharmacokinetics and efficacy data for CYC065 utilizing a frequent dosing schedule in patients with advanced solid cancers;
- Report initial safety and PK data from the Phase 1 study of an oral formulation of CYC065;
- Report initial safety and proof of concept data from the CYC065-venetoclax Phase 1 study in relapsed/refractory AML and MDS;
- Report initial safety and proof of concept data from the CYC065-venetoclax Phase 1 study in relapsed/refractory CLL;
- Report initial data from the sapacitabine-venetoclax Phase 1/2 study in patients with relapsed or refractory AML or MDS;
- Report initial data from the CYC140 Phase 1 First-in-Human study in relapsed or refractory leukemias; and
- Report data from the Phase 1b/2 IST of sapacitabine-olaparib combination in patients with BRCA mutant metastatic breast cancer when reported by the investigators.

About Cyclacel Pharmaceuticals, Inc.
Cyclacel Pharmaceuticals is a clinical-stage biopharmaceutical company developing innovative cancer medicines based on cell cycle, transcriptional regulation and DNA damage response biology. The transcriptional regulation program is evaluating CYC065 as a single agent in solid tumors and in combination with venetoclax in patients with relapsed or refractory AML/MDS and CLL. The DNA damage response program is evaluating an oral combination of sapacitabine and venetoclax in patients with relapsed or refractory AML/MDS. An IST is evaluating an oral combination of sapacitabine and olaparib in patients with BRCA mutant breast cancer. The anti-mitotic program is evaluating CYC140, a PLK1 inhibitor, in AML/MDS patients. 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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