Cyclacel Pharmaceuticals Announces First Patient Treated With Oral CYC065 in a Phase 1 Study in Patients With Advanced Solid Tumors

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BERKELEY HEIGHTS, N.J., Sept. 09, 2019 (GLOBE NEWSWIRE) -- Cyclacel Pharmaceuticals, Inc. (Nasdaq:CYCC, Nasdaq:CYCCP) ("Cyclacel" or the "Company"), a biopharmaceutical company developing innovative medicines based on cancer biology, announced treatment of the first patient with an oral formulation of CYC065, a CDK2/9 inhibitor, in part 3 of a Phase 1 study (CYC065-01) which is evaluating single agent CYC065 in patients with advanced solid cancers. Parts 1 and 2 of the study are evaluating CYC065 administered as an intravenous infusion.

“We are excited to report that the first patient has been treated with oral CYC065 in part 3 of our Phase 1 study,” said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. “We recently reported that in part 2 of the same study, a patient with endometrial cancer with MCL1 amplification achieved tumor shrinkage after single agent CYC065 administered by intravenous infusion. The study is being conducted at the Dana-Farber Cancer Institute. We look forward to reporting data from Part 2 and 3 of this study in 2020.”

Study CYC065-01 (NCT02552953) is intended to enroll up to approximately 70 patients with advanced cancers with the objective of determining safety, pharmacokinetics, pharmacodynamics and identifying the recommended Phase 2 dose (RP2D) of both intravenously and orally administered CYC065.

Data from 26 patients enrolled in part 1 were reported at the 2018 AACR Annual Meeting and RP2D was established for a 4-hour intravenous infusion of CYC065 once every 3 weeks. Consistent suppression of MCL1 over 24 hours after a single dose of CYC065 at RP2D has been observed in the majority of patients. Part 2 is testing a more frequent dosing schedule of one-hour infusions on Day 1, 2, 8 and 9 of a three week cycle. Part 3 is evaluating the oral formulation administered by the same dosing schedule as part 2.

About CYC065
CYC065, a second generation CDK2/9 inhibitor, is being evaluated in Phase 1 studies as a single agent in patients with advanced solid tumors and in combination with venetoclax in relapsed or refractory CLL, and in relapsed or refractory AML or MDS. It is mechanistically similar but has higher dose potency, *in vitro* and *in vivo*, and improved properties compared to seliciclib, a first generation CDK inhibitor. Similarly to FDA approved CDK4/6 inhibitors, CYC065 may be most useful in combination with other anticancer drugs, including BCL2 inhibitors, such as venetoclax, or HER2 inhibitors, such as trastuzumab. Preclinical data show that CYC065 may benefit patients with adult and pediatric hematological malignancies, including acute myeloid leukemias (AML), acute lymphocytic leukemias (ALL), and in particular those with MLL rearrangements, chronic lymphocytic leukemias (CLL), B-cell lymphomas, multiple myelomas, and certain solid tumors, including breast and uterine cancers, and neuroblastomas.

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 in combination with venetoclax in patients with relapsed or refractory CLL and AML/MDS. The DNA damage response program is evaluating an oral combination regimen of sapacitabine and venetoclax in patients with relapsed or refractory AML/MDS. An IST is evaluating an oral combination regimen 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 filings we file with the Securities and Exchange Commission, which 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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