Cyclacel Pharmaceuticals Reviews 2020 Achievements and Announces Key Business Objectives for 2021

January 11, 2021

– Anticancer Activity of Fadraciclib Monotherapy in Patients with MCL1 Amplified Solid Tumors–
– Appointment of Mark Kirschbaum, M.D. as Chief Medical Officer –
– $7 Million Strategic Investment by Fundamental Investor Acorn Bioventures–

BERKELEY HEIGHTS, N.J., Jan. 11, 2021 (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 2020 achievements and outlining the Company's key business objectives for 2021. The Company will present at Biotech Showcase™ Digital 2021 taking place virtually from January 11 to 15 with a prerecorded session of the company presentation. Spiro Rombotis, President & Chief Executive Officer, will provide an overview of the Company and progress in key programs. Cyclacel will host one-on-one meetings with investors and industry stakeholders during the event. Registered Biotech Showcase™ Digital 2021 attendees may request one-on-one meetings with Cyclacel through the partneringONE® system.

"With the recent appointment of Dr. Mark Kirschbaum as our CMO and the December 2020 strategic investment from Acorn Bioventures, we are well resourced to progress fadraciclib and CYC140, our two internally discovered molecules," said Spiro Rombotis, President and Chief Executive Officer. "Fadraciclib, a CDK2/9 inhibitor, has shown promising clinical activity and tolerability in patients with advanced cancers and CYC140, a PLK1 inhibitor, is in a first-in-human study. As the next step in our clinical development program we will evaluate both agents, dosed orally, across a broad spectrum of solid tumors and hematological malignancies as part of our strategy of identifying clinical activity which may lead to registration-enabling studies."

2020 Key Achievements

- Data from Phase 1 study of fadraciclib as a single agent reported at the Plenary Session of the 32nd EORTC-NCI-AACR (ENA) Symposium
  • Radiographically confirmed partial response (PR) after a month and a half on i.v. fadraciclib: MCL1-amplified endometrial cancer; failed seven lines of prior therapy; continuing treatment for more than 16 months with 96% reduction in target tumor lesions
  • High bioequivalence observed in 5 patients treated with oral fadraciclib
- Enrolled 19 patients evaluating i.v. fadraciclib in combination with venetoclax in patients with relapsed or refractory AML/MDS and CLL with evidence of antileukemic activity
- Enrolled five patients evaluating i.v. CYC140 in patients with advanced leukemias
- Enrolled 12 patients in Phase 1/2 study evaluating an oral regimen of sapacitabine in combination with venetoclax in patients with relapsed or refractory AML/MDS
- Announced peer-reviewed publication of a fadraciclib review in PLOS ONE. Authored by scientists from Cyclacel and The Institute of Cancer Research, London, the publication describes the discovery of fadraciclib and shows that its targeting of CDK2 and CDK9 leads to broad therapeutic potential
- Appointed Mark Kirschbaum, M.D. as Senior Vice President and Chief Medical Officer. Dr. Kirschbaum is a highly experienced hematologist/oncologist with over 30 years of experience in molecular medicine, new drug development, clinical trial design and patient care
- Appointed Brian Schwartz, M.D, formerly CMO at ArQule, Inc., and Karin L. Walker, Chief Accounting Officer of Prothena Corporation plc, to the Board of Directors
- Raised approximately $30 million in net cash in two equity financings and related warrant exercises providing estimated capital to early 2023

In 2021, Cyclacel will commence streamlined Phase 1/2 clinical studies, initially of oral fadraciclib and subsequently of oral CYC140, in a broad range of solid tumors and hematological malignancies. These studies are supported by fadraciclib's Phase 1 clinical data and its transcriptional mechanism of action enabling apoptosis of cancer cells and the extensive preclinical data of CYC140 demonstrating its antimitotic mechanism and broad therapeutic potential in several solid tumors and hematological

malignancies.

The clinical development plan for these studies calls for parallel evaluation of different schedules of the two agents in multiple cohorts defined by cancer histology and collection of biospecimens for translational analysis. The aim of these studies is to identify clinical activity which may lead to registration-enabling studies.

Key Business Objectives for 2021

- First patient dosed with oral fadraciclib in Phase 1/2 advanced solid tumor study
- First patient dosed with oral CYC140 in Phase 1/2 advanced solid tumor study
- Manufacture clinical supplies of fadraciclib and CYC140 for registration-enabling studies
- Data on safety and antileukemic activity from the i.v. fadraciclib-venetoclax Phase 1 study in relapsed/refractory AML and CLL
- Data from the sapacitabine-venetoclax Phase 1/2 study in relapsed/refractory AML or MDS
- Initial data from the CYC140 Phase 1 First-in-Human study in patients with advanced leukemias
- 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 mitosis biology. The transcriptional regulation program is evaluating fadraciclib, a CDK2/9 inhibitor, in solid tumors and hematological malignancies. The anti-mitotic program is evaluating CYC140, a PLK1 inhibitor, in advanced cancers. Cyclacel's strategy is to build a diversified biopharmaceutical business based on a pipeline of novel drug candidates addressing oncology and hematology indications. 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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