



Cyclacel Pharmaceuticals Reviews 2021 Achievements And Announces Key Business Objectives for 2022

January 6, 2022

– Now Enrolling Patients in Two Registration-Directed Trials for Lead Candidate, Oral Fadraciclib –

– Expecting Key Data Readouts for Oral Fadraciclib in 2022 –

– Planning to Launch Two Registration-Directed Studies for Differentiated Oral PLK1 Inhibitor, CYC140 –

BERKELEY HEIGHTS, N.J., Jan. 06, 2022 (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 2021 achievements and outlining the Company's key business objectives for 2022.

"This past year proved to be very productive for Cyclacel as we achieved our planned business objectives," said Spiro Rombotis, President and Chief Executive Officer. "First and foremost, we initiated two registration-directed, Phase 1/2 trials for our lead candidate fadraciclib, an oral CDK2/9 inhibitor. These studies are assessing fadraciclib activity across a range of solid tumors and hematological malignancies. In the solid tumor study we are enrolling patients at the third dose level using a schedule of twice daily dosing for five days, for 3 out of 4 weeks. In the leukemia study we are enrolling patients at the initial dosing level. We have also completed FDA review of an Investigational New Drug Application (IND) of CYC140, a differentiated oral PLK1 inhibitor, and received clearance to proceed with a registration-directed Phase 1/2 study in solid tumors. Finally, we strengthened our balance sheet in the year which provides a cash runway until early 2023."

"In early 2022 we expect to dose the first patient in our third, registration-directed, Phase 1/2 study, which will evaluate CYC140 across various solid tumors. We are currently planning our fourth registration-directed trial of CYC140 in hematological malignancies to follow soon thereafter. We also anticipate updates from collaborative, preclinical research studies providing valuable insights into which tumor histologies may be sensitive to CYC140's mechanism of action. We anticipate reporting initial data for oral fadraciclib in solid tumors and lymphomas at a major medical meeting in the first half of 2022, which could be an exciting year for our company."

2021 Key Achievements

- Seven patients with advanced solid tumors treated in the 065-101 study of oral fadraciclib
- Three internationally recognized cancer treatment centers now enrolling in the 065-101 study selected for their expertise with tumor types of interest
- First patient dosed in the 065-102 study of oral fadraciclib in patients with leukemia or myelodysplastic syndromes
- Preclinical studies in progress to inform clinical development of fadraciclib
- FDA clearance of our IND to proceed with 140-101, a streamlined, registration-directed, Phase 1/2 study of oral CYC140 in solid tumors
- Preclinical studies in progress to support selection of histologies for CYC140 Phase 1/2 study
- Raised \$14.5 million in gross proceeds in a public offering in the first quarter of 2021

Key Business Objectives for 2022

- First patient to be dosed with oral CYC140 in the 140-101 solid tumor study
- Initial data from Phase 1 dose escalation of the 065-101 solid tumor study of oral fadraciclib
- First patient to be dosed with oral CYC140 in the 140-102 leukemia study
- Commence Phase 2 proof of concept stage in the 065-101 solid tumor study of oral fadraciclib
- Initial data from Phase 1 dose-escalation of the 065-102 leukemia study of oral fadraciclib
- Commence Phase 2 proof of concept stage of oral fadraciclib in the 065-102 leukemia study

About Cyclacel Pharmaceuticals, Inc.

Cyclacel 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, and the anti-mitotic program CYC140, a PLK1 inhibitor, in patients with both solid tumors and hematological malignancies. 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, the potential effects of the COVID-19 pandemic, 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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