Cyclacel Pharmaceuticals Reviews 2022 Achievements and Announces Key Business Objectives for 2023

January 5, 2023

– Determination of Recommended Phase 2 Dose and Start of Phase 2 in 1Q 2023 for Oral Fadraciclib –

– 2/3 Partial Responses in Lymphoma and 11/15 Stable Disease in Advanced Solid Tumors –

– Expecting Key Data Readouts for Oral Fadraciclib in 2023 –

– Expecting Preliminary Safety and Efficacy Update for Oral Plogosertib (formerly CYC140) in Advanced Solid Tumors in 1H 2023 –

– Existing Cash Until End of 2023 Support Multiple Data Readouts –

BERKELEY HEIGHTS, N.J., Jan. 05, 2023 (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 2022 achievements and outlining the Company's key business objectives for 2023.

"2022 was a year of solid progress for Cyclacel highlighted by the clinical advancement of our two product candidates in Phase 1/2 clinical studies," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "Both fadraciclib, our CDK2/9 inhibitor, and plogosertib (formerly CYC140), our PLK1 inhibitor, have shown differentiated and competitive profiles in their respective classes. We believe that fadra is the only transcriptionally active CDK inhibitor to have shown single agent responses in both liquid and solid tumors with a good tolerability profile. We are seeing preliminary indications of single-agent activity in the ongoing Phase 1/2 trial of plogosertib in advanced solid tumors and lymphoma. We also estimate that our cash runway will fund operations through the end of 2023, providing sufficient funding over this catalyst-rich period."

"We believe that we are very close to identifying the recommended Phase 2 dose (RP2D) in the ongoing Phase 1/2 study of oral fadra for the treatment of advanced solid tumors and lymphoma," said Dr. Mark Kirschbaum M.D., Chief Medical Officer. "Fadra is showing signs of single agent activity in several tumor types including PRs in 2/3 T cell lymphoma patients and stable disease in certain solid tumors. Oral fadra has also maintained an acceptable safety and tolerability profile across multiple dosing cohorts. We expect to enter the Phase 2 segment of the trial in the first half of 2023, after completing the rapid accrual we have seen in Phase 1, and reviewing the safety, pharmacokinetics and correlative study data. To accelerate Phase 2 enrollment, we have expanded the number of clinical trial sites participating in the trial including certain widely recognized U.S. and international cancer centers. We expect to provide a data update at a major medical meeting in the first half of 2023 and initial data from the Phase 2 in the second half of 2023."

"We have also made encouraging progress with our second candidate, plogosertib," continued Dr. Kirschbaum. "The dose escalation stage of our Phase 1/2 study in advanced solid tumors and lymphoma is enrolling well. Based upon the molecule's differentiated profile and early observation of efficacy with three patients on treatment for at least 3 cycles, we believe plogosertib has the potential to demonstrate single-agent activity across a broad range of cancers. We anticipate reporting preliminary safety and efficacy data from the dose-escalation stage of the ongoing plogosertib Phase 1/2 study within 2023."

2022 Key Achievements

Fadraciclib

- Final dose-escalation level 6a to determine RP2D in the oral fadraciclib 065-101 Phase 1/2 study has enrolled 3 out of 6 patients
- Broad activity observed in the first 5 dose levels: 2/3 partial responses (PRs) in patients with T-cell lymphoma; 4 patients with cervical, endometrial, hepatocellular and ovarian cancer showed stable disease with target lesion reductions; and a patient with pancreatic cancer achieved stable disease for 5 cycles
- Achieved target engagement levels predicted to inhibit CDK2 and CDK9 for approximately 5 to 7 hours per dose on continuous dosing
- At the Company's R&D Day a principal investigator from Seoul National University Hospital showed preclinical data demonstrating sensitivity to fadra in biliary tract and pancreatic cancer cells obtained from patient specimens
- A publication from The University of Texas MD Anderson Cancer Center reported preclinical data against chronic lymphocytic leukemia (CLL) cell lines showing that fadraciclib, as a single agent and in combination with the BCL2 antagonist, venetoclax, depletes anti-apoptotic proteins and synergizes with venetoclax
- Reported positive preliminary data from the Phase 1/2 clinical trial of oral fadraciclib in patients with solid tumors and lymphoma at the ENA 2022 meeting

Plogosertib (formerly CYC140)

- Announced dosing of first patient in Phase 1/2 study of oral plogosertib in patients with advanced solid tumors and lymphomas
- No dose limiting toxicities observed to date in the first 3 dose levels
- Stable disease at the first dose level in an ongoing patient with metastatic, KRAS G12V mutated, non-small cell lung cancer for 9 cycles and a patient with metastatic ovarian cancer for 5 cycles

Corporate Highlights

- On October 31, 2022 the Company held an R&D Day (Webcast replay) at which updated clinical and preclinical data on fadraciclib and plogosertib were presented
- Announced the election by the preferred stockholders of Kenneth M. Ferguson, Ph.D. to the Board of Directors

Key Business Objectives for 2023

1H 2023

- First patient dosed with oral fadraciclib in Phase 2 proof-of-concept stage of 065-101 study in patients with advanced solid tumors and lymphoma
- Report final data from dose escalation stage and RP2D determination from the 065-101 study of oral fadraciclib in patients with advanced solid tumors and lymphoma at a major medical meeting
- Report interim Phase 1 data from 140-101 study of oral plogosertib in patients with advanced solid tumors and lymphoma

2H 2023

- Report interim data from initial cohorts in Phase 2 proof-of-concept stage of 065-101 study with oral fadraciclib in patients with advanced solid tumors and lymphoma
- Report interim data from dose escalation stage of 065-102 study with oral fadraciclib in patients with advanced leukemia
- Report final data from dose escalation stage of 140-101 study with oral plogosertib in advanced solid tumors and lymphoma

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 plogosertib, 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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