Cyclacel Pharmaceuticals Achieves Key Business Objectives in First Half of 2022 and Continues to Advance Clinical Pipeline

June 30, 2022

- Completed Enrollment in Phase 1 Dose Escalation with Oral Fadraciclib in Solid Tumors -

- No Dose Limiting Toxicities Observed at All Dose Levels Enrolled to Date -

- Demonstrated Evidence of Target Engagement for CDK2 and CDK9 -

- Early Anticancer Activity, Including Partial Response and Stable Disease with Tumor Shrinkage, Observed in Patients with Endometrial Cancer, Pancreatic Cancer and T Cell Lymphoma -

- R&D Day Planned for Fall 2022 -

BERKELEY HEIGHTS, N.J., June 30, 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 announced that it has achieved key business objectives in the first half of 2022 and provided a review of progress with its two clinical stage drug candidates.

"We are highly encouraged by clinical safety and anticancer activity observed with oral fadraciclib monotherapy to date," said Spiro Rombotis, President and Chief Executive Officer. "Based on available information we believe that a favorable tolerability profile, daily dosing and target engagement against CDK2 and CDK9 differentiates fadraciclib as potentially best-in-class. Data collected to date in fifteen patients suggest that fadraciclib may have activity across a range of solid tumors and lymphomas. With respect to our second strategic priority, we are actively advancing development of CYC140, our oral PLK1 inhibitor, and enrolling patients in a registration-directed Phase 1/2 study in solid tumors and lymphomas. We look forward to reporting additional data at our R&D Day in the fall of 2022."

"It is exciting to observe dose-related efficacy signals in certain solid tumors and lymphomas, and in particular endometrial cancer and T-cell lymphoma," noted Mark Kirschbaum M.D., Senior Vice President and Chief Medical Officer. "Based on the absence of dose-limiting toxicities at all dose levels, we are adding two dose levels in a protocol amendment to test higher doses of oral fadraciclib before determining the recommended Phase 2 dose which we anticipate in the second half of 2022."

1H 2022 Key Achievements and Corporate Updates

Fadraciclib

- Fifteen patients with advanced solid tumors and lymphomas treated with oral fadraciclib at all five dose levels as per protocol in the 065-101 dose escalation study.
- Demonstrated evidence of target engagement for CDK2 and CDK9 in cell assay system and patient PK data suggested that these targets are potentially inhibited at 100mg twice daily levels.
- A cutaneous T cell lymphoma (CTCL) patient achieved partial response (PR) in the first oral treatment cycle.
- A peripheral T cell lymphoma (PTCL) patient achieved 38% reduction in target lesions by PET scan in the first oral treatment cycle.
- An endometrial cancer patient achieved stable disease with 15% reduction of target lesions after the first oral treatment cycle. In an earlier study of intravenous fadraciclib as monotherapy, a patient with MCL1 amplified endometrial cancer achieved confirmed complete response (CR) and remains on study after two and a half years of treatment.
- A pancreatic cancer patient achieved stable disease by confirmatory scan for five oral treatment cycles.
- As no dose limiting toxicities have been observed, the Company has submitted a protocol amendment to the U.S. Food and Drug Administration (FDA) to escalate to two additional dose levels before determining recommended Phase 2 dose (RP2D).
- Based on good tolerability in 065-101, a protocol amendment in the 065-102 study of oral fadraciclib in patients with leukemia or myelodysplastic syndromes has enabled acceleration of the study by omitting dose levels two and three and now enrolling at dose level 4.

CYC140

- No dose limiting toxicities observed to date in 140-101, a Phase 1/2 study of oral CYC140 in solid tumors.
- An ovarian cancer patient in 140-101 achieved stable disease with tumor shrinkage after the first cycle.

Corporate Updates

- The Company is planning an R&D Day in the fall of 2022 to present updated data from the 065-101 and 140-101 clinical trials.
- The Company has also submitted an abstract to potentially present fadraciclib data from 065-101 at a cancer conference in the fall of 2022.

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.

Contacts

Company:	Paul McBarron, (908) 517-7330, pmcbarron@cyclacel.com
Investor Relations:	Irina Koffler, LifeSci Advisors, LLC, (646) 970-4681, ikoffler@lifesciadvisors.com