Cyclacel Announces Fadraciclib Abstract Selected for Oral Presentation in the Late Breaking and Best Proffered Paper Session at the 32nd EORTC-NCI-AACR Symposium 2020

September 21, 2020

BERKELEY HEIGHTS, N.J., Sept. 21, 2020 (GLOBE NEWSWIRE) -- Cyclacel Pharmaceuticals, Inc. (Nasdaq: CYCC) (Nasdaq: CYCCP) (Cyclacel or the Company), a biopharmaceutical company developing innovative medicines based on cancer cell biology, announced that an abstract highlighting clinical data with Cyclacel's CDK2/9 inhibitor fadraciclib has been selected for an oral presentation at the 32nd EORTC-NCI-AACR (ENA) Symposium 2020 being held virtually on October 24 – 25, 2020. The data is from an ongoing Phase 1 study of fadraciclib as a single agent in patients with advanced solid tumors.

Details for the presentations are as follows:

Title: Phase 1 safety, pharmacokinetic and pharmacodynamic study of fadraciclib (CYC065), a cyclin dependent kinase inhibitor, in patients with advanced cancers (NCT02552953)
Session Title: Late Breaking and Best Proffered Papers
Session Date and Time: Saturday 24 October 15:05 CET
Presentation Number: ORAL-002

The program can be accessed through the **EORTC-NCI-AACR website**.

About Cyclin-Dependent Kinases and Fadraciclib

Cyclin-dependent kinases (CDKs) are critical for cell cycle regulation and transcriptional elongation. Dysregulated CDKs have been linked to the cancer hallmarks of uncontrolled proliferation and increased survival. Fadraciclib (CYC065) is a potent orally and intravenously available inhibitor of CDK2 and CDK9.

In part 1 of a Phase 1, first-in-human study of fadraciclib as a single agent in patients with advanced solid tumors, target engagement and durable suppression of the MCL1 biomarker were observed after a single dose of fadraciclib. Tumor shrinkage and stable disease were observed in five patients with cyclin E, MCL1 and/or MYC amplified cancers.

The ongoing part 2 of the study is evaluating a more intensive dosing regimen than part 1. A heavily pretreated patient with MCL1 amplified endometrial cancer achieved a radiographically confirmed partial response (PR) after a month and a half on fadraciclib. Fadraciclib is also being evaluated in Phase 1 combination studies with venetoclax in patients with relapsed or refractory CLL and AML/MDS.

Preclinical data suggest that fadraciclib may benefit patients with adult and pediatric hematological malignancies such as AML, ALL, B-cell lymphomas, CLL, multiple myeloma and certain cyclin E-addicted or MYC-amplified solid tumors, including certain forms of breast cancer, neuroblastoma, ovarian cancer and uterine serous carcinoma.

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 fadraciclib as a single agent in solid tumors and in combination with venetoclax in patients with relapsed or refractory AML/MDS and CLL. The DNA damage response program is evaluating an oral combination of sapacitabine and venetoclax in patients with relapsed or refractory AML/MDS. An investigator-sponsored trial (IST) is evaluating an oral combination of sapacitabine and olaparib in patients with BRCA mutant breast cancer. The anti-mitotic program is evaluating CYC140, a PLK1 inhibitor, in advanced leukemias/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 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:	Russo Partners LLC, Eric Ando, (646) 218-4604, eric.ando@russopartnersllc.com

Source: Cyclacel