Cyclacel Pharmaceuticals Reports Second Quarter 2021 Financial Results and Provides Business Update

August 11, 2021

- Announces First Patients with Solid Tumors Dosed with Oral Fadraciclib -
- Additional Phase 1/2 Trials for Fadraciclib and CYC140 Expected to Follow -
- Cash Runway to Early 2023 -
- Conference Call Scheduled August 11, 2021 at 4:30 p.m. ET -

BERKELEY HEIGHTS, N.J., Aug. 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 reported its financial results for the second quarter 2021. The quarter's business highlights included an update on the Company's progress with fadraciclib and CYC140, Cyclacel's novel CDK2/9 and PLK1 inhibitors, respectively.

"After announcing In July that the first patient had been dosed with oral fadraciclib, two additional patients with advanced solid tumors have been treated, completing enrolment of the first dose level," said Spiro Rombotis, President and Chief Executive Officer. "We are encouraged by investigator interest in our fadraciclib 065-101 solid tumor study. In earlier clinical studies fadraciclib has demonstrated single-agent activity, including durable PR. We believe that fadraciclib is a leading, transcriptionally-active CDK inhibitor with a differentiated product profile. Pipeline momentum will continue to build with the planned opening of protocol 065-102, an oral fadraciclib study in patients with hematological malignancies, and later with the initiation of two similar protocols in solid tumors and hematological malignancies for our novel PLK1 inhibitor, CYC140. The second half of 2021 is an exciting period for Cyclacel, as we expand our clinical programs and increase our visibility as an oncology leader focused on cell cycle inhibition for the treatment of cancer. We look forward to reporting further updates as data from these studies become available."

Key Corporate Highlights

- **Oral fadraciclib -** First three patients with advanced solid tumors dosed in the 065-101 Phase 1/2, registration-directed trial. The study includes multiple cohorts defined by histology thought to be sensitive to the drug's mechanism of action and informed by the clinical activity of fadraciclib in MCL1, MYC and/or cyclin E amplified cancers. The cohorts include breast (metastatic, hormone receptor positive, post-CDK4/6 inhibitor; HER-2 refractory; or triple negative), cholangiocarcinoma, colorectal (including KRAS mutant), endometrial, hepatocellular, ovarian cancers and certain lymphomas. The study design also includes a basket cohort which will enroll patients with relevant biomarkers to the drug's mechanism regardless of histology. Previously single agent, intravenous fadraciclib has demonstrated durable suppression of MCL1 and other mechanistically-related proteins, including cyclin E and MYC, at tolerated doses.

- **Oral CYC140** – continued progress with IND-directed activities and manufacturing of clinical trial supplies. Initial data in preclinical models show that KRAS mutant cancers are sensitive to oral CYC140 inhibition. The Company expects to begin a study in patients with solid tumors in the second half of 2021. Similar to the fadraciclib clinical program, the CYC140 Phase 1/2 study will be a registration-directed trial using a streamlined design that will first determine the recommended Phase 2 dose (RP2D) for single-agent CYC140. Once the RP2D has been established, the trial will immediately enter into a proof-of-concept, cohort stage, using a Simon 2-stage design, where single agent CYC140 will be administered to patients across multiple cohorts based upon those histologies thought to be sensitive to the drug's mechanism of action.

Key Near-Term Business Objectives and Expected Timeline

2H 2021

- First patient to be dosed with oral fadraciclib in 065-102 Phase 1/2 leukemia study
- FDA clearance of IND filing; begin oral CYC140 Phase 1/2 advanced solid tumor study

1H 2022

- First patient to be dosed with oral CYC140 in Phase 1/2 leukemia study
- Phase 1 data with oral fadraciclib in advanced solid tumor 065-101 study

Financial Highlights

As of June 30, 2021, cash and cash equivalents totaled $43.6 million, compared to $47.8 million as of March 31, 2021. The decrease of $4.2 million was primarily due to net cash used in operating activities. The Company estimates that the cash resources will fund currently planned programs through early 2023.

Research and development expenses were $4.1 million for the three months ended June 30, 2021 as compared to $1.2 million for the same period in 2020. Research and development (R&D) expenses relating to fadraciclib increased by approximately $1.9 million for the three months ended June 30, 2021 with the start of the CYC065-101 study of fadraciclib in solid tumors and preparations for opening the 065-102 study of fadraciclib in leukemias. Additionally, R&D expenses related to CYC140 increased $1.0 million for the quarter as IND-directed activities are approaching completion and clinical trial supplies are being manufactured.

General and administrative expenses for the three months ended June 30, 2021 were $2.0 million, compared to $1.3 million for the same period of the previous year due to costs of approximately $0.4 million related to exiting a long-term facility lease, increased legal and professional expenses and recruitment costs.

United Kingdom research & development tax credits were $1.0 million for the three months ended June 30, 2021, as compared to $0.3 million for the same period in 2020 due to the increase in R&D expenditure.

Net loss for the three months ended June 30, 2021 was $5.1 million, compared to $2.2 million for the same period in 2020.

Conference call information:

Conference ID: CYCCQ221

US call: (866) 342-8591/ international call: +1 (203) 518-9713

Replay: US: (800) 839-5109 / international archive: +1 (402) 220-2688

Code for live and replay conference call is CYCCQ221 Webcast link.

For the live and archived webcast, please visit the Corporate Presentations page on the Cyclacel website at www.cyclacel.com.

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, 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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CYCLACEL PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS (LOSS)
(In $000s, except share and per share amounts)

	Three Months Ended June 30,	
	2020	**2021**
Revenues:		
Total revenues	-	-
Operating expenses:		
Research and development	1,163	4,101
General and administrative	1,309	1,999
Total operating expenses	2,472	6,100
Operating loss	(2,472)	(6,100)
Other income (expense):		
Foreign exchange gains (losses)	(2)	(13)
Interest income	4	4
Other income, net	18	18
Total other income (expense), net	20	9
Loss before taxes	(2,452)	(6,091)
Income tax benefit	286	964
Net loss	(2,166)	(5,127)
Dividend on convertible exchangeable preferred shares	(50)	(50)
Beneficial conversion feature of Series B preferred stock	-	-
Net loss applicable to common shareholders	$ (2,216)	$ (5,177)
Basic and diluted earnings per common share:		
Net loss per share – basic and diluted	$ (0.58)	$ (0.56)
Weighted average common shares outstanding	3,850,228	9,234,110

CYCLACEL PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEET
(In $000s, except share, per share, and liquidation preference amounts)

	December 31, 2020	**June 30, 2021**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 33,406	$ 43,639
Prepaid expenses and other current assets	2,063	2,564
Total current assets	35,469	46,203
Property and equipment, net	106	73
Right-of-use lease asset	1,227	58
Total assets	$ 36,802	$ 46,334

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Accounts payable	$ 514	$ 1,197
Accrued and other current liabilities	1,972	1,921
Total current liabilities	2,486	3,118
Lease liability	1,057	-
Total liabilities	3,543	3,118
Stockholders' equity	33,259	43,216
Total liabilities and stockholders' equity	$ 36,802	$ 46,334

SOURCE: Cyclacel Pharmaceuticals, Inc

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