Cyclacel Pharmaceuticals Reports Second Quarter 2020 Financial Results

August 12, 2020

- Conference Call Scheduled August 12, 2020 at 4:30 p.m. ET -

BERKELEY HEIGHTS, N.J., Aug. 12, 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, today reported its financial results for the second quarter 2020 and business highlights, including an update on its progress with fadraciclib, Cyclacel's novel CDK2/9 inhibitor.

The Company's net loss applicable to common shareholders for the three months ended June 30, 2020 was $2.2 million. As of June 30, 2020, cash and cash equivalents totaled $25.3 million. Based on current spending, the Company estimates it has sufficient resources to fund planned operations, including research and development, through the end of 2022.

“We believe fadraciclib is establishing a leadership position among MCL1 suppressing compounds in development. Our recent, peer-reviewed publication elaborates the mechanistic rationale for fadraciclib as an anti-cancer therapy signifying the benefits of inhibiting CDK2 and CDK9, two complementary cancer pathways,” said Spiro Rombotis, President and Chief Executive Officer. “We continue to be encouraged by observations of deep partial response and prolonged stable disease with tumor shrinkage as an intravenously administered monotherapy in patients with advanced solid tumors and antileukemic activity in combination with venetoclax. In parallel with evaluating fadraciclib in certain leukemias, we are executing a precision medicine strategy to evaluate the compound in patients with solid tumors with study enrollment expected to begin by the first quarter of 2021. As the global pandemic continues to unfold, our priorities are to ensure patient and employee safety and support efforts to stem COVID-19 disease as part of our corporate social responsibility. Despite the challenges we remain committed to our strategy of building an innovative pipeline addressing the rising problem of cancer resistance and achieving our clinical milestones to drive shareholder value.”

Key Corporate Highlights

- Announced publication of a peer-reviewed study of fadraciclib, in *PLOS ONE.* The publication, authored by scientists from Cyclacel and The Institute of Cancer Research, London, describes the discovery of fadraciclib and shows its ability to target CDK2 and CDK9, leading to broad therapeutic potential.

- **CYC065-01 Phase 1 part 2 single agent i.v. –** As previously reported a heavily pretreated patient with MCL1 amplified endometrial cancer achieved a radiographically confirmed partial response (PR) after a month and a half on fadraciclib at 213mg. This patient continues on therapy for more than a year and reduction in her target tumor lesions is 83%. An additional patient with cyclin E amplified ovarian cancer achieved stable disease with 29% tumor shrinkage after approximately four months at 213mg. We have submitted data for publication at a cancer conference later in the year.

- Based on data thus far, we are designing a Phase 1/2 precision medicine study to further evaluate fadraciclib as monotherapy and in combinations in patients with advanced solid tumors.

- **CYC065-01 Phase 1 part 3 single agent p.o. -** Initial data from an oral capsule formulation of fadraciclib given once daily to four patients with advanced solid tumors demonstrated a predictable pharmacokinetic profile closely overlapping the intravenous form with encouraging exposure levels.

- **CYC065-03 Phase 1 fadraciclib i.v. and venetoclax p.o. in AML/MDS -** We have dosed 11 heavily pretreated patients with relapsed/refractory (R/R) AML in five dose levels up to 200 mg/m^2 of fadraciclib in combination with venetoclax. Evidence of anticancer activity has been observed in four out of eleven patients treated. Preclinical data in AML suggest that targeting both MCL1 and BCL2 may be more beneficial than inhibiting either protein alone.

- **CYC065-02 Phase 1 fadraciclib i.v. and venetoclax p.o. in CLL -** We have dosed 5 patients with R/R CLL in four dose levels up to 150 mg/m^2 of fadraciclib in combination with venetoclax. Evidence of anticancer activity has been observed in two patients who achieved MRD negativity on the combination. Preclinical data suggest that targeting both BCL2 and

MCL1 in CLL may be more beneficial than single agent treatment in this setting as well.

- **CYC682-11 Phase 1 part 2 sapacitabine p.o. and venetoclax p.o. -** We have enrolled 12 patients in a dose escalation study in our DNA Damage Response (DDR) program evaluating an oral combination of sapacitabine and venetoclax in patients with R/R AML/MDS. Two patients, previously treated with combination therapies including hypomethylating agents, have achieved 5 and 6 cycles of treatment respectively. Sapacitabine is a nucleoside analogue that is active in AML and MDS R/R to prior therapy such as cytarabine or hypomethylating agents. Preclinical data demonstrated synergy of sapacitabine with BCL2 inhibition, which may offer an effective, oral treatment regimen for patients who have failed front-line therapy.

- **CYC140-01 Phase 1 CYC140 i.v. -** We have enrolled 6 patients in our first-in-human, dose escalation study evaluating CYC140 in patients with advanced leukemias. CYC140 is a small molecule, selective polo-like-kinase 1 (PLK1) inhibitor that has demonstrated potent and selective target inhibition and high activity in xenograft models of human cancers. In addition to hematological malignancies we are evaluating studies of CYC140 in solid tumors.

More information on our clinical trials can be found here.

Key Business Objectives

- Report updated fadraciclib Phase 1 safety and efficacy data with frequent i.v. dosing schedule in patients with advanced solid cancers;
- Report initial safety and PK data from Phase 1 study of fadraciclib oral formulation;
- Treat first patient in fadraciclib Phase 1/2 precision medicine study;
- Report initial data from fadraciclib-venetoclax Phase 1 study in R/R AML/MDS & CLL;
- Report initial data from sapacitabine-venetoclax Phase 1 study in R/R AML/MDS;
- Report initial data from CYC140 Phase 1 first-in-human study in R/R leukemias; and
- Report data from Phase 1b/2 sapacitabine-olaparib IST in BRCA mutant metastatic breast cancer when reported by the investigators.

Financial Highlights

As of June 30, 2020, cash and cash equivalents totaled $25.3 million, compared to $11.9 million as of December 31, 2019. The increase of $13.4 million was primarily due to net proceeds of $18.3 million from an equity financing in April 2020 and net cash used in operating activities of $4.7 million. There were no revenues for each of the three months ended June 30, 2020 and 2019.

Research and development expenses were $1.2 million for each of the three months ended June 30, 2020 and 2019. Research and development expenses relating to transcriptional regulation increased by approximately $0.2 million for the three months ended June 30, 2020 as we continue to progress the clinical evaluation of fadraciclib.

General and administrative expenses for the three months ended June 30, 2020 were $1.3 million, compared to $1.2 million for the same period of the previous year.

Total other income, net, for the three months ended June 30, 2020 was $20,000, compared to $0.2 million for the same period of the previous year. The decrease of approximately $0.2 million for the three months ended June 30, 2020 is primarily related to income received under an Asset Purchase Agreement with Thermo Fisher Scientific Inc.

United Kingdom research & development tax credits were $0.3 million for each of the three months ended June 30, 2020 and 2019.

Net loss for the three months ended June 30, 2020 was $2.2 million compared to $1.8 million for the same period in 2019.

The Company estimates that cash resources of $25.3 million as of June 30, 2020 will fund currently planned programs through 2022.

Conference call information:

US/Canada call: (877) 493-9121 / international call: (973) 582-2750

US/Canada archive: (800) 585-8367 / international archive: (404) 537-3406

Code for live and archived conference call is 2477369.

For the live and archived webcast, please visit the Corporate Presentations page on the Cyclacel website at www.cyclacel.com. The webcast will be archived for 90 days and the audio replay for 7 days.

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.

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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,	
	2019	**2020**
Revenues:		
Total revenues	-	-
Operating expenses:		
Research and development	1,153	1,163
General and administrative	1,184	1,309
Total operating expenses	2,337	2,472
Operating loss	(2,337)	(2,472)
Other income (expense):		
Foreign exchange gains (losses)	21	(2)
Interest income	56	4
Other income, net	170	18

Total other income (expense), net	247	20
Loss before taxes	(2,090)	(2,452)
Income tax benefit	307	286
Net loss	(1,783)	(2,166)
Dividend on convertible exchangeable preferred shares	(50)	(50)
Net loss applicable to common shareholders	$ (1,833)	$ (2,216)
Basic and diluted earnings per common share:		
Net loss per share – basic and diluted	$ (2.13)	$ (0.58)
Weighted average common shares outstanding	859,998	3,850,228

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

	December 31, 2019	June 30, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,885	$ 25,342
Prepaid expenses and other current assets	2,132	2,591
Total current assets	14,017	27,933
Property and equipment, net	27	20
Right-of-use lease asset	1,264	1,218
Total assets	$ 15,308	$ 29,171
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 890	$ 342
Accrued and other current liabilities	1,530	1,170
Total current liabilities	2,420	1,512
Lease liability	1,191	1,081
Other liabilities	-	-
Total liabilities	3,611	2,593
Stockholders' equity	11,697	26,578
Total liabilities and stockholders' equity	$ 15,308	$ 29,171

SOURCE: Cyclacel Pharmaceuticals, Inc.

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