Cyclacel Pharmaceuticals Reports First Quarter 2020 Financial Results

May 12, 2020

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

- Following Recent Financing Cash Runway to End of 2022 -

BERKELEY HEIGHTS, N.J., May 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 first quarter 2020 and business highlights, including an update on its progress with fadraciclib, Cyclacel's novel CDK inhibitor. The Company's net loss applicable to common shareholders for the three months ended March 31, 2020 was $1.3 million. As of March 31, 2020, cash and cash equivalents totaled $8.9 million. Following net proceeds of $18.4 million from an equity financing in April 2020, pro forma cash and cash equivalents total $27.3 million. Based on current spending, the Company estimates it has sufficient resources to fund planned operations, including research and development, to the end of 2022.

“The global pandemic is creating uncertainty in every business sector and it is clear that we need novel, science-based solutions to emerge from the crisis,” said Spiro Rombotis, President and Chief Executive Officer. “While our priorities are ensuring patient safety and addressing our social responsibility, we remain committed to our business strategy of building an innovative pipeline addressing the rising problem of cancer resistance. Fadraciclib is establishing a leadership position among MCL1 suppressing compounds in clinical development. We are encouraged by observations of deep response and prolonged stable disease with tumor shrinkage in both intravenous schedules tested this far. Importantly, initial clinical data with oral fadraciclib show concordance with intravenous pharmacokinetics. After strengthening our balance sheet, we will now turn our attention to executing a precision medicine strategy to evaluate fadraciclib in patients with solid tumors and achieve our other clinical milestones through late 2022.”

Key Corporate Highlights

- In light of the pandemic caused by the novel coronavirus and to ensure the health and wellbeing of our employees, patients and the communities we serve, we have redesigned our work flow and business processes in line with current standards and government recommendations. In addition, we are working hard to provide uninterrupted clinical supplies and maintain the integrity of our clinical research. At present, we have not experienced recruitment delays, and our clinical investigators continue to screen and enroll patients. As the future course of the pandemic is uncertain, we will continue to closely monitor developments.

- **CYC065-01 Phase 1 part 2 single agent i.v. -** We have previously reported that 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 and reduction in her target tumor lesions is 79% after nine months. An additional patient with cyclin E amplified ovarian cancer achieved stable disease with 29% tumor shrinkage after approximately four months at 213mg. 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 three 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 the venetoclax. Evidence of anticancer activity has been observed in multiple patients with blast reductions in peripheral blood. 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 two dose cohorts in our DNA Damage Response (DDR) program evaluating an oral combination of sapacitabine and venetoclax in patients with R/R AML/MDS. 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 5 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.

- **COVID-19 Collaboration -** We entered into an agreement with The University of Edinburgh to evaluate the potential of our CDK inhibitors, fadraciclib and seliciclib, for reducing runaway inflammation and subsequent lung injury in patients with COVID-19 disease.

More information on our clinical trials can be found at www.clinicaltrials.gov.

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 March 31, 2020, cash and cash equivalents totaled $8.9 million, compared to $11.9 million as of December 31, 2019. The decrease of $3.0 million was primarily due to net cash used in operating activities of $2.8 million and $0.1 million of net cash used in financing activities. There were no revenues for each of the three months ended March 31, 2020 and 2019.

Research and development expenses were $1.1 million for the three months ended March 31, 2020 as compared to $1.0 million for the same period in 2019. Research and development expenses relating to transcriptional regulation increased by almost $0.3 million for the three months ended March 31, 2020 as we continue to progress the clinical evaluation of fadraciclib.

General and administrative expenses for the three months ended March 31, 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 March 31, 2020 was $0.9 million, compared to $0.1 million for the same period of the previous year. The increase of $0.8 million for the three months ended March 31, 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 March 31, 2020 and 2019.

Net loss for the three months ended March 31, 2020 was $1.2 million, compared to $1.8 million for the same period in 2019.

The Company raised net proceeds of approximately $18.4 million from an equity financing in April 2020.

The Company estimates that cash resources of $8.9 million as of March 31, 2020 together with the $18.4 million net proceeds from the April 2020 financing 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 4198767.

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 December 31,	
	2019	**2020**
Revenues:		
Total revenues	-	-
Operating expenses:		
Research and development	1,012	1,106
General and administrative	1,192	1,318
Total operating expenses	2,204	2,424

Operating loss	(2,204)	(2,424)
Other income (expense):		
Foreign exchange gains (losses)	15	69
Interest income	79	28
Other income, net	-	817
Total other income (expense), net	94	914
Loss before taxes	(2,110)	(1,510)
Income tax benefit	268	290
Net loss	(1,842)	(1,220)
Dividend on convertible exchangeable preferred shares	(50)	(50)
Net loss applicable to common shareholders	$ (1,892)	$ (1,270)
Basic and diluted earnings per common share:		
Net loss per share – basic and diluted	$ (2.77)	$ (1.48)
Weighted average common shares outstanding	681,910	859,998

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

	December 31, 2019	March 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,885	$ 8,923
Prepaid expenses and other current assets	2,132	2,888
Total current assets	14,017	11,811
Property and equipment, net	27	25
Right-of-use lease asset	1,264	1,151
Total assets	$ 15,308	$ 12,987
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 890	$ 250
Accrued and other current liabilities	1,530	1,273
Total current liabilities	2,420	1,523
Lease liability	1,191	1,073
Other liabilities	-	-
Total liabilities	3,611	2,596
Stockholders' equity	11,697	10,391
Total liabilities and stockholders' equity	$ 15,308	$ 12,987

SOURCE: Cyclacel Pharmaceuticals, Inc.

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