Cyclacel Pharmaceuticals Reports Second Quarter 2019 Financial Results

August 13, 2019

- Conference Call Scheduled August 13, 2019 at 4:30 p.m. ET –

BERKELEY HEIGHTS, N.J., Aug. 13, 2019 (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 financial results and business highlights for the second quarter 2019. The Company's net loss applicable to common shareholders for the three months ended June 30, 2019 was $1.8 million. As of June 30, 2019 cash and cash equivalents totaled $15.2 million.

“We are excited to report new evidence of anticancer activity for CYC065. In part 2 of our Phase 1 study of CYC065 as a single agent, a patient with endometrial cancer with MCL1 amplification treated on the fourth dose level achieved tumor shrinkage. This patient was previously treated with liposomal doxorubicin, carboplatin, and multiple investigational therapies,” said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. “Following our recent announcement of the first patient dosed in a Phase 1/2 study with an oral combination of sapacitabine and venetoclax in relapsed or refractory AML or MDS, we are now dosing patients in five clinical studies in pursuit of our strategy of overcoming cancer resistance mechanisms through combinations of our candidates with approved drugs. The first two patients in the relapsed or refractory CLL study evaluating the combination of CYC065 and venetoclax remain on treatment for 4 and 6 cycles respectively. A total of 4 patients with BRCA mutant breast cancer have been treated in the Phase 1/2 investigator sponsored trial (IST) evaluating sapacitabine and olaparib and one patient has achieved partial response (PR). With projected cash to the end of 2020 we look forward to delivering on multiple data outcomes from our ongoing studies.”

Key Company Highlights

- Reported first evidence of anticancer activity in part 2 of the Phase 1 study (065-01) as a single agent testing a frequent dosing schedule of four, one-hour infusions every three weeks in which a patient with endometrial cancer with MCL1 amplification treated on the fourth dose level of 213mg achieved tumor shrinkage;
- Reported that patients with relapsed/refractory CLL treated in the 065-02 study with CYC065 plus venetoclax are continuing treatment after ibrutinib front-line failure;
- Announced treatment of the first patient in a Phase 1 study (065-03) evaluating the safety and effectiveness of CYC065, a CDK2/9 inhibitor shown to durably suppress MCL1, in combination with venetoclax, a BCL2 inhibitor, in patients with relapsed or refractory AML or MDS. Preclinical data confirmed synergy of CYC065 and venetoclax, suggesting that the suppression of both BCL2 and MCL1 may be more beneficial than inhibiting either one alone;
- Announced treatment of the first patient in part 2 of a Phase 1/2 study (682-11) evaluating the safety and effectiveness of an oral regimen of sapacitabine in combination with venetoclax in patients with relapsed or refractory AML or MDS. Sapacitabine is a nucleoside analogue that is active in AML and MDS relapsed or refractory to prior therapy such as cytarabine or hypomethylating agents. Combining sapacitabine with venetoclax may offer an effective, oral treatment regimen for patients who have failed front-line therapy;
- Following an amendment of the Phase 1 study (065-01) of single agent CYC065 in patients with advanced cancers part 3 of the study will evaluate an oral form of CYC065.

Key Upcoming Business Objectives

- Report initial data from the CYC065-venetoclax Phase 1 studies in relapsed/refractory leukemias;
- Report initial data from the sapacitabine-venetoclax Phase 1 study in patients with relapsed or refractory AML or MDS;
- Report initial data from the CYC140 Phase 1 First-in-Human study;
- Report initial data and bioavailability from the Phase 1 study of an oral formulation of CYC065;
- Report updated CYC065 Phase 1 data with frequent dosing schedule in patients with advanced solid cancers;
- Report data from the IST Phase 1b/2 trial of sapacitabine-olaparib combination in patients with BRCA mutant metastatic breast cancer when reported by the investigators;
- Determine regulatory pathway and submissibility of sapacitabine in elderly AML patients.

Financial Highlights

As of June 30, 2019, cash and cash equivalents totaled $15.2 million compared to $17.5 million as of December 31, 2018. The decrease of $2.3 million was primarily due to net cash used in operating activities of $6.3 million, offset by net proceeds from a Common Stock Sales Agreement with H.C. Wainwright of $4.1m.

Research and development expenses were $1.2 million for the three months ended June 30, 2019 compared to $1.2 million for the same period in 2018.

General and administrative expenses were $1.2 million for the three months ended June 30, 2019 compared to $1.3 million for the same period in 2018.

Other income, net for the three months ended June 30, 2019 was $0.2 million compared to $0.1 million for the same period of the previous year.

The United Kingdom R&D tax credit was $0.3 million for the three months ended June 30, 2019 compared to $0.5 million for the same period in 2018.

Net loss for the three months ended June 30, 2019 was $1.8 million compared to $1.9 million for the same period in 2018. With the projected cash-sparing benefits accruing from the MD Anderson alliance the Company believes that cash and marketable securities, which were approximately $15.2 million as of June 30, 2019, will be sufficient to finance operations through the end of 2020.

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 7654539
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 CYC065 in combination with venetoclax in patients with relapsed or refractory CLL and AML/MDS. The DNA damage response program is evaluating an oral combination regimen of sapacitabine and venetoclax in patients with relapsed or refractory AML/MDS. The anti-mitotic program is evaluating CYC140, a PLK1 inhibitor, in AML/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, Alexander Fudukidis, (646) 942-5632, alex.fudukidis@russopartnersllc.com

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

	Three Months Ended June 30,	
	2018	**2019**
Revenues:		
Total revenues	-	-
Operating expenses:		
Research and development	1,182	1,153
General and administrative	1,283	1,184
Total operating expenses	2,465	2,337
Operating loss	(2,465)	(2,337)
Other income (expense):		
Foreign exchange gains (losses)	(39)	21
Interest income	84	56
Other income, net	66	170
Total other income (expense), net	111	247
Loss before taxes	(2,354)	(2,090)
Income tax benefit	502	307
Net loss	(1,852)	(1,783)
Dividend on convertible exchangeable preferred shares	(50)	(50)
Net loss applicable to common shareholders	$ (1,902)	$ (1,833)
Basic and diluted earnings per common share:		
Net loss per share – basic and diluted	$ (0.16)	$ (0.11)
Weighted average common shares outstanding	11,997,447	17,199,974

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

	December 31,	June 30,
	2018	**2019**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 17,504	$ 15,159
Prepaid expenses and other current assets	2,283	2,991
Total current assets	19,787	18,150
Property and equipment, net	36	29
Right-of-use lease asset	-	1,285

Total assets	$ 19,823	$ 19,464
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,719	$ 1,106
Accrued and other current liabilities	1,732	1,394
Total current liabilities	4,451	2,500
Lease liability	-	1,233
Other liabilities	100	-
Total liabilities	4,551	3,733
Stockholders' equity	15,272	15,731
Total liabilities and stockholders' equity	$ 19,823	$ 19,464

SOURCE: Cyclacel Pharmaceuticals, Inc.