Cyclacel Pharmaceuticals Reports Third Quarter 2019 Financial Results

November 13, 2019

– Investigator-Reported Partial Response in Phase 1 Study of CYC065 as Single Agent –

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

BERKELEY HEIGHTS, N.J., Nov. 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 third quarter 2019. The Company's net loss applicable to common shareholders for the three months ended September 30, 2019 was $2.0 million. As of September 30, 2019 cash and cash equivalents totaled $13.0 million.

“The investigators evaluating CYC065, our CDK2/9 inhibitor, as a single agent have reported that a heavily pretreated patient with MCL1 amplified endometrial cancer achieved a partial response (PR) with tumor shrinkage of 48%,” said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. “If this PR is confirmed with a follow up scan, it will provide further support that MCL1 dependent cancers may be sensitive to CYC065. We have previously reported that CYC065 durably suppresses MCL1 in cancer patients and believe that it is a leader amongst MCL1 suppressing medicines. In parallel, we have enrolled our first patient with an oral form of CYC065 and are continuing to recruit patients in Phase 1 studies evaluating CYC065 in combination with venetoclax in patients with relapsed or refractory AML, CLL or MDS. Altogether we are dosing patients in five clinical studies in pursuit of our strategy of overcoming cancer resistance through combinations of our candidates with approved drugs. 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 anticancer activity in part 2 of 065-01, the Phase 1 study of CYC065 as a single agent; a patient with MCL1 amplified endometrial cancer achieved partial response with 48% tumor shrinkage after 4 cycles of treatment at 213mg as reported by the investigators;
- Reached the second dose level in part 3 of 065-01 evaluating an oral form of CYC065 in patients with advanced cancers;
- Enrolled eight patients in the 065-03 Phase 1 study evaluating CYC065 in combination with venetoclax in patients with relapsed or refractory AML/MDS;
- Opened two new sites in the 065-02 study of CYC065 in combination with venetoclax in patients with relapsed/refractory CLL;
- Data from three ongoing studies have been selected for presentation at the 61st American Society of Hematology Annual Meeting. The presentations will provide updates for CYC065 in combination with venetoclax in patients with relapsed or refractory AML/MDS or CLL and sapacitabine in combination with venetoclax in patients with relapsed or refractory AML/MDS; and
- Continued enrollment in part 2 of the 682-11 Phase 1/2 study evaluating an oral regimen of sapacitabine in combination with venetoclax in patients with relapsed or refractory AML/MDS.

Key Upcoming Business Objectives

- Presentations at the 61stAmerican Society of Hematology Annual Meeting;
- Report updated safety, pharmacokinetics and efficacy of CYC065 Phase 1 data with frequent dosing schedule in patients with advanced solid cancers;
- Report initial safety and PK data from the Phase 1 study of an oral formulation of CYC065;
- Report initial safety and proof of concept data from the CYC065-venetoclax Phase 1 study in relapsed/refractory AML and MDS;
- Report initial safety and proof of concept data from the CYC065-venetoclax Phase 1 study in relapsed/refractory CLL;
- Report initial data from the sapacitabine-venetoclax Phase 1/2 study in patients with relapsed or refractory AML or MDS;
- Report initial data from the CYC140 Phase 1 First-in-Human study in relapsed or refractory leukemias;
- 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; and

- Determine regulatory pathway and submissibility of sapacitabine in elderly AML patients.

Financial Highlights

As of September 30, 2019, cash and cash equivalents totaled $13.0 million compared to $17.5 million as of December 31, 2018. The decrease of $4.5 million was primarily due to net cash used in operating activities of $8.3 million, offset by net proceeds from a Common Stock Sales Agreement with H.C. Wainwright & Co., LLC of $4.1 million. In October 2019, we received $1.2 million in United Kingdom, research & development tax credits not included in the above amounts.

Research and development expenses were $1.1 million for the three months ended September 30, 2019 compared to $1.2 million for the same period in 2018.

General and administrative expenses were $1.3 million for each of the three months ended September 30, 2019 and 2018.

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

The accrued United Kingdom research and development tax credit was $0.3 million for each of the three months ended September 30, 2019 and 2018.

Net loss for the three months ended September 30, 2019 was $1.9 million compared to $2.1 million for the same period in 2018. With the projected cash-sparing benefits accruing from the alliance with The University of Texas MD Anderson Cancer Center, the Company believes that cash and marketable securities, which were approximately $13.0 million as of September 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 8636118

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. An IST is evaluating an oral combination regimen of sapacitabine and olaparib in patients with BRCA mutant breast cancer. 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, Jan Medina, (646) 942-5632, Jan.Medina@russopartnersllc.com

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

	Three Months Ended September 30,	
	2018	**2019**
Revenues:		
Total revenues	-	-
Operating expenses:		
Research and development	1,205	1,063
General and administrative	1,250	1,285
Total operating expenses	2,455	2,348
Operating loss	(2,455)	(2,348)
Other income (expense):		
Foreign exchange gains (losses)	1	79
Interest income	85	42
Other income, net	-	53
Total other income (expense), net	86	174
Loss before taxes	(2,369)	(2,174)
Income tax benefit	301	273
Net loss	(2,068)	(1,901)
Dividend on convertible exchangeable preferred shares	(50)	(50)
Net loss applicable to common shareholders	$ (2,118)	$ (1,951)
Basic and diluted earnings per common share:		
Net loss per share – basic and diluted	$ (0.18)	$ (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,	September 30,
	2018	**2019**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 17,504	$ 12,967
Prepaid expenses and other current assets	2,283	2,869
Total current assets	19,787	15,836

Property and equipment, net	36	28
Right-of-use lease asset	-	1,213
Total assets	$ 19,823	$ 17,077

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Accounts payable	$ 2,719	$ 887
Accrued and other current liabilities	1,732	1,184
Total current liabilities	4,451	2,071
Lease liability	-	1,154
Other liabilities	100	-
Total liabilities	4,551	3,225
Stockholders' equity	15,272	13,852
Total liabilities and stockholders' equity	$ 19,823	$ 17,077

SOURCE: Cyclacel Pharmaceuticals, Inc.