Cyclacel Pharmaceuticals Reports First Quarter 2021 Financial Results

May 12, 2021

- Announces IND Authorization by FDA for Fadraciclib, a CDK2/9 Inhibitor, in Solid Tumors -
- Recent Publication Reported that Overactive KRAS Mutants are Impeded by CDK9 Inhibition -
- Following Recent Financing, Cash Runway Extended to Early 2023 -
- Conference Call Scheduled May 12, 2021 at 4:30 p.m. ET -

BERKELEY HEIGHTS, N.J., May 12, 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 first quarter 2021 and business highlights, including an update on its progress with fadraciclib and CYC140, Cyclacel's novel CDK2/9 and PLK1 inhibitors, respectively.

“During the quarter, we have made significant progress in bringing our two oral targeted development candidates into mid-stage clinical development. Following recent FDA authorization of our IND for oral fadraciclib, we will finalize contract discussions with sites and open our multi-cohort Phase 1b/2 study in patients with solid tumors,” said Spiro Rombotis, President and Chief Executive Officer. “We believe fadraciclib is establishing a strong position among compounds in clinical development that specifically address cancer resistance mechanisms, including suppression of MCL1, MYC and cyclin E. A recent publication identified potential utility of CDK9 inhibitors in KRAS mutant colorectal cancer, one of the tumor types in our study. Together with our oral CYC140 PLK1 inhibitor program, which has shown in preclinical models that KRAS mutant cancers are sensitive to CYC140 inhibition, we hope to provide valuable alternatives to patients with these difficult to treat malignancies. After strengthening our balance sheet in the quarter, we are executing a precision medicine strategy to achieve multiple milestones and data read outs over the next two years.”

Key Corporate Highlights

- **CYC065-101 Phase 1b/2 oral fadraciclib in advanced solid tumors** - announced that the U.S. Food & Drug Administration (FDA) has authorized Cyclacel’s Investigational New Drug (IND) application for oral fadraciclib to proceed. This Phase 1b/2 registration-directed trial 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 cyclin E amplified cancers. The cohorts include breast, colorectal (including KRAS mutant), endometrial/uterine, 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.

- A recent publication by researchers led by Frank McCormick, PhD of University of California San Francisco and NCI’s Frederick National Lab for Cancer Research reported that overactive KRAS mutants are impeded by CDK9 inhibition[1]. These data expand on previous findings, which show that dual CDK2/9 inhibition is an optimal strategy to treat colorectal cancer[2], that KRAS mutant pancreatic cancer is sensitive to CDK9 inhibition[3], and that fadraciclib showed efficacy against KRAS mutant lung cancer in preclinical PDX models[4]. Collectively these publications suggest the potential for the therapeutic use of fadraciclib in KRAS-mutated cancers, including colorectal, lung and pancreatic.

- **CYC140 PLK1 inhibitor program -** commenced IND-directed activities and manufacturing of clinical trial supplies for oral CYC140. Initial data in preclinical models show that KRAS mutant cancers are sensitive to oral CYC140 inhibition.

- Phase 1b/2 Investigator Sponsored Trial (IST) of sapacitabine-olaparib combination in patients with BRCA mutant metastatic breast cancer – investigators reported that out of 9 patients enrolled, 5 have achieved partial response (PR), 3 stable disease (SD), and one patient has progressed.

- Announced the closing of an underwritten public offering for net proceeds to the Company of approximately $13.5 million, after deducting placement agent fees and other offering expenses. Existing and new institutional investors participated in the offering. In addition, the Company received approximately $4.5 million in the quarter through warrant exercises.

Key Near-Term Business Objectives and Expected Timeline

1H 2021

- First patient dosed with oral fadraciclib in Phase 1b/2 advanced solid tumor study

2H 2021

- First patient dosed with oral fadraciclib in Phase 1b/2 leukemia study
- First patient dosed with oral CYC140 in Phase 1/2 advanced solid tumor study

1H 2022

- First patient dosed with oral CYC140 in Phase 1/2 leukemia study
- Phase 1 data with oral fadraciclib in advanced solid tumor study
- Update data from the Phase 1b/2 IST of sapacitabine-olaparib combination in patients with BRCA mutant metastatic breast cancer when reported by the investigators

Financial Highlights

As of March 31, 2021, cash and cash equivalents totaled $47.8 million, compared to $33.4 million as of December 31, 2020. The increase of $14.4 million was primarily due to $18.0 million of net cash provided by financing activities, offset by net cash used in operating activities of $3.6 million. There were no revenues for each of the three months ended March 31, 2021 and 2020.

Research and development expenses were $2.6 million for the three months ended March 31, 2021 as compared to $1.1 million for the same period in 2020. Research and development expenses relating to the CDK inhibitor program increased by approximately $0.8 million for the three months ended March 31, 2021 as clinical evaluation of fadraciclib is progressing.

General and administrative expenses for the three months ended March 31, 2021 were $1.7 million, compared to $1.3 million for the same period of the previous year due to an increase in legal and professional expenses and recruitment costs.

Total other income, net, for the three months ended March 31, 2021 was $0.1 million, compared to $0.9 million for the same period of the previous year. The decrease of $0.8 million for the three months ended March 31, 2021 is primarily related to income received under an Asset Purchase Agreement with Thermo Fisher Scientific Inc.

United Kingdom research & development tax credits were $0.7 million for the three months ended March 31, 2021, as compared to $0.3 million for the same period in 2020 as a direct consequence of increased qualifying research and development expenditure.

Net loss for the three months ended March 31, 2021 was $3.5 million, compared to $1.2 million for the same period in 2020.

The Company raised net proceeds of approximately $13.5 million from an equity financing in March 2021. The Company also received an additional $4.5 million of proceeds from warrant exercises.

The Company estimates that cash resources of $47.8 million as of March 31, 2021 will fund currently planned programs through early 2023.

Conference call information:

Conference ID 2763358 Webcast link

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

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

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

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[1] Pui Lai L, et al, *SLAS Discovery* I-II 2021, https://journals.sagepub.com/doi/abs/10.1177/24725552211008853.

[2] Somarelli JA, et al, *Mol Cancer Ther*, 2020 19 2516. DOI: 10.1158/1535-7163.MCT-20-0454.

[3] Blake DR, et al, *Science Signalling*, 2019, https://pubmed.ncbi.nlm.nih.gov/31311847/.

[4] Kawakami M, et al J Natl Cancer Inst, 2017 109, https://pubmed.ncbi.nlm.nih.gov/28376145/.

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 December 31,	
	2020	**2021**
Revenues:		
Total revenues	-	-
Operating expenses:		
Research and development	1,106	2,566
General and administrative	1,318	1,739
Total operating expenses	2,424	4,305
Operating loss	(2,424)	(4,305)
Other income (expense):		
Foreign exchange gains (losses)	69	10
Interest income	28	4
Other income, net	817	126
Total other income (expense), net	914	140
Loss before taxes	(1,510)	(4,165)
Income tax benefit	290	687
Net loss	(1,220)	(3,478)
Dividend on convertible exchangeable preferred shares	(50)	(50)
Beneficial conversion feature of Series B preferred stock	-	-
Net loss applicable to common shareholders	$ (1,270)	$ (3,528)
Basic and diluted earnings per common share:		
Net loss per share – basic and diluted	$ (1.48)	$ (0.50)
Weighted average common shares outstanding	859,998	7,099,037

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

	December 31, 2020	March 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 33,406	$ 47,777
Prepaid expenses and other current assets	2,063	2,686
Total current assets	35,469	50,463
Property and equipment, net	106	173
Right-of-use lease asset	1,227	1,181
Total assets	$ 36,802	$ 51,817
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 514	$ 871
Accrued and other current liabilities	1,972	1,901
Total current liabilities	2,486	2,772
Lease liability	1,057	996
Total liabilities	3,543	3,768
Stockholders' equity	33,259	48,049
Total liabilities and stockholders' equity	$ 36,802	$ 51,817

SOURCE: Cyclacel Pharmaceuticals, Inc.

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