Cyclacel Pharmaceuticals Reports First Quarter 2022 Financial Results and Provides Business Update

May 11, 2022

- Oral Fadraciclib Demonstrating Strong Safety Profile with Continuous Dosing; anticipate entering Phase 2 POC in 2H 2022 -

- First Patients Dosed in Phase 1/2 Study of Oral PLK1 Inhibitor CYC140 for Treatment of Advanced Solid Tumors and Lymphomas -

- Publication Confirming Fadraciclib Suppresses MCL1 and Synergistic Activity with Venetoclax in CLL -

- Cash Runway through Mid-2023 -

- Conference Call Scheduled for May 11, 2022 at 4:30 pm EDT -

BERKELEY HEIGHTS, N.J., May 11, 2022 (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 announced first quarter 2022 financial results and provided a business update.

“We are pleased to report another productive quarter for Cyclacel, which included continued expansion of our three, registration-directed, clinical trials and publication of research findings supporting our drug development strategy,” said Spiro Rombotis, Chief Executive Officer of Cyclacel. “Oral fadraciclib, our CDK2/9 drug candidate, is proving to be well tolerated in 065-101, our Phase 1/2 solid tumor and lymphoma study, having reached dose level 5 in the dose escalation stage which provides for daily dosing over 4 out of 4 weeks. In our PLK1 program, we have dosed the first patients in the streamlined Phase 1/2 trial of CYC140 for the treatment of solid tumors and lymphomas. We have optimized the properties of CYC140 to fit its apoptosis-driven mechanism, including short half-life and differentiated structural and biological properties, compared to other PLK1 inhibitors in development. We therefore believe CYC140 has the potential to demonstrate activity across a wide range of solid tumors, as a single agent and in combinations.”

“A growing body of preclinical research supports the clinical development plan of fadraciclib. In April, we announced publication of research from The University of Texas MD Anderson Cancer Center highlighting fadraciclib’s antileukemic activity in CLL. Fadraciclib treatment resulted in suppression of MCL1, a key target protein. In addition, synergy of fadraciclib in combination with venetoclax was observed against primary CLL cell lines, including those with 17p deletion. With funding estimated through mid-2023, we are continuing to execute on our clinical development plan. We look forward to presenting initial fadraciclib clinical data in solid tumors and lymphomas, in the coming weeks, determining the recommended Phase 2 dose and entering proof of concept stage in the second half of 2022.”

Key Highlights

- **Fadraciclib 065-101 Phase 1/2 study in advanced solid tumors:** Phase 1 dose escalation has reached dose level 5 (100mg given twice a day for 5 days for 4 weeks in a 4-week cycle) with a favorable patient safety profile and appropriate pharmacokinetic data observed thus far. The study is enrolling at four sites with several additional sites planning to join the proof-of-concept stage of this registration-directed study in 2H 2022. The Phase 2 part includes seven histologically defined cohorts thought to be sensitive to the drug’s mechanism: breast, colorectal (including KRAS mutant), endometrial/uterine, hepatobiliary, ovarian cancers and lymphomas. The study also includes an eighth basket cohort which will enroll patients regardless of histology with biomarkers relevant to the drug’s mechanism, including MCL1, MYC and/or cyclin E amplified.

- **Fadraciclib 065-102 Phase 1/2 study in patients with leukemias or myelodysplastic syndromes**. This study is now enrolling at City of Hope and MD Anderson Cancer Center and is treating patients at dose level one. Once the recommended Phase 2 dose (RP2D) for single-agent, oral fadraciclib is determined, the study will enter into proof-of-concept, cohort stage, where fadraciclib will be administered, both as a single agent and in combinations, to patients in up to seven cohorts relevant to the drug’s mechanism of action and informed by the clinical activity of fadraciclib in previous studies. Single-agent cohorts will include patients with acute myeloid leukemia (AML) or myelodysplastic syndromes (MDS) who have an inadequate response or have progressed on venetoclax combinations with hypomethylating agent (HMA) or low dose Ara C and relapsed/refractory AML or MDS patients with FLT3, KIT or MAPK pathways (including N and K RAS, BRAF, PTPN11, NF1). The trial will also include patients with CLL who have progressed after at least two lines of therapy including a BTK inhibitor and/or venetoclax.

  Announced publication confirming fadraciclib suppresses MCL1 and synergizes with venetoclax in chronic lymphocytic leukemia. Results from the study confirmed that fadraciclib inhibited CDK9 mediated transcription, reduced levels of the short-lived, anti-apoptotic protein MCL1, and induced apoptosis in primary CLL cells. The data highlighted the

importance of continuous treatment to prevent recovery of MCL1 protein levels. Furthermore, fadraciclib was shown to combine synergistically with the BCL2 antagonist, venetoclax, and demonstrated even greater synergy when targeted against 17p deleted CLL cells which were not sensitive to either agent alone.

- **CYC140 140-101 Phase 1/2 study in solid tumors and lymphomas.** This registration-directed study opened in April at City of Hope and MD Anderson Cancer Center and is enrolling patients in the Phase 1 dose escalation stage. The study uses a streamlined design and will initially determine RP2D for single-agent oral CYC140. Following RP2D, the trial will immediately enter into proof-of-concept, cohort stage, using a Simon 2-stage design. In this stage CYC140 will be administered to patients in up to seven mechanistically relevant cohorts including patients with bladder, breast, colorectal (including KRAS mutant), hepatocellular and biliary tract, and lung cancers (both small cell and non-small cell), as well as lymphomas plus an eighth basket cohort which will enroll patients with biomarkers relevant to the drug's mechanism.

More information on our clinical trials can be found here.

Financial Highlights

As of March 31, 2022, cash and cash equivalents totaled $29.6 million, compared to $36.6 million as of December 31, 2021. Subsequent to the end of the first quarter, the Company received $3.6 million of United Kingdom research & development tax credits and $1.3 million in royalty receipts providing pro forma March 31, 2022, cash and cash equivalents of $34.5 million. The Company estimates that its available cash will fund currently planned programs through June 2023.

Research and development (R&D) expenses were $5.0 million for the three months ended March 31, 2022, as compared to $2.6 million for the same period in 2021. R&D expenses relating to fadraciclib were $3.6 million for the three months ended March 31, 2022, as compared to $1.7 million for the same period in 2021 due to increase in clinical trial costs associated with ongoing clinical trials evaluating fadraciclib in Phase 1/2 studies along with an increase in non-clinical expenditures. R&D expenses related to CYC140 were $1.1 million for the three months ended March 31, 2022, as compared to $0.7 million for the same period in 2021 due to clinical trial costs associated with the opening of clinical sites for CYC140 Phase 1/2 studies.

General and administrative expenses for the three months ended March 31, 2022, were $1.6 million, compared to $1.7 million for the same period of the previous year due to a decrease in professional and recruitment costs.

Total other income, net, for the three months ended March 31, 2022, was $1.3 million, compared to $0.1 million for the same period of the previous year. The increase of $1.2 million for the three months ended March 31, 2022, is primarily related to royalty income received from Thermo Fisher Scientific Corporation.

United Kingdom research & development tax credits were $1.1 million for the three months ended March 31, 2022, as compared to $0.7 million for the same period in 2021 as a direct consequence of increased qualifying research and development expenditure. Tax credit receipts of $3.6 million in respect of the financial year ended December 31, 2021, were received in May 2022.

Net loss for the three months ended March 31, 2022, was $4.1 million, compared to $3.5 million for the same period in 2021.

Conference call information:

US/Canada call: (866) 342-8591 / international call: (203) 518-9713

US/Canada archive: (800) 839-6136 / international archive: (402) 220-2572

Code for live and archived conference call is CYCCQ122. Webcast link

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 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, the potential effects of the COVID-19 pandemic, 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 OFOPERATIONS (LOSS)
(In $000s, except share and per share amounts)

	Three Months Ended March 31,	
	2022	**2021**
Revenues:		
Total revenues	$ -	$ -
Operating expenses:		
Research and development	4,954	2,566
General and administrative	1,605	1,739
Total operating expenses	6,559	4,305
Operating loss	(6,559)	(4,305)
Other income (expense):		
Foreign exchange gains (losses)	29	10
Interest income	4	4
Other income, net	1,280	126
Total other income (expense), net	1,313	140
Loss before taxes	(5,246)	(4,165)
Income tax benefit	1,138	687
Net loss	(4,108)	(3,478)
Dividend on convertible exchangeable preferred shares	(50)	(50)
Net loss applicable to common shareholders	$ (4,158)	$ (3,528)
Net loss per share – basic and diluted	$ (0.42)	$ (0.50)
Weighted average common shares outstanding	9,993,135	7,009,037

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

	March 31	December 31
	2022	**2021**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 29,639	$ 36,559
Prepaid expenses and other current assets	6,759	4,383
Total current assets	36,398	40,942
Property and equipment, net	57	64
Right-of-use lease asset	15	30
Non-current deposits	2,980	1,551
Total assets	$ 39,450	$ 42,587
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,850	$ 2,117

Accrued and other current liabilities	3,175	3,177
Total current liabilities	6,025	5,294
Lease liability	15	30
Total liabilities	6,040	5,324
Stockholders' equity	33,410	37,263
Total liabilities and stockholders' equity	$ 39,450	$ 42,587

SOURCE: Cyclacel Pharmaceuticals, Inc.