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

November 9, 2022

- Oral Fadraciclib Daily Dosing Well Tolerated in 18 Evaluable Patients Treated in Dose-Escalation of Phase 1/2 Trial in Advanced Solid Tumors and Lymphoma -

- Two Partial Responses in Lymphoma and 11 Stable Diseases in Advanced Solid Tumors -

- Expect to Determine Recommended Phase 2 Dose for Oral Fadraciclib and Start Phase 2 in 1Q 2023 -

- Encouraging Activity in First Dose Level of Oral CYC140, PLK1 Inhibitor, with Durable Stable Disease in Two Patients with Ovarian and KRAS G12V mutated Non-Small Cell Lung Cancers -

- Cash Runway To End of 2023 -

- Conference Call Scheduled for November 9, 2022 at 4:30 pm ET -

BERKELEY HEIGHTS, NJ, Nov. 09, 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 third quarter 2022 financial results and provided a business update.

“Our recent R&D Day highlighted interim clinical data emerging from our ongoing Phase 1/2 study of oral fadraciclib in solid tumors and lymphoma,” said Spiro Rombotis, President and Chief Executive Officer. “We are excited about fadra’s tolerability profile, as well as clear evidence of its anticancer activity as a single agent in late-line patients with lymphoma, gynecological, liver and pancreatic cancers. Moreover, we are seeing this activity during dose-escalation which is designed to evaluate safety. We expect to shortly determine the recommended Phase 2 dose (RP2D) and advance into Phase 2 proof-of-concept stage. We look forward to reporting updated data from our ongoing Phase 1/2 studies of fadraciclib and CYC140 in 2023.”

“We have presented progress with our two clinical-stage programs, oral fadraciclib (CDK2/9 inhibitor) and oral CYC140 (PLK1 inhibitor), at our recent R&D Day and the ENA 2022 meeting,” said Mark Kirschbaum, M.D., Chief Medical Officer. “In the 065-101 study of oral fadra, we have reached the sixth dose level after observing that fadra was well tolerated in the first five dose levels. Two out of three lymphoma patients achieved partial response and 11/15 patients with cervical, endometrial, hepatocellular and ovarian cancers achieved stable disease with target lesion reductions. A pancreatic patient achieved stable disease for 5 cycles of treatment. In addition, we achieved levels of fadraciclib that are adequate to inhibit CDK2 and CDK9 for approximately 5 to 7 hours per dose on continuous dosing. At our R&D Day, we also reported preliminary data from the first two dose levels of our Phase 1/2 study of oral CYC140 in patients with advanced solid tumors and lymphoma. We were surprised to observe stable disease at the first dose level in an ongoing patient with metastatic, KRAS G12V mutated, non-small cell lung cancer for 6 cycles and a patient with metastatic ovarian cancer for 5 cycles. We believe that CYC140 is differentiated from other PLK1 inhibitors by its PLK-centric kinase profile and by inhibiting BRD4, a validated, epigenetic target in cancer biology.”

Key Corporate Highlights

- On October 31, 2022 the Company held an R&D Day (Webcast replay) at which updated clinical and preclinical data on fadraciclib and CYC140 were presented:

Interim results from oral fadraciclib 065-101 Phase 1/2 study in advanced solid tumors and lymphoma

- 18 evaluable patients with advanced solid tumors or lymphoma were treated in DL 1-5 (median treatment duration of 2.4 cycles; range 1-5 cycles)
- Well tolerated at all dose levels thus far
- 2/3 partial responses (PR) in T-cell lymphoma patients; 4 patients with cervical, endometrial, hepatocellular and ovarian cancer) showed stable disease with target lesion reductions and a pancreatic cancer patient achieved stable disease for 5 cycles
- Achieved target engagement levels predicted to inhibit CDK2 and CDK9 for approximately 5 to 7 hours per dose on continuous dosing
- Enrollment continues at DL6 (150mg twice a day, Monday-Friday, weeks 1-4)
- A principal investigator from Seoul National University Hospital presented preclinical data showing sensitivity to fadra in biliary tract and pancreatic cancer cells obtained from patient specimens

Interim findings from oral CYC140 140-101 Phase 1/2 study in advanced solid tumors and lymphoma

- No dose limiting toxicities observed to date in the first two doses levels (DL1-2)
- Stable disease at dose level 1 in an ongoing patient with metastatic, KRAS G12V mutated, non-small cell lung cancer for 6 cycles and a patient with metastatic ovarian cancer for 5 cycles

- Enrollment continues in the 065-102 study of oral fadraciclib in patients with advanced leukemia.

- The Company will not be pursuing further development of sapacitabine and has advised Daiichi Sankyo Co., Ltd., the licensor, that it wishes to terminate their license agreement for commercial reasons with the termination expected to be effective as of March 23, 2023.

Key Near-Term Business Objectives and Expected Timeline

4Q 2022

- Determine recommended Phase 2 dose (RP2D) with oral fadraciclib from the Phase 1 stage of 065-101 study with oral fadraciclib in patients with advanced solid tumors and lymphoma

1H 2023

- First patient dosed with oral fadraciclib in Phase 2 proof-of-concept stage of 065-101 study in patients with advanced solid tumors and lymphoma
- Report final data from dose escalation stage of 065-101 study with oral fadraciclib in patients with advanced solid tumors and lymphoma
- Report interim data from 140-101 study with oral CYC140 in patients with advanced solid tumors and lymphoma

2H 2023

- Report interim data from initial cohorts in Phase 2 proof-of-concept stage of 065-101 study with oral fadraciclib in patients with advanced solid tumors and lymphoma
- Report interim data from dose escalation stage of 065-102 study with oral fadraciclib in patients with advanced leukemia
- Report final data from dose escalation stage of 140-101 study with oral CYC140 in advanced solid tumors and lymphoma

Financial Highlights

As of September 30, 2022, cash and cash equivalents totaled $23.7 million, compared to $36.6 million as of December 31, 2021. Net cash used in operating activities was $15.7 million for the nine months ended September 30, 2022 compared to $14.0 million for the same period of 2021. The Company estimates that its available cash will fund currently planned programs to the end of 2023.

Research and development (R&D) expenses were $4.4 million for the three months ended September 30, 2022, as compared to $4.2 million for the same period in 2021. R&D expenses relating to fadraciclib were $2.5 million for the three months ended September 30, 2022, as compared to $3.3 million for the same period in 2021 due to decrease in clinical trial costs of $0.3 million associated with ongoing clinical trials evaluating fadraciclib in Phase 1/2 studies and a reduction of $0.5 million in non-clinical expenditures. R&D expenses related to CYC140 were $1.7 million for the three months ended September 30, 2022, as compared to $0.7 million for the same period in 2021 due to clinical trial costs associated with the CYC140 Phase 1/2 study.

General and administrative expenses for the three months ended September 30, 2022, were $2.1 million, compared to $1.8 million for the same period of the previous year due to an increase in professional and legal costs

Total other income, net, for the three months ended September 30, 2022, was $0.4 million, compared to $13,000 for the same period of the previous year. The increase of $0.3 million for the three months ended September 30, 2022, is primarily related to foreign exchange gains.

United Kingdom research & development tax credits were $1.0 million for each of the three months ended September 30, 2022 and September 30, 2021 and are directly correlated to qualifying research and development expenditure.

Net loss for the three months ended September 30, 2022, was $5.1 million, compared to $5.0 million for the same period in 2021.

Conference call information:

US/Canada call: (800) 579-2543 / international call: (785) 424-1789

US/Canada archive: (888) 276-5315 / international archive: (402) 220-2332

Code for live and archived conference call is CYCCQ322. 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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SOURCE: Cyclacel Pharmaceuticals, Inc.

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

	Three Months Ended September 30,	
	2022	**2021**
Revenues:		
Total revenues	-	-
Operating expenses:		
Research and development	4,413	4,217
General and administrative	2,054	1,781
Total operating expenses	6,467	5,998
Operating loss	(6,467)	(5,998)
Other income (expense):		
Foreign exchange gains (losses)	276	9
Interest income	67	4
Other income, net	14	-
Total other income (expense), net	357	13
Loss before taxes	(6,110)	(5,985)
Income tax benefit	1,014	998
Net loss	(5,096)	(4,987)
Dividend on convertible exchangeable preferred shares	(50)	(50)
Net loss applicable to common shareholders	$ (5,146)	$ (5,037)
Basic and diluted earnings per common share:		
Net loss per share – basic and diluted	$ (0.42)	$ (0.54)
Weighted average common shares outstanding	12,314,679	9,368,056

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

	September 30, 2022	**December 31, 2021**

ASSETS		
Current assets:		
Cash and cash equivalents	$ 23,706	$ 36,559
Prepaid expenses and other current assets	4,209	4,383
Total current assets	27,915	40,942
Property and equipment, net	37	64
Right-of-use lease asset	153	30
Non-current deposits	2,916	1,551
Total assets	$ 31,021	$ 42,587
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 983	$ 2,117
Accrued and other current liabilities	3,370	3,177
Total current liabilities	4,353	5,294
Lease liability	107	30
Total liabilities	4,460	5,324
Redeemable common stock	4,494	-
Stockholders' equity	22,067	37,263
Total liabilities and stockholders' equity	$ 31,021	$ 42,587