Cyclacel Pharmaceuticals Reports Fourth Quarter and Full Year 2011 Financial Results

Conference Call Scheduled March 29, 2012 at 4:30 p.m. Eastern Time

BERKELEY HEIGHTS, N.J., March 29, 2012 (GLOBE NEWSWIRE) -- Cyclacel Pharmaceuticals, Inc. (Nasdaq:CYCC) (Nasdaq:CYCCP) ("Cyclacel" or the "Company") announced today its financial results and business highlights for the fourth quarter and full year 2011. The Company's net loss applicable to common stockholders for the fourth quarter of 2011 was $3.8 million, or $0.07 per basic and diluted share, compared to a net loss applicable to common stockholders of $3.4 million, or $0.07 per basic and diluted, share for the fourth quarter of 2010. For the year ended December 31, 2011, the Company reported a net loss applicable to common stockholders of $16.0 million, or $0.32 per basic and diluted share, compared to a net loss of $19.7 million or $0.52 per basic and diluted share, for the year ended December 31, 2010. As of December 31, 2011, cash and cash equivalents totaled $24.4 million.

"We were pleased in the fourth quarter of 2011 to achieve our major objective of opening the randomized stage of SEAMLESS, a registration-directed, Phase 3 study of sapacitabine in elderly patients with acute myeloid leukemia (AML)," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "The randomized stage was initiated following a favorable review of the available data from a pilot Phase 1/2 study and the lead-in part of SEAMLESS by the independent monitoring committee as provided in our Special Protocol Assessment (SPA) agreement with the US Food and Drug Administration (FDA). Beyond SEAMLESS, we reported encouraging clinical results showing that sapacitabine is active in patients with myelodysplastic syndromes (MDS) after treatment failures of front-line hypomethylating agents and in patients with solid tumors, including those found to be carriers of BRCA mutations."

Fourth Quarter 2011 and Recent Highlights

- Commenced the randomized stage of SEAMLESS, a pivotal Phase 3, registration-directed, trial of sapacitabine oral capsules as a front-line treatment of elderly patients with newly diagnosed AML who are not candidates for intensive induction chemotherapy. SEAMLESS is being conducted under an SPA agreement with the FDA.

- Reported results at the 2011 American Society of Hematology annual meeting, from a pilot, Phase 1/2 clinical trial evaluating the same treatment regimen as used in the active arm of SEAMLESS. The study enrolled 25 patients with AML aged 70 years or older, 76% of which were aged 75 years or older. Thirty-day mortality from all causes was 4% and 60-day mortality 12%. The overall response rate was 40%. Median overall survival was 231 days and 44% of patients were still alive.

- Announced topline response data from an ongoing, multicenter, Phase 2 randomized trial of sapacitabine, in older patients with MDS after treatment failure of hypomethylating agents, such as azacitidine and/or decitabine. Eight patients responded with two complete remissions (CR), two complete remissions with incomplete platelet count recovery (CRp) and four major hematological improvements of platelet counts or neutrophils. More than 50% of the patients are still alive and longer follow-up is needed to assess 1-year survival and overall survival.

- Commenced an investigator-initiated, Phase 2/3 multicenter, randomized trial comparing sapacitabine to low dose cytarabine (the "Pick a Winner Programme LI-1 Trial") in approximately 100 patients aged 60 years or older who are unfit for intensive chemotherapy with previously untreated AML or high risk MDS conducted by the U.K.'s Leukaemia Lymphoma Research and UK National Cancer Research Institute (NCRI) Working Group.[1]

- Commenced an investigator-initiated, Phase 2 trial of sapacitabine in combination with cyclophosphamide and rituximab in patients with previously treated chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) and 11q22-23 deletion at The University of Texas MD Anderson Cancer Center. Deletion at chromosome 11q22-23 is associated with deletion of the Ataxia Telangiectasia Mutated (ATM) gene, an important element of the HRR pathway.[2]

- Announced interim topline data from ongoing clinical studies with sapacitabine in heavily pretreated patients with advanced solid tumors, including Phase 2 single-agent data in non-small cell lung cancer (NSCLC) and Phase 1 data in combination with Cyclacel's seliciclib in breast, ovarian, pancreatic and other cancers. Partial responses (PR) and stable disease were observed in both studies. In the Phase 1 trial, responding patients were found to be carriers of BRCA mutations.

- Held an Analyst & Investor meeting which reviewed sapacitabine's mechanism of action, recent Cyclacel clinical data and

the development plan for sapacitabine.

- Entered into a purchase agreement with certain existing institutional stockholders raising approximately $3.0 million in gross proceeds. The proceeds from the financing will be used to fund ongoing litigation-related expenses on certain intellectual property and otherwise for general corporate purposes.

Cyclacel's Key Milestones for 2012

- Continue enrollment in the SEAMLESS pivotal Phase 3 study of sapacitabine in AML;
- Report updated Phase 2 sapacitabine data in 2nd line MDS following previous treatment with hypomethylating agents;
- Report updated Phase 2 sapacitabine data in AML preceded by MDS following previous treatment with hypomethylating agent(s) for the preceding MDS;
- Report updated Phase 2 sapacitabine data in NSCLC; and
- Report updated Phase 1 sapacitabine and seliciclib combination data in patients with solid tumors.

Fourth Quarter and Full Year 2010 Financial Results

For the fourth quarter of 2011, Cyclacel reported a net loss applicable to common stockholders of $3.8 million, or $0.07 per basic and diluted share, compared to a net loss applicable to common stockholders of $3.4 million, or $0.07 per basic and diluted share, for the fourth quarter of 2010. Total research and development (R&D) expenses in the fourth quarter of 2011 were $2.2 million compared to $1.4 million in the fourth quarter of 2010. The increase in R&D expenses in the fourth quarter of 2011 compared to the fourth quarter of 2010 was primarily related to costs associated with the SEAMLESS Phase 3 clinical trial. Total selling, general and administrative expenses (SG&A) amounted to $1.6 million in the fourth quarter of 2011 compared to $2.0 million for the fourth quarter of 2010. The decrease is primarily due to reduced stock-based compensation costs, consultancy and other professional costs.

For the year ended December 31, 2011, Cyclacel reported a net loss applicable to common stockholders of $16.0 million, or $0.32 per basic and diluted share, compared to a net loss applicable to common stockholders of $19.7 million, or $0.52 per basic and diluted share, for the year ended December 31, 2010. Total product revenues for the years ended December 31, 2011 and 2010 were $0.7 million and $0.6 million, respectively. In 2010, the Company recorded higher than anticipated product returns of approximately $0.2 million, related to expiring product with a two-year shelf-life that were previously sold into the marketplace. Total R&D expenses for the year ended December 31, 2011 were $9.2 million compared to $6.4 million for the year ended December 31, 2010. The $2.8 million increase in expenditures was primarily due to $1.6 million of contractual expenses, resulting from an achievement of a milestone triggered by the opening of enrollment in our SEAMLESS Phase 3 trial, pursuant to our license agreement with Daiichi Sankyo under which we licensed certain patent rights for sapacitabine, and an increase in sapacitabine related clinical trial expenses.

Total SG&A expenses for the year ended December 31, 2011 were $7.5 million compared to $10.1 million for the year ended December 31, 2010. The decrease was primarily due to decreased compensation costs, stock-based compensation charges and rent for our former Bothell, Washington facility, the lease for which terminated in December 2010. Total other income and expense, net, for the year ended December 31, 2011 was $0.6 million of income, compared to $0.4 million of expense for the same period in 2010. The net loss applicable to common stockholders for the year ended December 31, 2011, was $16.0 million, or $0.32 per basic and diluted share, compared to net loss applicable to common stockholders of $19.7 million, or $0.52 per basic and diluted share for the same period in 2010. The net loss for the year ended December 31, 2010 included a $3.5 million non-cash expense, with respect to a deemed dividend on convertible exchangeable preferred shares when these shares were converted into common stock during 2010.

Cash and cash equivalents totaled $24.4 million as of December 31, 2011. Cyclacel expects that its cash resources are sufficient to meet anticipated short-term working capital needs and fund on-going sapacitabine clinical trials for at least the next twelve months.

Conference call and Webcast Information:

Cyclacel will conduct a conference call on March 29, 2012 at 4:30 p.m. Eastern Time to review the fourth quarter and year-end 2011 results. Conference call and webcast details are as follows:

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 63215634

For the live and archived webcast, please visit the Corporate Presentations and Events 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 Acute Myeloid Leukemia (AML)

AML is a cancer of the blood cells that progresses rapidly and if not treated, could be fatal in a few months. AML is generally a disease of older people and is uncommon before the age of 40. The average age of a patient with AML is about 67 years. There are more than 12,300 new cases of AML, of which about half are elderly, and nearly 9,000 deaths are caused by this cancer each year in the United States. A recently published review of The University of Texas MD Anderson Cancer Center's historical experience with front-line intensive induction chemotherapy for AML patients aged 70 years or older, excluding patients with favorable karyotypes, demonstrated that while 45% achieved a complete remission, median overall survival was only 4.6 months and was associated with a 4-week death rate of 26% and an 8-week death rate of 36% (Kantarjian, H, et al, *Blood*, DOI 10.1182/blood-2010-03-276485).

About sapacitabine

Sapacitabine (CYC682), an orally-available nucleoside analogue, is currently being evaluated in SEAMLESS, a registration-directed, Phase 3 trial in elderly patients with newly diagnosed acute myeloid leukemia (AML), Phase 2 trials in patients with hematological malignancies, including myelodysplastic syndromes (MDS), cutaneous T-cell lymphoma (CTCL), chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL), and non-small cell lung cancer (NSCLC) and in a Phase 1 trial in combination with seliciclib in patients with advanced solid tumors. Sapacitabine acts through a novel DNA single-strand breaking mechanism, leading to production of DNA double strand breaks (DSBs) and/or checkpoint activation. Unrepaired DSBs cause cell death. Repair of sapacitabine-induced DSBs is dependent on the homologous recombination DNA repair (HRR) pathway. Both sapacitabine and CNDAC, its major metabolite, have demonstrated potent anti-tumor activity in preclinical studies.

Over 350 patients have received sapacitabine in Phase 2 studies in AML, MDS, CTCL and NSCLC. Sapacitabine has been administered to approximately 170 patients in five Phase 1 studies with both hematological malignancies and solid tumors. In June 2009 at the Annual Meeting of the American Society of Hematology (ASH), Cyclacel reported data from a randomized Phase 2, single-agent study of sapacitabine including promising 1-year survival in elderly patients with AML aged 70 years or older. In June 2011 at the Annual Meeting of the American Society of Clinical Oncology (ASCO), Cyclacel reported data from a pilot Phase 1/2 study including promising response rate, low 4-week and 8-week mortality in elderly patients with AML aged 70 years or older receiving sapacitabine alternating with decitabine. The FDA and the European Medicines Agency have designated sapacitabine as an orphan drug for the treatment of both AML and MDS. Sapacitabine is part of Cyclacel's pipeline of small molecule drugs designed to target and stop uncontrolled cell division.

About Cyclacel Pharmaceuticals, Inc.

Cyclacel is a biopharmaceutical company developing oral therapies that target the various phases of cell cycle control for the treatment of cancer and other serious diseases. Sapacitabine (CYC682), an orally-available, cell cycle modulating, nucleoside analogue, is in the SEAMLESS Phase 3 trial being conducted under an SPA with the FDA for the front-line treatment of AML in the elderly and Phase 2 studies for myelodysplastic syndromes, lung cancer and chronic lymphocytic leukemia. Seliciclib (CYC202 or R-roscovitine), an orally-available, CDK (cyclin dependent kinase) inhibitor, is in Phase 2 studies for the treatment of lung cancer and nasopharyngeal cancer and in a Phase 1 trial in combination with sapacitabine. Cyclacel's ALIGN Pharmaceuticals subsidiary markets directly in the U.S. Xclair® Cream for radiation dermatitis, Numoisyn® Liquid and Numoisyn® Lozenges for xerostomia. Cyclacel's strategy is to build a diversified biopharmaceutical business focused in hematology and oncology based on a portfolio of commercial products and a development pipeline of novel drug candidates. Please visit www.cyclacel.com for additional information.

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.

[1] For more information please refer to: http://www.controlled-trials.com/ISRCTN40571019.

[2] For more information please refer to: http://clinicaltrials.gov/ct2/show/NCT01253460.

CYCLACEL PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	For the three months ended December 31,		Year ended December 31,		Period from August 13, 1996 (inception) to December 31,
	2010	2011	2010	2011	2011
			($000s)		
Revenues:					
Collaboration and research and development revenue	—	—	100	—	3,100
Product revenue	142	175	574	699	3,021
Grant revenue	(5)	—	12	—	3,648
	137	175	686	699	9,769
Operating expenses:					
Cost of goods sold	108	87	418	360	1,752
Research and development	1,445	2,201	6,414	9,206	185,799
General and administrative	2,015	1,630	10,120	7,521	89,487
Goodwill and intangibles impairment	—	—	—	—	7,934
Restructuring costs	—	—	—	—	2,634
Total operating expenses	3,568	3,918	16,952	17,087	287,606
Operating loss	(3,431)	(3,743)	(16,266)	(16,388)	(277,837)
Other income (expense):					
Costs associated with aborted 2004 IPO	—	—	—	—	(3,550)
Payment under guarantee	—	—	—	—	(1,652)
Change in valuation of derivative	—	(20)	—	(20)	(328)
Change in valuation of warrants	105	(14)	(338)	629	6,699
Warrant re-pricing	—	—	—	—	(44)
Foreign exchange gains/(losses)	(5)	(15)	(68)	(74)	(4,329)
Interest income	13	12	37	45	13,725
Interest expense	(3)	—	(43)	—	(4,677)
Total other income (expense), net	110	(37)	(412)	580	5,844
Loss before taxes	**(3,321)**	**(3,780)**	**(16,678)**	**(15,808)**	**(271,993)**
Income tax benefit	151	122	657	565	18,444
Net loss	**(3,170)**	**(3,658)**	**(16,021)**	**(15,243)**	**(253,549)**
Dividends on preferred ordinary shares	—	—	—	—	(38,123)
Deemed dividend on convertible exchangeable preferred shares	—	—	(3,515)	—	(3,515)
Dividend on convertible exchangeable preferred shares	(182)	(182)	(167)	(728)	(3,657)
Net loss applicable to common stockholders	(3,352)	(3,840)	(19,703)	(15,971)	(298,844)

Net loss per share — basic and diluted	$(0.07)	$(0.07)	$(0.52)	$(0.32)
Weighted average common shares outstanding	45,913,399	54,216,324	37,844,695	50,301,144

CYCLACEL PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

	As of December 31, 2010	As of December 31, 2011
ASSETS	**($000s)**	**($000s)**
Current assets:		
Cash and cash equivalents	29,495	24,449
Inventory	174	182
Prepaid expenses and other current assets	1,382	1,200
Total current assets	31,051	25,831
Property, plant and equipment (net)	408	167
Total assets	31,459	25,998
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	1,723	1,763
Accrued and other current liabilities	4,132	4,664
Warrants liability	680	71
Total current liabilities	6,535	6,498
Total liabilities	6,535	6,498
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized at December 31, 2010 and 2011, respectively; 1,213,142 shares issued and outstanding at December 31, 2010 and 2011, respectively. Aggregate preference in liquidation of $13,344,562 and $13,708,505 at December 31, 2010 and December 31, 2011, respectively	1	1
Common stock, $0.001 par value; 100,000,000 shares authorized at December 31, 2010 and 2011, respectively; 46,564,914 and 54,220,458 shares issued and outstanding at December 31, 2010 and 2011, respectively	47	54
Additional paid in capital	266,666	276,452
Accumulated other comprehensive loss	31	57
Deficit accumulated during the development stage	(241,821)	(257,064)
Total stockholders' equity	24,924	19,500
Total liabilities and stockholders' equity	31,459	25,998

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