March 27, 2013

Cyclacel Pharmaceuticals Reports Fourth Quarter and Full Year 2012 Financial Results

Conference Call Scheduled March 27, 2013 at 4:30 p.m. Eastern Time

BERKELEY HEIGHTS, N.J., March 27, 2013 (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 2012. The Company's net loss applicable to common stockholders for the fourth quarter of 2012 was $4.9 million, or $0.59 per basic and diluted share, compared to a net loss applicable to common stockholders of $3.8 million, or $0.50 per basic and diluted share, for the fourth quarter of 2011. For the year ended December 31, 2012, the Company reported a net loss applicable to common stockholders of $13.9 million, or $1.68 per basic and diluted share, compared to a net loss of $16.0 million or $2.22 per basic and diluted share, for the year ended December 31, 2011. As of December 31, 2012, cash and cash equivalents totaled $16.4 million.

"In 2012 we continued to make progress with the SEAMLESS Phase 3 study of sapacitabine in Acute Myeloid Leukemia (AML). At a year-end review the independent committee overseeing SEAMLESS identified no safety or efficacy concerns and recommended that the study should continue as planned," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "Sapacitabine's potential in other indications continues to evolve. Recent data from a Phase 2 study demonstrated that sapacitabine nearly doubled expected survival of patients with myelodysplastic syndromes (MDS) after treatment failure of hypomethylating agents. In a Phase 1 study, sapacitabine, in combination with Cyclacel's seliciclib, showed antitumor activity in cancer patients found to be carriers of BRCA mutations. We plan to report updated data from both on-going studies as soon as mature follow-up is reached. We have broadened sapacitabine's patent estate with certain claims supporting market exclusivity to 2030. We continue to prudently manage our cash needs and have received an aggregate of $4.4 million through our Aspire Capital agreement and a government grant of $1.9 million supporting development of CYC065, our second-generation cyclin dependent kinase (CDK) inhibitor."

Fourth Quarter 2012 and Recent Highlights

Sapacitabine in Acute Myeloid Leukemia

- Randomized as of today 162 patients or approximately 33% of the projected number of patients in SEAMLESS.
- Convened the second meeting of the independent Data Safety Monitoring Board (DSMB) of the SEAMLESS, Phase 3, randomized, registration-directed study of sapacitabine in elderly patients with AML. The DSMB recommended that the study should continue as planned after reviewing available data from 119 randomized patients. The DSMB noted that no safety or efficacy concerns were identified. SEAMLESS is being conducted under a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA). The DMSB will conduct additional periodic reviews and will perform a futility assessment once 212 events are observed.
- Pooled updated survival data from the Phase 1/2 pilot study and the lead-in phase of SEAMLESS evaluating the sequential regimen of sapacitabine and decitabine were presented at the 54th American Society of Hematology conference. The data demonstrated median overall survival of 238 days, or approximately 8 months. Forty-six patients with a median age of 77 years (range 70-90) were treated with alternating cycles of sapacitabine and decitabine. Thirty-three patients (72%) were 75 years or older. Sixteen patients (35%) survived 1 year or longer. The number of patients alive at 3 months was 38 (83%), 6 months 30 (65%), 12 months 16 (35%) and 18 months 12 (26%). Among 33 patients (72%) who are 75 years or older, median overall survival was 263 days, or approximately 9 months, and 1-year survival was 36%.
- Results published in The Lancet Oncology showed promising response rate and overall survival observed in elderly patients aged 70 years or older with newly diagnosed AML or AML in first relapse enrolled in a Phase 2 study of single-agent sapacitabine.

Sapacitabine in Myelodysplastic Syndromes

- Reported results at The Eighth Annual Hematologic Malignancies 2012 Conference from the Phase 2 randomized trial of sapacitabine in older patients with intermediate-2 or high-risk MDS after treatment failure of front-line hypomethylating (HMA) agents, such as azacitidine and/or decitabine. The data showed that sapacitabine nearly doubled expected survival in this population. The study enrolled 63 patients aged 60 years or older with intermediate-2 or high-risk MDS. Median overall survival for all patients in the three arms was 252 days (approximately 8 months). Median overall survival for 41 of 63 patients with 10% to 19% blasts in their bone marrow was 274 days or approximately 9 months. Twenty-two percent of patients were still alive.

Sapacitabine in Solid Tumors

- Reported at the 2012 American Society of Clinical Oncology (ASCO) Annual Meeting interim data from an open label, single arm, Phase 1 escalation trial of sapacitabine, in combination with seliciclib, Cyclacel's CDK inhibitor, as an orally-administered sequential treatment regimen in heavily-pretreated patients with advanced solid tumors. The regimen showed early evidence of antitumor activity in particular in cancer patients found to be carriers of BRCA mutations.

Other highlights

- The personalized medicine potential of sapacitabine was presented at the 8th National Cancer Research Institute Cancer Conference. Translational findings demonstrated the potential for sapacitabine to be used alone or in combination to treat homologous recombination repair (HRR) defective tumors, such as cancers with ATM or BRCA defects.
- Issued U.S. Patent 8,349,792 and European Patent 2,101,790. Both patents include claims to combination treatment of sapacitabine with HDAC (histone deacetylase) inhibitors. The patents provide exclusivity until June 2029 and December 2027 respectively. The patents include claims to combinations of sapacitabine and HDAC inhibitors, pharmaceutical compositions comprising sapacitabine and HDAC inhibitors, and methods of treating various cancers including leukemias, lymphomas and lung cancer with such compositions.
- Issued U.S. Patent 8,124,593 which grants claims to a specified method of administration of sapacitabine with certain claims supporting market exclusivity to 2030 adding to existing composition of matter patents.
- Received a grant award of approximately $1.9 million from the UK Government's Biomedical Catalyst to complete investigational new drug (IND)-directed preclinical development of CYC065, a novel, orally available, second generation, CDK inhibitor.
- Entered into a common stock purchase agreement with Aspire Capital Fund, LLC (Aspire). Aspire committed to purchase up to $20 million of Cyclacel's common stock from time to time as directed by Cyclacel over two years at formula prices based on the market price at the time of each sale.
- Entered into separate Securities Exchange Agreements with two stockholders pursuant to which the Company issued an aggregate 748,455 shares of its common stock to the stockholders in exchange for delivery to the Company of an aggregate 417,003 shares of the Company's 6% Exchangeable Convertible Preferred Stock.
- Issued a court order on March 6, 2013 by the United States District Court for the District of Delaware ordering a Stipulation and Order For Stay as to all pending dates on the court's calendar for a period of thirty (30) days in the pending litigation between Cyclacel Pharmaceuticals, Inc. and Celgene Corporation regarding four of the Company's patents claiming the use of romidepsin injection in T-cell lymphomas and Celgene's use and administration of its ISTODAX® (romidepsin for injection) product. The stay relates to all proceedings, including the 'Markman' (or claim construction) hearing previously scheduled for March 14, 2013.

Cyclacel's Key Milestones for 2013

- Continue enrollment in the SEAMLESS pivotal, Phase 3 study in AML;
- Report upcoming DSMB reviews of SEAMLESS;
- Report Phase 2, updated survival data for sapacitabine in MDS following treatment failure of hypomethylating agents;
- Announce registration-directed, clinical development plan for sapacitabine in MDS following treatment failure of hypomethylating agents;
- Report updated Phase 1 sapacitabine and seliciclib combination data in patients with solid tumors;
- Report outcome of 'Markman' patent construction hearing on romidepsin intellectual property litigation.

Financial Highlights

For the fourth quarter of 2012, Cyclacel reported a net loss applicable to common stockholders of $4.9 million, or $0.59 per basic and diluted share, compared to a net loss applicable to common stockholders of $3.8 million, or $0.50 per basic and diluted share, for the fourth quarter of 2011. Total research and development (R&D) expenses in the fourth quarter of 2012 were $2.0 million compared to $2.2 million in the fourth quarter of 2011. Total general and administrative expenses (G&A) amounted to $2.7 million in the fourth quarter of 2012 compared to $1.4 million for the fourth quarter of 2011. The increase is primarily due to an increase in legal, consultancy and other professional costs and reduced stock-based compensation costs. Total other expense was $0.4 million in the fourth quarter of 2012, which was primarily due to a non-cash consideration related to the stock purchase agreement with Aspire, compared to no expense in 2011.

Cash and cash equivalents totaled $16.4 million as of December 31, 2012. 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 27, 2013 at 4:30 p.m. Eastern Time to review the fourth quarter and year-end 2012 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 19638297

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 sapacitabine

Sapacitabine (CYC682), an orally-available nucleoside analogue, is currently being studied in SEAMLESS, an ongoing, Phase 3, registration-directed trial in elderly patients aged 70 years or older with newly diagnosed AML who are not candidates for or have refused induction chemotherapy. Sapacitabine is also the subject of Phase 2 trials in patients with hematological malignancies, including AML, myelodysplastic syndromes (MDS), cutaneous T-cell lymphoma (CTCL), chronic lymphocytic leukemia and small lymphocytic lymphoma, and non-small cell lung cancer (NSCLC), and 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 650 patients have received sapacitabine in clinical studies in patients with AML, MDS, CTCL, NSCLC, hematological malignancies and solid tumors. At the 2012 ASH Annual Meeting, data from the pilot study and lead-in phase of SEAMLESS showed promising response rate, overall survival and low 30-day and 60-day mortality in elderly patients with AML aged 70 years or older receiving sapacitabine alternating with decitabine. Data, presented at The Eighth Annual Hematologic Malignancies 2012 Conference, from an ongoing, multicenter, Phase 2 randomized trial of single-agent oral sapacitabine capsules in older patients with intermediate-2 or high-risk myelodysplastic syndromes (MDS) after treatment failure of front-line hypomethylating agents, such as azacitidine and/or decitabine, showed sapacitabine nearly doubled expected survival of elderly patients with MDS after front-line therapy failure. Results 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, were published in *The Lancet Oncology* in November 2012. In a Phase 1 study, sapacitabine, in combination with Cyclacel's seliciclib, showed antitumor activity in cancer patients found to be carriers of BRCA mutations. 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, Cyclacel's most advanced product candidate, is the subject of SEAMLESS, a Phase 3 trial being conducted under an SPA with the FDA as front-line treatment for acute myeloid leukemia (AML) in the elderly, and other studies for myelodysplastic syndromes (MDS), chronic lymphocytic leukemia (CLL) and solid tumors including breast, lung, ovarian and pancreatic cancer. Cyclacel's strategy is to build a diversified biopharmaceutical business focused in hematology and oncology based on 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.

CYCLACEL PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(In $000s, except share and per share amounts)

(Unaudited)

	Three Months Ended December 31,		Year Ended December 31,		Period from August 13, 1996 (inception) to December 31,
	2011	2012	2011	2012	2012
Revenues:					
Collaboration and research and development revenue	$ —	$ —	$ —	$ —	$ 3,100
Grant revenue	—	5	—	69	3,717
Total revenues	—	5	—	69	6,817
Operating expenses:					
Research and development	2,201	1,996	9,206	6,592	192,391
Selling, general and administrative	1,406	2,663	6,542	8,580	89,411
Goodwill and intangible impairment	—	—	—	—	2,747
Restructuring costs	—	—	—	—	2,634
Total operating expenses	3,607	4,659	15,748	15,172	287,183
Operating loss	(3,607)	(4,654)	(15,748)	(15,103)	(280,366)
Other income (expense):					
Costs associated with aborted 2004 IPO	—	—	—	—	(3,550)
Payment under guarantee	—	—	—	—	(1,652)
Non-cash consideration with stock purchase agreement	—	(423)	—	(423)	(423)
Change in valuation of Economic Rights	—	(50)	—	(23)	(23)
Change in valuation of other liabilities measured at fair value	(34)	—	609	51	6,378
Foreign exchange (losses)/gains	(15)	55	(74)	292	(4,005)
Interest income	12	5	45	22	13,747
Interest expense	—	—	—	—	(4,567)
Other income	—	—	—	77	77
Total other income (expense).	(37)	(413)	580	(4)	5,982
Loss from continuing operations before taxes	(3,644)	(5,067)	(15,168)	(15,107)	(274,384)
Income tax benefit	122	637	565	1,351	19,795
Net loss from continuing operations	(3,522)	(4,430)	(14,603)	(13,756)	(254,589)
Discontinued operations:					
(Loss) income from discontinued operations, net of tax of $0 for the three months and year ended December 31, 2011 and $337 for the three months and year ended December 31, 2012	(136)	(334)	(640)	570	(12,146)
Net loss	(3,658)	(4,764)	(15,243)	(13,186)	(266,735)
Dividends on preferred ordinary shares	—	—	—	—	(38,123)
Deemed dividend on convertible exchangeable preferred shares	—	—	—	—	(3,515)
Dividend on convertible exchangeable preferred shares	(182)	(182)	(728)	(728)	(4,385)
Net loss applicable to common shareholders	$ (3,840)	$ (4,946)	$ (15,971)	$ (13,914)	$ (312,758)

Net loss per share, continuing operations — Basic and diluted	$ (0.48)	$ (0.55)	$ (2.13)	$ (1.75)
Net income (loss) per share, discontinued operations — Basic and diluted	$ (0.02)	$ (0.04)	$ (0.09)	$ 0.07
Net loss per share — Basic and diluted	$ (0.50)	$ (0.59)	$ (2.22)	$ (1.68)
Weighted average common shares outstanding	7,673,096	8,429,269	7,185,877	8,291,802

CYCLACEL PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In $000s, except share amounts)

(Unaudited)

	As of December 31 2011	As of December 31 2012
ASSETS		
Current assets:		
Cash and cash equivalents	$ 24,449	$ 16,412
Prepaid expenses and other current assets	1,069	1,599
Current assets of discontinued operations	313	861
Total current assets	25,831	18,872
Property, plant and equipment (net)	167	129
Long-term assets of discontinued operations	—	353
Total assets	$ 25,998	$ 19,354
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,717	$ 2,259
Accrued liabilities and other current liabilities	4,183	5,601
Economic rights	—	1,120
Other liabilities measured at fair value	71	20
Current liabilities of discontinued operations	527	335
Total current liabilities	6,498	9,335
Total liabilities	6,498	9,335
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized at December 31, 2011 and December 31, 2012; 1,213,142 shares issued and outstanding at December 31, 2011 and December 31, 2012. Aggregate preference in liquidation of $13,708,505 and $14,436,390 at December 31, 2011 and December 31, 2012, respectively	1	1
Common stock, $0.001 par value; 100,000,000 shares authorized at December 31, 2011 and December 31, 2012; 7,745,780 and 8,686,484 shares issued and outstanding at December 31, 2011 and December 31, 2012, respectively	8	9
Additional paid-in capital	276,498	280,211
Accumulated other comprehensive loss	57	48
Deficit accumulated during the development stage	(257,064)	(270,250)
Total stockholders' equity	19,500	10,019
Total liabilities and stockholders' equity	$ 25,998	$ 19,354

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