



March 25, 2014

Cyclacel Pharmaceuticals Reports Fourth Quarter and Full Year 2013 Financial Results

European Expansion of SEAMLESS Phase 3 Study Initiated; Potentially Trebling Participating Sites

-- Conference Call Scheduled March 25, 2014 at 4:30 p.m. EDT --

BERKELEY HEIGHTS, N.J., March 25, 2014 (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 2013. The Company's net loss applicable to common shareholders for the fourth quarter of 2013 was \$3.6 million, or \$0.19 per basic and diluted share, compared to a net loss applicable to common shareholders of \$4.9 million, or \$0.59 per basic and diluted share, for the fourth quarter of 2012. For the year ended December 31, 2013, the Company reported a net loss applicable to common shareholders of \$19.5 million, or \$1.28 per basic and diluted share, compared to a net loss applicable to common shareholders of \$13.9 million or \$1.68 per basic and diluted share, for the year ended December 31, 2012. As of December 31, 2013, cash and cash equivalents totaled \$31.1 million.

"We are pleased to report initiation of our first European study centers as we execute on our plan to potentially treble the number of sites in our Phase 3 SEAMLESS trial in AML," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "Following the recent European launch of decitabine, we conducted a pre-qualification survey in which more than 100 European hospitals expressed interest in participating in SEAMLESS. We expect to open approximately 80 of these, resulting in a trebling of SEAMLESS sites, including 39 in the US. With just US sites enrolling until now, we are approaching the fourth periodic safety review by the study's DSMB. With a total of over 100 sites participating in the AML study, we estimate completion of enrollment by the end of this year and topline data next year. Following Phase 2 data reported at ASH 2013, demonstrating a near doubling of expected median survival of older patients with MDS after treatment failure of hypomethylating agents, we are designing a randomized, controlled trial of sapacitabine in this underserved patient population. We plan to disclose our registration plans for this new indication later this year after consultation with regulatory and clinical experts and evaluation of feasibility."

Fourth Quarter 2013 and Recent Highlights

Drug Development

-- Sapacitabine in SEAMLESS, pivotal, Phase 3 study for first-line treatment in elderly patients with acute myeloid leukemia (AML):

- Study enrollment, from just US centers until now, is approximately 60%; expansion into Europe initiated; expected to approximately treble the total number of enrolling sites.
- The independent Data Safety Monitoring Board (DSMB) performed the third periodic safety review and recommended that the study should continue as planned after reviewing available data from 212 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).

-- Sapacitabine in MDS

- Reported primary endpoint data from an ongoing, open-label, multicenter, randomized Phase 2 trial of sapacitabine in older patients with MDS after treatment failure of front-line hypomethylating agents, such as azacitidine and/or decitabine. The 7-day dose regimen (Arm G) appears to be a better schedule with a one-year survival rate of 38%, median overall survival of approximately 10 months and response rate of 19%. The 30-day mortality from all causes for all patients is 5%. Data were presented in December 2013 during the American Society of Hematology (ASH) Meeting and Exposition.

-- Sapacitabine exclusivity

- Reported that the US Patent and Trademark Office (USPTO) issued multiple patents extending the market exclusivity of sapacitabine to at least 2030. The patents claim, among others, methods of use for sapacitabine for the treatment of AML and MDS, including the dosing regimen used in SEAMLESS, as well as claims to methods of treating cancer comprising sapacitabine together with DNA methyltransferase inhibitors, including azacitidine and decitabine, and

combination treatment of sapacitabine with HDAC (histone deacetylase) inhibitors in various cancers.

Cyclacel's Key Milestones for 2014

-- Sapacitabine in SEAMLESS:

- Continue enrollment and expand study into Europe to at least double enrolling sites
- Report next interim periodic DSMB review at approximately 300 patients enrolled
- Report DSMB interim analysis for fertility after 212 events
- Complete enrollment

-- Sapacitabine in MDS:

- Announce registration-directed, clinical development plan in MDS following treatment failure after hypomethylating agents

-- Sapacitabine in solid tumors:

- Report updated Phase 1 sapacitabine and seliciclib combination data in patients with solid tumors including those carrying the gBRCA mutation

-- Advance early pipeline

Financial Highlights

Revenue from the three months and year ended December 31, 2013, was \$0.3 million and \$1.1 million as compared to \$5,000 and \$69,000 for the same period of the previous year. The revenue is a grant award from the UK government, totaling \$1.9 million, to progress CYC065, the Company's Cyclin Dependent Kinase inhibitor, to IND.

Research and development expenses increased to \$2.5 million and \$11.3 million for the three months and year ended December 31, 2013, as compared to \$2.0 million and \$6.6 million for the same period of the previous year. The increases in 2013 were primarily due to enrollment-related activities of the SEAMLESS registration study, including drug manufacturing costs and other outsourced services.

General & administrative expenses for the three months and year ended December 31, 2013, were \$1.8 million and \$7.8 million as compared to \$2.7 million and \$8.6 million for the previous year. The decreases in 2013 were primarily due to lower legal and professional fees.

The income tax benefit, which is a refund the Company elects to receive from the UK tax authorities based on eligible research and development expenses, was \$1.7 million for the year ended December 31, 2013 compared to \$1.4 million for the previous year.

Net loss from continuing operations for the fourth quarter of 2013 was \$3.6 million compared to a net loss from continuing operations of \$4.4 million for the fourth quarter of 2012. Net loss from continuing operations for the year ended December 31, 2013 was \$10.2 million compared to \$13.8 million for the year ended December 31, 2012. Net loss applicable to common shareholders was \$3.6 million, or \$0.19 per basic and diluted share, and \$19.5 million, or \$1.28 per basic and diluted share, for the fourth quarter and year ended December 31, 2013 compared to a net loss applicable to common shareholders of \$4.9 million, or \$0.59 per basic and diluted share, and \$13.9 million, or \$1.68 per basic and diluted share for the fourth quarter and year ended December 31, 2012.

Cash position at year end was \$31.1 million compared to \$16.4 million at the end of 2012. The increase is attributable to net proceeds from an underwritten offering of \$19.0 million, \$8.6 million from sales of common stock through the equity line with Aspire Capital LLC and \$5.5 million from the sale to Celgene Corporation of romidepsin-related patents, a non-core program, offset by \$18.2 million used in operating activities.

Conference call and Webcast Information:

Cyclacel will conduct a conference call on March 25, 2014 at 4:30 p.m. Eastern Time to review the fourth quarter and year-end 2013 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 9003037

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 analog, is 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 in Phase 2 trials in patients with 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 (HR) pathway. Both sapacitabine and CNDAC, its major metabolite, have demonstrated potent anti-tumor activity in preclinical studies.

Over 800 patients have received sapacitabine in clinical studies in patients with AML, MDS, CTCL, NSCLC, hematological malignancies and solid tumors. Data, presented at the 2012 American Society of Hematology Meeting and Exposition (ASH), 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. 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. Data, presented at the 2013 ASH 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. In a Phase 1 study, sapacitabine, in combination with Cyclacel's seliciclib, showed antitumor activity, including durable partial responses, in patients with breast, ovarian and pancreatic cancers found to be carriers of gBRCA 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 and in particular those carrying gBRCA mutations. 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.

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

	Three Months Ended		Year Ended		Period from
	December 31,	December 31,	December 31,	December 31,	August 13, 1996 (inception) to December 31,
	2012	2013	2012	2013	2013
Revenues:					
Collaboration and research and development revenue	\$ —	\$ —	\$ —	\$ —	\$ 3,100
Grant revenue	5	299	69	1,084	4,801
Total revenues	<u>5</u>	<u>299</u>	<u>69</u>	<u>1,084</u>	<u>7,901</u>
Operating expenses:					
Research and development	1,996	2,491	6,592	11,277	203,668
General and administrative	2,663	1,782	8,580	7,781	97,192
Goodwill and intangible impairment	—	—	—	—	2,747
Restructuring costs	—	—	—	—	2,634
Total operating expenses	<u>4,659</u>	<u>4,273</u>	<u>15,172</u>	<u>19,058</u>	<u>306,241</u>
Operating loss	<u>(4,654)</u>	<u>(3,974)</u>	<u>(15,103)</u>	<u>(17,974)</u>	<u>(298,340)</u>
Other income (expense):					
Costs associated with aborted 2004 IPO	—	—	—	—	(3,550)
Payment under guarantee	—	—	—	—	(1,652)
Non-cash consideration associated with stock purchase agreement	(423)	(98)	(423)	(98)	(521)
Change in valuation of Economic Rights	(50)	—	(23)	570	547
Change in valuation of other liabilities measured at fair value	—	—	51	—	6,378
Foreign exchange gains (losses)	55	18	292	62	(3,943)
Interest income	5	1	22	13	13,760
Interest expense	—	—	—	—	(4,567)
Other income, net	—	27	77	5,547	5,624
Total other (expense) income, net	<u>(413)</u>	<u>(52)</u>	<u>(4)</u>	<u>6,094</u>	<u>12,076</u>
Loss from continuing operations before taxes	<u>(5,067)</u>	<u>(4,026)</u>	<u>(15,107)</u>	<u>(11,880)</u>	<u>(286,264)</u>
Income tax benefit	637	452	1,351	1,670	21,465
Net loss from continuing operations	<u>(4,430)</u>	<u>(3,574)</u>	<u>(13,756)</u>	<u>(10,210)</u>	<u>(264,799)</u>
Discontinued operations:					
Income(loss) from discontinued operations	3	21	907	91	(11,718)
Income tax on discontinued operations	(337)	(6)	(337)	(34)	(371)
Net (loss) income from discontinued operations.	<u>(334)</u>	<u>15</u>	<u>570</u>	<u>57</u>	<u>(12,089)</u>
Net loss	<u>(4,764)</u>	<u>(3,559)</u>	<u>(13,186)</u>	<u>(10,153)</u>	<u>(276,888)</u>
Dividend on preferred ordinary shares	—	—	—	—	(38,123)
Deemed dividend on convertible exchangeable preferred shares	—	—	—	(9,027)	(12,542)

Dividend on convertible exchangeable preferred shares	<u>(182)</u>	<u>(50)</u>	<u>(728)</u>	<u>(298)</u>	<u>(4,683)</u>
Net loss applicable to common shareholders	<u>\$ (4,946)</u>	<u>\$ (3,609)</u>	<u>\$ (13,914)</u>	<u>\$ (19,478)</u>	<u>\$ (332,236)</u>
Net loss per share, continuing operations - Basic and diluted	<u>\$ (0.55)</u>	<u>\$ (0.19)</u>	<u>\$ (1.75)</u>	<u>\$ (1.29)</u>	
Net (loss) income per share, discontinued operations - Basic and diluted	<u>\$ (0.04)</u>	<u>\$ 0.00</u>	<u>\$ 0.07</u>	<u>\$ 0.00</u>	
Net loss per share - Basic and diluted	<u>\$ (0.59)</u>	<u>\$ (0.19)</u>	<u>\$ (1.68)</u>	<u>\$ (1.28)</u>	
Weighted average common shares outstanding.	<u>8,429,269</u>	<u>19,037,890</u>	<u>8,291,802</u>	<u>15,158,225</u>	

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

	As of December 31, 2012	As of December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 16,412	\$ 31,146
Prepaid expenses and other current assets	1,599	3,388
Current assets of discontinued operations	<u>861</u>	<u>639</u>
Total current assets	18,872	35,173
Property, plant and equipment (net)	129	275
Long-term assets of discontinued operations	<u>353</u>	<u>72</u>
Total assets	<u>\$ 19,354</u>	<u>\$ 35,520</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,259	\$ 2,545
Accrued and other current liabilities	5,601	4,672
Economic Rights measured at fair value	1,120	-
Other liabilities measured at fair value	20	20
Current liabilities of discontinued operations	<u>335</u>	<u>260</u>
Total current liabilities	<u>9,335</u>	<u>7,497</u>
Total liabilities	<u>9,335</u>	<u>7,497</u>
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized at December 31, 2012 and 2013; 1,213,142 and 335,273 shares issued and outstanding at December 31, 2012 and 2013, respectively. Aggregate preference in liquidation of \$14,436,390 and \$3,989,749 at December 31, 2012 and 2013, respectively	1	-
Common stock, \$0.001 par value; 100,000,000 shares authorized at December 31, 2012 and 2013; 8,686,484 and 19,369,332 shares issued and outstanding at December 31, 2012 and 2013, respectively	9	19
Additional paid-in capital	280,211	317,543
Accumulated other comprehensive (income) loss	48	(109)
Deficit accumulated during the development stage	<u>(270,250)</u>	<u>(289,430)</u>
Total stockholders' equity	<u>10,019</u>	<u>28,023</u>

Total liabilities and stockholders' equity

\$ 19,354 \$ 35,520