



Cyclacel Pharmaceuticals Reports Third Quarter 2011 Financial Results

SEAMLESS Phase 3 trial design simplified; FDA confirmed that SPA remains valid

Conference Call Scheduled November 14, 2011 at 4:30 p.m. Eastern Time

BERKELEY HEIGHTS, N.J., Nov. 14, 2011 (GLOBE NEWSWIRE) -- Cyclacel Pharmaceuticals, Inc. (Nasdaq:CYCC) (Nasdaq:CYCCP) (Cyclacel or the Company), announced today its financial results and business highlights for the third quarter of 2011. The Company's net loss applicable to common shareholders for the third quarter of 2011 was \$3.6 million, or \$0.07 per basic and diluted share, compared to a net loss applicable to common shareholders of \$4.0 million or \$0.11 per basic and diluted share, for the third quarter of 2010. For the nine months ended September 30, 2011, the Company reported a net loss applicable to common shareholders of \$12.1 million, or \$0.25 per basic and diluted share, compared to a net loss of \$16.3 million, or \$0.47 per basic and diluted share, for the nine months ended September 30, 2010.

The Company also announced that it has implemented a simplification in the design of the on-going SEAMLESS Phase 3 study of sapacitabine as front-line treatment in elderly patients with Acute Myeloid Leukemia (AML) converting it into a 2-arm from the original 3-arm design, following the recent recommendation by the SEAMLESS Data Safety Monitoring Board, or DSMB, to continue SEAMLESS. The 2-arm design compares sapacitabine dosed sequentially with decitabine versus decitabine alone. Cyclacel has received written confirmation from the US Food and Drug Administration (FDA) that, following the modification in the trial design, the previously agreed Special Protocol Assessment (SPA) agreement remains valid.

"The original 3-arm design of SEAMLESS was based on the information available at that time," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "Since then the safety and efficacy data from the pilot Phase 1/2 study have encouraged us to amend the protocol into a 2-arm design, comparing the regimen of sapacitabine dosed sequentially with decitabine versus decitabine alone. The objective of the amendment is to increase the chance of detecting an improvement in survival while staying within our existing budget and forecasted time frame. We have been encouraged by the pace of early enrollment of patients and investigator interest in SEAMLESS. We are looking forward to achieving our patient enrollment targets in SEAMLESS as our highest priority."

Design Details of SEAMLESS Phase 3 study in AML

SEAMLESS is a registration-directed Phase 3 study of sapacitabine as front-line treatment in patients with newly diagnosed AML *de novo* or AML preceded by antecedent hematological disorder who were not treated with hypomethylating agents, aged 70 years or older, who are not candidates for or have refused intensive induction chemotherapy. The study will enroll approximately 485 patients who will be randomized 1:1 or about 243 patients into each of two arms: sapacitabine dosed sequentially with decitabine versus decitabine alone. A prespecified interim analysis for futility will be performed and reviewed by the DSMB when 212 deaths have occurred. The primary objective is to detect with 90% power an improvement in overall survival at a statistical significance level of p-value equal to or less than 0.05. The original 3-arm design required a statistical significance level of p-value equal to or less than 0.025 for each of two pairwise comparisons. The secondary objectives are to compare the response rates in terms of complete remission (CR), complete remission with incomplete platelet recovery (CRp), partial response (PR), hematologic improvement (HI), stable disease (SD) and their corresponding durations, transfusion requirements, number of days in hospital, one-year survival and safety.

Business Highlights

- Data from the lead-in portion of the SEAMLESS Phase 3 trial of sapacitabine in elderly patients with AML confirmed the safety and tolerability observed in the pilot Phase 1/2 study and met the criteria prespecified in the protocol and SPA to proceed to the randomized stage of the study;
- DSMB recommended continuation of the SEAMLESS Phase 3 trial of sapacitabine in elderly patients with AML who are not eligible for intensive chemotherapy;
- Amended SEAMLESS Phase 3 trial protocol to a 2-arm design: sapacitabine alternating with decitabine versus decitabine;
- Received written confirmation from FDA that the SPA agreement regarding SEAMLESS, which was announced in September 2010, remains valid for the 2-arm design;

- Commenced an investigator-initiated, Phase 2 trial of sapacitabine in combination with cyclophosphamide and rituximab in patients with relapsed chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) hematological malignancies and 11q22-23 deletion at The University of Texas MD Anderson Cancer Center; and
- Raised net proceeds of \$9.3 million in an underwritten registered direct offering.

Product Revenue

Cyclacel's product revenues were comprised of sales of Xclair® Cream for radiation dermatitis and Numoisyn® Liquid and Numoisyn® Lozenges for xerostomia. Product revenues for the quarter and nine months ended September 30, 2011 were \$0.2 million and \$0.5 million, respectively, compared to approximately \$0.2 million and \$0.4 million, respectively, for the same periods in 2010.

Costs and Expenses

Total operating expenses remained the same at \$4.2 million for the each of the three months ended September 30, 2011 and 2010. For the nine months ended September 30, 2011, total operating expenses were \$13.2 million, which included a \$1.6 million milestone payment to Daiichi-Sankyo, as compared to \$13.4 million for the same period in 2010.

Research and Development Expenses

Research and development expenses for the third quarter of 2011 increased to \$2.1 million as compared to \$1.5 million for the same period in 2010. For the nine months ended September 30, 2011, research and development expenses were \$7.0 million as compared to \$5.0 million for the same period in 2010. The increase was primarily due to a \$1.6 million milestone payment in the first quarter payable to Daiichi-Sankyo as part of our contractual obligation resulting from sapacitabine's entry into Phase 3 trials and clinical trial costs related to SEAMLESS.

Selling, General and Administrative Expenses

Total selling, general and administrative expenses decreased by approximately \$0.5 million from \$2.6 million for the third quarter of 2010 to \$2.1 million for the third quarter of 2011. For the nine months ended September 30, 2011 total selling, general and administrative expenses were \$5.9 million as compared to \$8.1 million for the same period in 2010. The decrease of \$2.2 million in expenses was primarily attributable to a net decrease in professional and consultancy costs, the elimination of costs related to a facility lease that expired in December 2010 and a decrease in compensation-related costs.

Cash and Cash Equivalents

As of September 30, 2011, Cyclacel's cash and cash equivalents were \$27.7 million compared to \$29.5 million as of December 31, 2010.

NASDAQ notification

Received notification from NASDAQ that the Company failed to comply with the minimum \$1 bid price requirement for continued listing set forth in Marketplace Rule 5450(a)(1).

Upcoming Milestones

- Presentation of updated sapacitabine data from the Phase 1/2 pilot study in elderly patients with AML at the 2011 American Society of Hematology (ASH) annual meeting;
- Report interim data from the Phase 2 study of sapacitabine in non-small cell lung cancer (NSCLC);
- Report interim data from the Phase 1 combination study of sapacitabine and seliciclib in patients with solid tumors; and
- Report patient biomarker analysis from the APPRAISE Phase 2b randomized discontinuation study of seliciclib in patients with NSCLC.

Conference call and Webcast Information:

Cyclacel will conduct a conference call on November 14, 2011 at 4:30 p.m., Eastern Time, to review the third quarter and nine months ended September 30, 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 25156473.

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.

Analyst & Institutional Investor Meeting

The Company will hold an Analyst and Institutional Investor meeting on December 7, 2011 in New York City. The meeting will include a discussion of treatment alternatives for elderly patients with acute myeloid leukemia by an expert hematologist, the design of the SEAMLESS Phase 3 trial and a discussion of the potential utility of sapacitabine in non-small cell lung cancer (NSCLC) by a thoracic oncology expert. Details of the event will be provided in a forthcoming announcement.

About Acute Myeloid Leukemia (AML)

AML is a cancer of 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 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 elderly AML patients aged 70 years or older demonstrated that while 45% of patients achieved a complete remission, median overall survival was only 4.6 months and 36% of patients died within the first 8 weeks of treatment, underscoring the unmet need in this patient setting. Currently there are no therapies approved for use in elderly AML patients not eligible for intensive chemotherapy.

About Special Protocol Assessment (SPA)

A Special Protocol Assessment is a binding written agreement with the FDA that the sponsor's proposed trial protocol design, clinical endpoints and statistical analyses are acceptable to support regulatory approval. Final marketing approval depends on efficacy results, adverse event profile and an evaluation of the benefit/risk of a treatment as demonstrated in the trial. For further information regarding the SPA process, please visit the FDA website, www.fda.gov.

About Sapacitabine

Sapacitabine (CYC682), an orally-available nucleoside analogue, is currently being evaluated in the SEAMLESS registration-directed, Phase 3 trial in front-line elderly acute myeloid leukemia (AML) and Phase 2 trials in patients with hematological malignancies and solid tumors. Sapacitabine acts through a dual mechanism, interfering with DNA synthesis by causing single-strand DNA breaks and inducing arrest of cell cycle progression mainly at G2-Phase. Both sapacitabine and CNDAC, its major metabolite, have demonstrated potent anti-tumor activity in preclinical studies. Over 300 patients have received sapacitabine in Phase 2 studies in AML, myelodysplastic syndromes (MDS), cutaneous T cell lymphoma (CTCL) and non-small cell lung cancer (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 October 2011 the independent Data Safety Monitoring Board (DSMB) of SEAMLESS recommended that the Phase 3 study should continue as planned. The U.S. 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 Phase 3 development for the front-line treatment of acute myeloid leukemia 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 products, 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 current filings that have been filed 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
(Unaudited)

	For the three months ended September 30		For the nine months ended September 30		Period from August 13, 1996 (inception) to December 31,
	2010	2011	2010	2011	2010
	(\$000s)				
Revenues:					
Collaboration and research and development revenue	—	—	100	—	3,100
Product revenue	159	164	432	524	2,846
Grant revenue	—	—	16	—	3,648
	<u>159</u>	<u>164</u>	<u>548</u>	<u>524</u>	<u>9,594</u>
Operating expenses:					
Cost of goods sold	76	95	310	273	1,665
Research and development	1,469	2,066	4,968	7,005	183,598
General and administrative	2,612	2,051	8,103	5,891	87,857
Goodwill and intangibles impairment	—	—	—	—	7,934
Restructuring costs	—	—	—	—	2,634
Total operating expenses	<u>4,157</u>	<u>4,212</u>	<u>13,381</u>	<u>13,169</u>	<u>283,688</u>
Operating loss	(3,998)	(4,048)	(12,833)	(12,645)	(274,094)
Other income (expense):					
Costs associated with aborted 2004 IPO	—	—	—	—	(3,550)
Payment under guarantee	—	—	—	—	(1,652)
Change in valuation of derivative	—	—	—	—	(308)
Change in valuation of warrants	73	440	(443)	643	6,713
Warrant re-pricing	—	—	—	—	(44)
Foreign exchange gains/(losses)	(25)	28	(63)	(59)	(4,314)
Interest income	7	9	24	33	13,713

Interest expense	<u>(7)</u>	<u>—</u>	<u>(40)</u>	<u>—</u>	<u>(4,677)</u>
Total other income (expense), net	<u>48</u>	<u>477</u>	<u>(522)</u>	<u>617</u>	<u>5,881</u>
Loss before taxes	<u>(3,950)</u>	<u>(3,571)</u>	<u>(13,355)</u>	<u>(12,028)</u>	<u>(268,213)</u>
Income tax benefit	<u>143</u>	<u>126</u>	<u>506</u>	<u>443</u>	<u>18,322</u>
Net loss	<u>(3,807)</u>	<u>(3,445)</u>	<u>(12,849)</u>	<u>(11,585)</u>	<u>(249,891)</u>
Dividends on preferred ordinary shares	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>	<u>(38,123)</u>
Deemed dividend on convertible exchangeable preferred shares	<u>—</u>	<u>—</u>	<u>(2,915)</u>	<u>—</u>	<u>(3,515)</u>
Dividend on convertible exchangeable preferred shares	<u>(182)</u>	<u>(182)</u>	<u>(585)</u>	<u>(546)</u>	<u>(3,475)</u>
Net loss applicable to common stockholders	<u>(3,989)</u>	<u>(3,627)</u>	<u>(16,349)</u>	<u>(12,131)</u>	<u>(295,004)</u>
Net loss per share — basic and diluted	<u>\$(0.11)</u>	<u>\$(0.07)</u>	<u>\$(0.47)</u>	<u>\$(0.25)</u>	
Weighted average common shares outstanding	<u>37,030,436</u>	<u>53,711,678</u>	<u>35,125,522</u>	<u>48,981,743</u>	

CYCLACEL PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	<u>As of</u>	<u>As of</u>
	<u>December</u>	<u>September</u>
	<u>31, 2011</u>	<u>30, 2011</u>
	<u>(\$000s)</u>	<u>(\$000s)</u>
ASSETS		
Current assets:		
Cash and cash equivalents	29,495	27,675
Inventory	174	165
Prepaid expenses and other current assets	<u>1,382</u>	<u>941</u>
Total current assets	31,051	28,781
Property, plant and equipment (net)	<u>408</u>	<u>165</u>
Total assets	<u>31,459</u>	<u>28,946</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	1,723	1,101
Accrued and other current liabilities	4,132	4,797
Warrants liability	<u>680</u>	<u>37</u>
Total current liabilities	<u>6,535</u>	<u>5,935</u>
Total liabilities	<u>6,535</u>	<u>5,935</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized at December 31, 2010 and September 30, 2011; 1,213,142 shares issued and outstanding at December 31, 2010 and September 30, 2011; Aggregate preference in liquidation (including undeclared cumulative dividends) of \$13,344,562 and 13,526,533 at December 31, 2010 and September 30, 2011, respectively.	1	1
Common stock, \$0.001 par value; 100,000,000 shares authorized at December 31, 2010 and September 30, 2011, respectively; 46,564,914 and 54,212,643 shares issued and outstanding at December 31, 2010 and September 30, 2011, respectively	47	55
Additional paid in capital	266,666	276,312
Accumulated other comprehensive loss	31	49
Deficit accumulated during the development stage	<u>(241,821)</u>	<u>(253,406)</u>
Total stockholders' equity	<u>24,924</u>	<u>23,011</u>
Total liabilities and stockholders' equity	<u>31,459</u>	<u>28,946</u>

Investors/Media:

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