January 7, 2013

Cyclacel Reviews 2012 Achievements and Announces Key Business Objectives for 2013

- SEAMLESS DSMB recommended that the study should continue as planned -

- Company to Presentat the Biotech Showcase™ 2013 Conference on Monday January 7, 2013 at 3:15 pm PT -

BERKELEY HEIGHTS, N.J., Jan. 7, 2013 (GLOBE NEWSWIRE) -- Cyclacel Pharmaceuticals, Inc. (Nasdaq:CYCC) (Nasdaq:CYCCP) (Cyclacel or the Company) today reviewed 2012 achievements and provided an outline of the Company's key clinical development objectives for 2013, which will be highlighted at the Company's presentation during the Biotech Showcase™ 2013 Conference at 3:15 pm Pacific Time on Monday, January 7, 2013, at the Parc 55 Wyndham Hotel in San Francisco, CA.

"During 2012, we advanced the clinical development of sapacitabine in multiple indications. For example, in our SEAMLESS, Phase 3, registration-directed study, of sapacitabine in elderly patients with newly diagnosed acute myeloid leukemia (AML), our lead indication, we exceeded 100 patients enrolled with 37 trial sites open," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "In addition, the independent committee overseeing SEAMLESS recently recommended that the study should continue as planned and identified no safety or efficacy concerns. We are encouraged by the continued investigator interest in SEAMLESS and plan to open additional sites during 2013. Updated survival data in AML with sequential administration of sapacitabine and decitabine is promising and provided further support for the SEAMLESS Phase 3 study. With regard to other disease indications, recent Phase 2 data demonstrated that sapacitabine nearly doubled expected survival of elderly patients with myelodysplastic syndromes (MDS) after treatment failure of hypomethylating agents. For 2013, we are focused on executing our product development plan for sapacitabine in AML, MDS and other cancers using, among other funds, the proceeds of the recent funding agreement with Aspire Capital. We are also advancing CYC065, our second-generation cyclin dependent kinase (CDK) inhibitor, enabled by a $1.9 million grant from the UK Government."

2012 Milestones and Accomplishments

Drug Development

- Convened the second periodic 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 recently 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).

- Reported results at the 2012 American Society of Hematology Annual Meeting from the pilot study and lead-in phase of SEAMLESS evaluating the same treatment regimen of sapacitabine dosed sequentially with decitabine, as used in the experimental arm of SEAMLESS. Among 46 patients treated median overall survival is 238 days, or approximately 8 months. The number of patients still alive at 3 months was 38 (83%), at 6 months 30 (65%), at 12 months 16 (35%) and at 18 months 12 (26%). Sixteen patients (35%) survived 1 year or longer. Among 33 patients (72%) who are 75 years or older, median overall survival is 263 days, or approximately 9 months, and 1-year survival is 36%. Nineteen patients (41%) responded including 10 with complete responses (CRs). Median time to response is 2 cycles, i.e., one cycle of decitabine and one cycle of sapacitabine (range 1-10). Twenty-seven patients (59%) received 5 or more cycles. Two dose-limiting toxicities were observed. Thirty-day mortality from all causes was 4%. Sixty-day mortality from all causes was 13%.

- Published in The Lancet Oncology peer-reviewed journal results from a Phase 2 randomized trial of single-agent sapacitabine in elderly patients aged 70 years or older with newly diagnosed AML or AML in first relapse.

- Presented updated data at two separate sessions at The Eighth Annual Hematologic Malignancies 2012 Conference from an ongoing, multicenter, Phase 2 randomized trial of sapacitabine in older patients with intermediate-2 or high-risk MDS after treatment failure of front-line hypomethylating agents, such as azacitidine (Vidaza®) and/or decitabine (Dacogen®). Median overall survival to date for all 63 patients in the Phase 2 study is approximately 8 months. For 41 out of 63 patients with 10% to 19% blasts in their bone marrow median overall survival is approximately 9 months. Twenty-two percent of patients are still alive and longer follow-up is needed to assess 1-year survival and overall survival of each arm. Earlier data from this study were presented at the American Society of Clinical Oncology (ASCO) 2012 Annual Meeting.

- Participated in the Phase 2 portion of the UK investigator-sponsored, Phase 2/3 randomized trial comparing, among other drugs, sapacitabine versus low dose cytarabine. Approximately 55 patients aged 60 years or older with previously untreated AML or high-risk MDS were treated with sapacitabine with approximately half in the "Pick a Winner Programme" and half in the "LI-1 Trial" protocols. Recently, the study's Data Monitoring & Ethics Committee did not recommend sapacitabine for the next phase of the LI-1 Trial based on the criterion that sapacitabine as a single agent was not likely to double one year survival versus low-dose cytarabine. The company-sponsored, ongoing SEAMLESS study of previously untreated AML patients aged 70 years or older is comparing the regimen of sapacitabine dosed sequentially with decitabine versus decitabine alone with the aim of reducing the risk of death by 27.5%.

- Presented new data at the ASCO 2012 Annual Meeting from an open label, single arm, Phase 1 escalation trial of a combination of the Company's drug candidates, sapacitabine and seliciclib, as an orally-administered, sequential treatment regimen in heavily-pretreated patients with advanced solid tumors. The maximum tolerated dose (MTD) for the regimen was reported as sapacitabine 50 mg twice daily for 7 days followed by seliciclib 1200 mg twice daily for 3 days. Among 19 patients treated at the MTD, 3 partial responses (PR) occurred in patients with breast, ovarian and pancreatic cancer and 1 stable disease in a patient with ovarian cancer. Thirteen of the 19 patients are BRCA-mutation carriers, of which 7 were poly ADP-ribose polymerase (PARP) inhibitor-naïve and 6 had prior PARP inhibitor treatment. All 4 responding patients were PARP inhibitor-naïve, BRCA-mutation carriers. Stable disease was achieved in 6 additional patients treated with the dosing schedules below MTD.

- Presented preclinical translational research results for sapacitabine at the 103rd Annual Meeting of the American Association of Cancer Research (AACR). The findings further support the potential for sapacitabine to be used alone or in combinations to treat homologous recombination repair (HRR) defective tumors, such as ATM or BRCA defective tumors.

- Highlighted the personalized medicine potential of sapacitabine at the 8th National Cancer Research Institute Cancer Conference with translational findings demonstrating the combination potential of sapacitabine in patients with BRCA1/2 or HRR pathway defects.

- Issued U.S. Patent No. 8,124,593 by The U.S. Patent and Trademark Office, which grants claims to a specified method of administration of sapacitabine, adding to existing composition of matter patents and supporting market exclusivity out to 2030.

- 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.

- Presented preclinical results for Cyclacel's Polo-Like Kinase 1 (Plk1) and Aurora A kinase inhibitors, at the 103rd Annual Meeting of the AACR. Also, separately, reported biological characterization of a potent and selective, preclinical-stage, Plk1 inhibitor, from Cyclacel's novel Plk1 inhibitor series with sensitivity in a panel of esophageal cancer cell lines correlating with p53 status, a potential biomarker to identify responders in future clinical trials.

Corporate Developments

- Entered into a common stock purchase agreement with Aspire Capital Fund, LLC (Aspire). Aspire has committed to purchase up to $20 million of Cyclacel's common stock from time to time as directed by Cyclacel over the next two years at formula prices based on the market price at the time of each sale. Under the agreement, Aspire purchased $1 million of Cyclacel common stock at a per share price equal to the closing price of $6.29 on December 13, 2012 the date immediately prior to the closing date.

- Entered into a purchase agreement with certain existing institutional stockholders raising $2.9 million, net of certain fees and expenses. The proceeds from the financing are being used to fund ongoing litigation-related expenses involving specified Cyclacel intellectual property.

- Entered into a Securities Exchange Agreement with Tang Capital Partners, LP (Tang) pursuant to which the Company issued 631,561 shares of its common stock to Tang in exchange for Tang's delivery to the Company of 351,990 shares of the Company's 6% Exchangeable Convertible Preferred Stock. Tang approached the Company with the proposed exchange transaction. The terms of the exchange were determined by arms-length negotiations between the parties. Following this transaction a total of 861,152 shares of Preferred Stock will remain outstanding.

- Entered into an agreement with Sinclair Pharmaceuticals Limited to terminate the distribution agreements relating to the promotion and sale of Xclair®, Numoisyn® Lozenges and Numoisyn® Liquid in exchange for a minimum of approximately $1 million in royalty payments through September 2015.

- Implemented a 1-for-7 reverse stock split of shares of common stock in order to satisfy the $1.00 minimum bid

requirement for continued listing on the NASDAQ Global Market.

2013 Key Upcoming Business Objectives

- Continue enrollment in SEAMLESS pivotal, Phase 3 study;
- Report next interim periodic DSMB review of SEAMLESS;
- Report updated Phase 2 sapacitabine data in 2nd line MDS following treatment failure after hypomethylating agents;
- Announce registration-directed, clinical development plan for sapacitabine in 2nd line MDS following treatment failure after hypomethylating agents;
- Report updated Phase 1 sapacitabine and seliciclib combination data in patients with solid tumors;
- Report updated Phase 2 sapacitabine data in non-small cell lung cancer (NSCLC); and
- Report outcome of so-called Markman patent construction hearing on romidepsin intellectual property litigation.

For the live and archived webcast of the Company's presentation at the Biotech Showcase™ 2013 San Francisco conference 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 biopharmaceutical company developing oral therapies that target the various phases of cell cycle control for the treatment of cancer and other serious diseases. The Company's most advanced oral product candidate, sapacitabine, is the subject of SEAMLESS, a Phase 3 trial being conducted under an SPA with the FDA as front-line treatment of acute myeloid leukemia (AML) in the elderly and Phase 2 studies for AML, myelodysplastic syndromes (MDS), chronic lymphocytic leukemia (CLL) and solid tumors including breast, lung, ovarian and pancreatic cancer. Cyclacel's pipeline includes seliciclib, a CDK inhibitor, in Phase 2 for lung and nasopharyngeal cancer and in Phase 1 in combination with sapacitabine; and CYC065, a second generation CDK inhibitor, in IND-directed development. 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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