Cyclacel Provides Corporate Update at OneMedForum Conference

BERKELEY HEIGHTS, N.J., Jan. 11, 2012 (GLOBE NEWSWIRE) -- Cyclacel Pharmaceuticals, Inc. (Nasdaq:CYCC) (Nasdaq:CYCCP) ("Cyclacel" or the "Company") today summarized its 2011 achievements and set forth the Company's key business objectives for 2012 in a presentation given by Spiro Rombotis, President and Chief Executive Officer, at the 5th Annual OneMedForum Conference held this week in San Francisco, California.

"During 2011, we continued to make important progress advancing the development of sapacitabine in both hematologic malignancies and solid tumors with multiple clinical studies currently in progress," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "We are encouraged by the pace of patient enrollment and investigator interest in SEAMLESS, our pivotal Phase 3 trial of sapacitabine as a front-line treatment of acute myeloid leukemia (AML), which was initiated in 2011. For 2012, we are focused on executing our product development plan for sapacitabine with a target of having approximately fifty clinical trial sites open."

Review of 2011 Accomplishments

Sapacitabine

- Opened enrollment of the SEAMLESS pivotal Phase 3, randomized, registration-directed, trial for the Company's sapacitabine oral capsules as a front-line treatment of elderly patients aged 70 years or older with newly diagnosed AML who are not candidates for intensive induction chemotherapy. SEAMLESS is being conducted under a Special Protocol Assessment (SPA) agreement that Cyclacel reached with the U.S. Food and Drug Administration (FDA). SEAMLESS builds on promising response rate and overall survival (OS) 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 and a Phase 1/2 clinical study examining the safety and efficacy of sapacitabine administered sequentially with decitabine.

- Reported results at the 2011 American Society of Clinical Oncology meeting from a pilot study evaluating the same treatment regimen of sapacitabine dosed sequentially with decitabine, as used in the active arm of SEAMLESS. In the multicenter, pilot Phase 1/2 clinical trial examining the safety and effectiveness of oral sapacitabine administered sequentially with decitabine, 30-day mortality from all causes was 4.5% and 60-day mortality from all causes was 9.5%. The overall response rate (ORR) was 34.8%.

- 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 to proceed to the randomized stage of the study. The independent Data Safety Monitoring Board (DSMB) of SEAMLESS recommended that the study should enter the randomized stage as planned.

- Reported updated results at the 2011 American Society of Hematology meeting, from the Phase 1/2 clinical trial evaluating the same treatment regimen of sapacitabine dosed sequentially with decitabine, as the active arm in SEAMLESS. The study enrolled 25 patients 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 from all causes was 12%. The ORR rate was 40%. Median OS is 231 days and 44% of patients are still alive.

- Presented preclinical results for sapacitabine at the 2011 American Association for Cancer Research meeting describing potential mechanism-based drug combinations. Together with previous publications these findings further support the rationale for clinical testing of sapacitabine with inhibitors of DNA repair in both solid tumors and hematological malignancies.

- 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. Previous findings show that cells with HRR pathway defects are particularly sensitive to sapacitabine. Sapacitabine may therefore be of particular benefit to patients with ATM-defective blood cancers.

- 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.

"We are encouraged that single agent sapacitabine has anti-tumor activity in patients with NSCLC," said Judy H. Chiao, M.D., Vice President, Clinical Development and Regulatory Affairs of Cyclacel. "We have also observed anti-tumor activity of sapacitabine in combination with seliciclib in BRCA-mutation positive patients with breast, pancreatic and ovarian cancers, which may be directly related to sapacitabine's enhanced activity against cancer cells that are deficient in the homologous recombination DNA repair (HRR) pathway."

Seliciclib and Second Generation CDK Inhibitors

- Announced the publication of preclinical data in the Proceedings of the National Academy of Sciences (PNAS), demonstrating that cyclin E plays a major role in making Human Epidermal growth factor Receptor 2 positive (HER2+) breast cancer resistant to trastuzumab (Herceptin®), a widely used medicine for breast cancer patients who test positive for HER2. The publication provides a rationale for exploring Cyclacel's orally available CDK inhibitors in this patient population.

- Topline data from the APPRAISE, Phase 2b, randomized discontinuation, double-blinded, placebo-controlled, study of oral seliciclib capsules as a third or more line treatment in patients with NSCLC showed no difference in median progression free survival between the seliciclib and placebo arms (48 versus 53 days respectively), but an increase in median OS favoring seliciclib over placebo (388 versus 218 days respectively). Published pre-clinical work indicated that K-Ras mutational status, cyclin D1 and cyclin E1 protein levels correlated strongly with tumor sensitivity towards seliciclib. In order to explore this possible molecular rationale for the difference in OS, the Company retrospectively collected and analyzed available biopsy samples from APPRAISE patients who granted informed consent. As only 30 patient samples were available from the 152 APPRAISE patients who gave consent, results of the retrospective analysis were insufficient to allow meaningful correlation. A new prospectively designed study is required to test the hypothesis that these biomarkers can predict therapeutic effect of seliciclib in patients with advanced stage NSCLC.

Corporate Developments

- Hosted an Analyst and Institutional Investor meeting to review the clinical development program for sapacitabine including the design of SEAMLESS and provide an expert overview of sapacitabine's mechanism of action and future approaches for clinical investigation, both as a single agent and in combinations, discussion of treatment alternatives for elderly patients with AML by expert hematologists and treatment alternatives for patients with NSCLC who progress on currently available therapies by a thoracic oncology expert.

- Cyclacel raised approximately $10.4 million in gross proceeds through an underwritten offering through the sale of common stock and warrants, before deducting placement agent fees and offering expenses.

Key Upcoming Business Objectives

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

Financial information

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.

For the live and archived webcast of the Company's presentation at the OneMedForum 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 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. 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 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 study 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 seliciclib

Seliciclib is an orally-available CDK inhibitor molecule that selectively inhibits multiple enzyme targets, CDK2, CDK7 and CDK9, which are central to the process of cell division and cell cycle control. Seliciclib treatment has been reported to inhibit the two major DNA double-strand break (DSB) repair pathways, homologous recombination DNA repair (HRR) and non-homologous end joining (NHEJ), by reducing expression of components of each pathway (Federico, M., et al, Mol Cancer, 2010, 9, 208). Seliciclib has been evaluated to date in approximately 380 patients and is currently in randomized Phase 2 trials in patients with previously treated lung cancer and nasopharyngeal cancer.

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 a Phase 3 trial being conducted under a SPA with the U.S. FDA 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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