January 13, 2014

Cyclacel Reviews 2013 Achievements and Announces Key Business Objectives for 2014

- Company to Present at the Biotech Showcase(TM) 2014 Conference at 9:30 a.m. PST, Monday, Jan. 13, 2014 -

BERKELEY HEIGHTS, N.J., Jan. 13, 2014 (GLOBE NEWSWIRE) -- Cyclacel Pharmaceuticals, Inc. (Nasdaq:CYCC) (Nasdaq:CYCCP) (Cyclacel or the Company) today reviewed 2013 achievements and provided an outline of the Company's key clinical development objectives for 2014, which will be highlighted at the Company's presentation during the Biotech Showcase™ 2014 Conference at 9:30 a.m. PST, Monday, Jan. 13, 2014, at the Parc 55 Wyndham HotelUnion Square at 55 Cyril Magnin Street in San Francisco.

"During 2013, we continued to progress with the clinical development of sapacitabine in acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS)," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "In our SEAMLESS, Phase 3, registration-directed study of sapacitabine in elderly patients with newly diagnosed AML, our lead indication, we have achieved 50% enrollment and expect to at least double enrolling sites by expanding into Europe. In addition, the independent Data Safety Monitoring Board overseeing SEAMLESS recently recommended, after a review of 212 randomized patients, that the study should continue as planned and identified no safety or efficacy concerns. With regard to MDS, Phase 2 data reported at ASH 2013 showed a one year survival outcome at 38% with a near doubling of expected median survival of older patients with MDS after treatment failure of hypomethylating agents."

"For 2014, we are focused on completing the enrollment of SEAMLESS by the end of the year. The Company is funded to achieve this milestone. Additionally, we plan to advance the clinical development of sapacitabine in MDS and other cancers using existing resources, including the funding agreement with Aspire Capital, and advance our earlier pipeline, including CYC065, our second-generation cyclin dependent kinase (CDK) inhibitor, which is supported by government grant funding."

2013 Milestones and Accomplishments

Drug Development

- Sapacitabine in SEAMLESS, our pivotal Phase 3 study for first-line treatment in elderly patients with AML:
    - Study enrolment reached 50% in 2013; expansion into Europe expected to at least double the 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 at a poster on Dec. 8, 2013 during the 2013 American Society of Hematology (ASH) Meeting and Exposition held in New Orleans.
- Sapacitabine in solid tumors
    - Announced updated data showing that sapacitabine has activity against a majority of ovarian cancer samples taken from patients, including resistant tumors. The data were reported at a poster presentation during the American Association of Cancer Research (AACR) conference "Advances in Ovarian Cancer from concept to clinic" held in Sep. 2013.
    - Reported updated data from an open label, single arm, Phase 1 escalation trial of sapacitabine and the company's seliciclib, a CDK inhibitor, as an all-oral, sequentially-administered regimen in heavily-pretreated

patients with advanced solid tumors. Of 38 patients with incurable solid tumors and adequate organ function enrolled in the study, 16 were found to be BRCA mutation carriers. Four patients with BRCA-deficient, breast, ovarian and pancreatic cancers achieved confirmed partial responses with promising durability, with the longest lasting more than 78 weeks. Stable disease of 12 weeks or more was observed in eight additional patients, including two with BRCA-deficient ovarian and breast cancers, lasting 64 weeks and 21 weeks respectively. The data was reported at the at the 104th Annual Meeting of the AACR and the AACR Annual Meeting Program Committee selected this study for inclusion at a press conference highlighting major developments reported during the Annual Meeting.

- 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.
- Early pipeline
    - Announced that oral seliciclib (a CDK2, -7, -9 inhibitor) is to be evaluated in an investigator-initiated clinical study to treat rheumatoid arthritis (RA) supported by an approximately $1.5 million grant from the U.K.'s Medical Research Council. Enabled by the clinical development experience in solid tumors, investigators believe that seliciclib's mechanism of action and oral administration route may be of benefit in treating patients with RA.
    - Progressed investigational new drug (IND)-directed preclinical development of CYC065, a novel, orally available, second generation, CDK inhibitor, supported by a grant award of approximately $1.9 million from the UK Government's Biomedical Catalyst.
    - Received a grant award of approximately $3.7 million from the UK Government's Biomedical Catalyst to complete IND-directed preclinical development of CYC140, a novel, orally available, Polo-Like Kinase 1 (Plk1) inhibitor.

Corporate Developments

- Received $5.5 million from Celgene Corporation (Celgene) for the sale of four Cyclacel romidepsin-related patents to Celgene and dismissal of all claims in the related patent litigation.
- Closed an underwritten offering for net proceeds of approximately $19.0 million after deduction of offering expenses.
- Converted 877,869 shares of preferred stock into 1,684,471 shares of common stock and as a result, 335,273 shares of preferred stock remain outstanding.
- Entered into a common stock purchase agreement with Aspire Capital Fund, LLC (Aspire) where 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.

2014 Key Upcoming Business Objectives

- 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 futility after 212 events
    - Complete enrollment
- Sapacitabine in MDS:
    - Announce registration-directed, clinical development plan in 2nd line 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

For the live and archived webcast of the Company's presentation at the Biotech Showcase™ 2014 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 seven 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. 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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