Cyclacel Pharmaceuticals reports financial results for first quarter 2011

-- Conference Call Scheduled May 12, 2011 at 4:30 p.m. Eastern Time --

Berkeley Heights, NJ, May 12, 2011 – Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP; Cyclacel or the Company), a biopharmaceutical company developing oral therapies that target the various phases of cell cycle control for the treatment of cancer and other serious disorders, today reported its financial results and business highlights for the first quarter ended March 31, 2011.

The net loss for the first quarter of 2011 was $4.6 million as compared to a net loss of $5.1 million for the same period in 2010. As of March 31, 2011, cash and cash equivalents totaled $25.4 million. The Company's net loss applicable to common stockholders for the first quarter of 2011 was $4.8 million or $0.10 per basic and diluted share, compared to a net loss applicable to common stockholders of $5.8 million or $0.18 per basic and diluted share for the first quarter of 2010.

"With the SEAMLESS Phase 3 trial open and enrolling patients with acute myeloid leukemia, or AML, Cyclacel is a step closer to our ultimate goal of getting sapacitabine to patients in need and potentially the market," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "We are looking forward to the upcoming presentation at a major medical conference of pilot study data of sapacitabine in combination with decitabine in patients with AML. In addition, we expect to report later this year additional sapacitabine data in hematological malignancies and non-small lung cancer, or NSCLC, and seliciclib biopsy analysis data in NSCLC. "

Business Highlights

- Opened enrollment of the SEAMLESS pivotal Phase 3 study for 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). The trial builds on promising 1-year survival 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.
- Announced publication of preclinical data in the Proceedings of the National Academy of Sciences, 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 population of patients with breast cancer.
- Presented preclinical results for two Cyclacel clinical compounds, sapacitabine and CY116, at the 102nd Annual Meeting of the American Association of Cancer Research in Orlando, Florida.

First Quarter 2011 Financial Results

Product Revenue

Revenues for the quarter were $0.2 million, compared to $0.3 million for the same period in 2010. Cyclacel's product revenues were comprised of sales of Xclair® Cream for radiation dermatitis and Numoisyn® Liquid and Numoisyn® Lozenges for xerostomia.

Research and Development Expenses

Research and development expenses in the first quarter of 2011 were $3.1 million compared to $2.2 million for the same period in 2010. The increase in costs of $0.9 million is primarily due to $1.6 million of contractual expenses, resulting from the achievement of a milestone triggered by the opening of enrollment in our SEAMLESS trial, pursuant to the Daiichi-Sankyo license under which Cyclacel licenses certain patent rights for sapacitabine. This cost was partially offset by reductions of $0.4 million in stock-based and other employee related compensation.

Selling, General and Administrative Expenses

Total selling, general and administrative expenses for the first quarter of 2011 were $1.8 million, compared to $2.4 million for

the same period in 2010 with the $0.6 million decrease primarily related to professional and consultancy costs.

Cash and Cash Equivalents

As of March 31, 2011, Cyclacel's cash and cash equivalents were $25.4 million compared to $29.5 million as of December 31, 2010. The Company expects that its cash resources are sufficient to meet anticipated short-term working capital needs and fund on-going sapacitabine clinical trials for at least the next twelve months.

Cyclacel's Goals for 2011

- Present pilot study data of sapacitabine in combination with decitabine in patients with AML;
- Present additional sapacitabine data in hematological malignancies both as a single agent and in combination with other anticancer agents;
- Report Data Safety Monitoring Board (DSMB) review of safety data from the SEAMLESS Phase 3 AML study;
- Report top line Phase 2 sapacitabine data in NSCLC; 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 May 12, 2011 at 4:30 p.m. Eastern Time to review the first quarter 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) 642-1687 / international archive: (706) 645-9291
Code for live and archived conference call is 66220600

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.

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), a cell cycle modulating nucleoside analog, is in Phase 3 development for the treatment of acute myeloid leukemia in the elderly under a Special Protocol Assessment agreement with the U.S. Food and Drug Administration, and in Phase 2 studies for myelodysplastic syndromes and lung cancer. Seliciclib (CYC202 or R-roscovitine), a 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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View the full press release in PDF format (316KB)