Cyclacel Pharmaceuticals reports second quarter 2010 financial results

BERKELEY HEIGHTS, NJ – August 5, 2010 – Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP), 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 second quarter of 2010.

Total operating expenses for the quarter and six months ended June 30, 2010 decreased to $4.5 million and $9.2 million, respectively, versus $5.5 million and $11.0 million, respectively, for the same periods in 2009. Cyclacel reported a net loss of $6.5 million, or $0.18 per diluted share for the second quarter of 2010, compared to a net loss of $7.4 million, or $0.36 per diluted share, for the same period in 2009. For the six months ended June 30, 2010, Cyclacel reported a net loss of $12.4 million, or $0.36 per diluted share, compared to a net loss of $12.7 million, or $0.62 per diluted share in the same period in 2009. Cyclacel's financial results for the second quarter of 2010 included a non-cash charge of $2.5 million related to the deemed dividend on the exchange of preferred stock to common stock that occurred during the second quarter. Cyclacel's financial results for the second quarter of 2009 included a non-operating expense of $1.7 million related to payments due as a consequence of the headcount reductions implemented in 2009.

"We are in ongoing dialogue with the Food and Drug Administration (FDA) regarding our Special Protocol Assessment (SPA) request for a randomized, registration-directed, Phase 3 study of sapacitabine in elderly patients with acute myeloid leukemia (AML)," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. “Following the FDA's acceptance that our proposed primary endpoint of overall survival and key design components of our Phase 3 study are eligible for SPA, we have been preparing to initiate the study, subject to FDA action on the SPA, including contacting prospective investigators. We are also excited about the FDA's grant of orphan designation for sapacitabine for both AML and myelodysplastic syndromes (MDS). In addition we presented at ASCO interim Phase 2 data in patients with MDS which demonstrated that sapacitabine is active in patients refractory to hypomethylating agents. We look forward to reporting top line results from the APPRAISE non-small cell lung cancer (NSCLC) Phase 2b trial with seliciclib and also interim NSCLC Phase 2 data with sapacitabine."

Business Highlights

- Granted orphan designation by the FDA for sapacitabine for the treatment of both AML and MDS;
- Presented interim results from a Phase 2 trial of sapacitabine in older patients with MDS at ASCO demonstrating clinical activity in patients refractory to hypomethylating agents;
- Six presentations at AACR Annual Meeting highlighted Cyclacel's innovative and diverse oncology targeted pipeline including data on CYC065, a second-generation CDK inhibitor, with activity against drug-resistant cancers; and
- Cyclacel added to Russell Microcap® Index.

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 six months ended June 30, 2010 were $0.1 million and $0.3 million, respectively, compared to $0.2 million and $0.5 million, respectively, for the same periods in 2009. Product revenues for the second quarter were negatively impacted by return of expiring product with a two-year shelf-life. Our supplier has recently increased product shelf life to three years.

Selling, General and Administrative Expenses

Total selling, general and administrative expenses for the second quarter of 2010 increased to $3.1 million as compared to $2.3 million for the second quarter of 2009. For the six months ended June 30, 2010 total selling, general and administrative expenses were $5.5 million versus $4.5 million for the same period in 2009. The increase in selling, general and administrative expenses was primarily due to increased spending on professional and consultancy costs.

Research and Development Expenses

Cyclacel's research and development expenses for the second quarter of 2010 decreased to $1.3 million as compared to $2.7 million for the same period in 2009. For the six months ended June 30, 2010 research and development expenses were $3.5 million as compared to $5.8 million for the same period in 2009. The $1.4 million decrease in research and development expenses was primarily associated with the Company's lower cost base following headcount reductions in 2008 and 2009 and the concentration of resources on sapacitabine, Cyclacel's lead drug candidate.

Cash and Cash Equivalents

As of June 30, 2010, Cyclacel's cash and cash equivalents were $19.5 million compared to $11.5 million as of December 31, 2009. The Company expects its existing capital resources should be adequate to fund operations and current commitments into 2012.

Upcoming Milestones

- FDA action regarding the SPA for the Phase 3 study of sapacitabine in elderly patients with AML;
- Initiation of Phase 3 study of sapacitabine in elderly patients with AML;
- Report NSCLC interim Phase 2 data with sapacitabine; and
- Report top line results from APPRAISE NSCLC Phase 2b trial with seliciclib.

Conference call and Webcast Information:

Cyclacel management will review second quarter 2010 financial and business highlights on a conference call scheduled for today at 4:30 p.m. Eastern. Conference call and webcast details are as follows:

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 91437070.

Webcast: 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 disorders. Three product candidates are in clinical development: Sapacitabine (CYC682), a cell cycle modulating nucleoside analog, is in Phase 2 studies for the treatment of acute myeloid leukemia in the elderly, 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. CYC116, an Aurora kinase and VEGFR2 inhibitor, is in a Phase 1 trial in patients with solid tumors. 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, the risk that Cyclacel will 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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