Cyclacel Pharmaceuticals reports third quarter 2010 financial results

BERKELEY HEIGHTS, NJ – November 11, 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 diseases, today reported its financial results and business highlights for the third quarter of 2010.

Cyclacel reported a net loss applicable to common shareholders of $4.0 million, or $0.11 per share for the third quarter of 2010, compared to a net loss applicable to common shareholders of $3.4 million, or $0.15 per share, for the same period in 2009. For the nine months ended September 30, 2010, Cyclacel reported a net loss applicable to common shareholders of $16.3 million, or $0.47 per share, compared to a net loss applicable to common shareholders of $16.2 million, or $0.76 per share in the same period in 2009.

“During the quarter we have made important progress with regard to advancing sapacitabine oral capsules into late stage development. We have reached agreement with the FDA regarding a Special Protocol Assessment (SPA) on the design of “SEAMLESS”, our planned, pivotal Phase 3 trial in acute myeloid leukemia (AML),” said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. “We have started to recruit clinical study sites and are pleased to learn that the key features of the Phase 3 study design are acceptable to AML investigators. In addition we have bolstered our balance sheet and continued to develop sapacitabine in patients with myelodysplastic syndromes (MDS) and non-small cell lung cancer (NSCLC). We will be presenting Phase 2 MDS survival data at the annual meeting of the American Society of Hematology in December 2010.”

Business Highlights

- In September 2010, the Company announced that it reached agreement with the U.S. Food and Drug Administration (FDA) under the Special Protocol Assessment (SPA) process on the design of SEAMLESS, a pivotal, randomized Phase 3 trial in elderly patients aged 70 years or older with newly diagnosed AML who are not candidates for intensive induction chemotherapy. The SPA process allows for FDA evaluation of a clinical trial protocol intended to form the primary basis of an efficacy claim in support of a new drug application and provides an agreement that the study design, including trial size, clinical endpoints and/or data analyses are acceptable to the FDA. The primary endpoint of the trial is an improvement in overall survival.
- In October 2010, the Company completed a private placement for net proceeds of approximately $14.1 million after the deduction of offering expenses with the potential for an additional $6.5 million in net proceeds to the Company should the investors exercise their right to acquire additional units at any time up to nine months after closing. The units consist of one share of common stock and 0.5 of a warrant, with each whole warrant representing the right to purchase one share of common stock at an exercise price of $1.92 per share for a period of five years.

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 nine months ended September 30, 2010 were $0.2 million and $0.4 million, respectively, compared to $0.2 million and $0.7 million, respectively, for the same periods in 2009. The decrease in product revenue for nine months ended September 30, 2010 was due to higher than anticipated product returns of approximately $0.2 million, related to expiring product with a two-year shelf-life previously sold into the marketplace. Since the first quarter of 2010, our manufacturer has increased shelf life of certain of our products to three years.

Costs and Expenses

Total operating expenses for the quarter ended September 30, 2010 increased to $4.2 million compared to $3.7 million for the same period in 2009. For the nine months ended September 30, 2010, total operating expenses decreased to $13.4 million compared to $14.7 million for the same period in 2009.

Research and Development Expenses

Cyclacel’s research and development expenses for the third quarter of 2010 increased to $1.5 million as compared to $1.4 million for the same period in 2009. For the nine months ended September 30, 2010 research and development expenses were $5.0 million as compared to $7.2 million for the same period in 2009. The $2.2 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.

Selling, General and Administrative Expenses

Total selling, general and administrative expenses for the third quarter of 2010 increased to $2.6 million as compared to $2.2 million for the third quarter of 2009. For the nine months ended September 30, 2010 total selling, general and administrative expenses were $8.1 million versus $6.7 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.

Cash and Cash Equivalents

As of September 30, 2010, Cyclacel's cash and cash equivalents were $18.5 million compared to $11.5 million as of December 31, 2009. The Company's cash and cash equivalents does not include $14.1 million in net proceeds from the private placement completed in October 2010.

Upcoming Milestones

- Present Phase 2 one-year survival data of sapacitabine in patients with MDS at the annual meeting of the American Society of Hematology in December 2010;
- Initiate the SEAMLESS Phase 3 study of sapacitabine in elderly patients with AML;
- Report top line results from the APPRAISE NSCLC Phase 2b trial of seliciclib; and
- Report interim Phase 2 data of sapacitabine in patients with NSCLC.

Conference call and Webcast Information:

Cyclacel management will review third 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 22901304.

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 diseases. Three product candidates are in clinical development. Sapacitabine (CYC682), a cell cycle modulating nucleoside analog, will be entering 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 is 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. 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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