Cyclacel reports second quarter 2011 financial results

-- Conference Call Scheduled August 11, 2011 at 4:30 p.m. Eastern Time --

Berkeley Heights, NJ, August 11, 2011 – Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP; Cyclacel or the Company), announced today its financial results and business highlights for the second quarter of 2011.

The Company's net loss applicable to common stockholders for the second quarter of 2011 was $3.7 million, or $0.08 per basic and diluted share, compared to a net loss applicable to common stockholders of $6.5 million or $0.18 per basic and diluted share, for the second quarter of 2010. For the six months ended June 30, 2011, the Company reported a net loss applicable to common stockholders of $8.5 million, or $0.18 per basic and diluted share, compared to a net loss of $12.4 million, or $0.36 per basic and diluted share, for the six months ended June 30, 2010.

"We are encouraged by the data presented at the 2011 ASCO meeting from a pilot study evaluating sapacitabine dosed sequentially with decitabine, a treatment regimen that mirrors the lead-in arm of our on-going Phase 3 SEAMLESS study," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "We have recently completed patient enrollment in the lead-in stage of SEAMLESS which reflects continued interest by investigators and patients in our program. Later this year the SEAMLESS Drug Safety Monitoring Board, or DSMB, will conduct its first review of the lead-in data which, if positive, would enable the randomization stage of SEAMLESS to begin. We are excited about our progress toward realizing the potential of sapacitabine and the rest of our innovative pipeline."

Business Highlights

- Completed patient enrollment in the lead-in stage of the sapacitabine Phase 3 SEAMLESS study of elderly patients with AML who are not eligible for intensive chemotherapy.
- Reported results at the 2011 ASCO meeting from a pilot study evaluating the same treatment regimen of sapacitabine dosed sequentially with decitabine, as one of the arms in SEAMLESS, the registration-directed, Phase 3 study of sapacitabine in elderly patients with newly diagnosed acute myeloid leukemia. In the multicenter, 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 was 34.8%.
- Completed an underwritten registered direct offering for an aggregate of 7,617,646 units, at an offering price of $1.36 per unit, for gross proceeds of $10.4 million. Each unit consists of (i) one share of common stock, and (ii) a five-year warrant to purchase 0.5 share of common stock at an exercise price of $1.36 per share, exercisable beginning six months after the date of issuance.
- Amended the sapacitabine licensing agreement with Daiichi Sankyo, whereby Daiichi Sankyo irrevocably waived a termination right it possessed under a provision of the license agreement. The amendment further provides that the royalty on future net sales of sapacitabine be increased by a percentage between 1.25% and 1.50% depending on the level of net sales of sapacitabine realized.
- Continued enrolment in the sapacitabine Phase 2 study in patients with Non-Small Cell Lung Cancer, or NSCLC, who failed at least one prior therapy.
- Continued collection of patient specimens from the APPRAISE randomized, double-blinded, randomized discontinuation, Phase 2b study of seliciclib in patients with NSCLC who failed at least two prior therapies.

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, 2011 were $0.2 million and $0.4 million, respectively, compared to approximately $19,000 and $0.3 million, respectively, for the same periods in 2010.

Costs and Expenses

Total operating expenses for the quarter ended June 30, 2011 decreased to $4.0 million compared to $4.5 million for the same period in 2010. For the six months ended June 30, 2011, total operating expenses decreased to $9.0 million, which included a $1.6 million milestone payment, compared to $9.2 million for the same period in 2010.

Research and Development Expenses

Research and development expenses for the second quarter of 2011 increased to $1.9 million as compared to $1.3 million for the same period in 2010. For the six months ended June 30, 2011, research and development expenses were $4.9 million as compared to $3.5 million for the same period in 2010. The increase was due to a $1.6 million milestone in the first quarter payable to Daiichi-Sankyo as part of our contractual obligation resulting from sapacitabine's entry into Phase 3 trials.

Selling, General and Administrative Expenses

Total selling, general and administrative expenses for the second quarter of 2011 decreased to $2.0 million as compared to $3.1 million for the second quarter of 2010. For the six months ended June 30, 2011 total selling, general and administrative expenses were $3.8 million as compared to $5.5 million for the same period in 2010. The decrease of $1.6 million in expenses was primarily attributable to a net decrease in professional and consultancy costs and, to a lesser extent, a decrease in salaries and also an elimination of costs related to a facility lease that expired in December 2010.

Cash and Cash Equivalents

As of June 30, 2011, Cyclacel's cash and cash equivalents were $20.6 million compared to $29.5 million as of December 31, 2010. The Company's cash and cash equivalents do not include approximately $9.3 million in net proceeds from the underwritten offering completed in July 2011.

Upcoming Milestones

- DSMB decision to enable the commencement of the randomized part of the SEAMLESS pivotal Phase 3 study of sapacitabine in AML;
- Presentation of additional sapacitabine data in hematological malignancies, both as a single agent and in combination with other anticancer agents;
- Presentation of Phase 2 sapacitabine data in NSCLC; and
- 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 August 11, 2011 at 4:30 p.m., Eastern Time, to review the second quarter and six months ended June 30, 2011 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: (855) 859-2056 / international archive: (404) 537-3406.

Code for live and archived conference call is 89030684.

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 front-line treatment of acute myeloid leukemia in the elderly and 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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