Cyclacel Pharmaceuticals reports third quarter 2006 financial results

Short Hills, NJ, November 13, 2006 - Cyclacel Pharmaceuticals, Inc. (Nasdaq: CYCC) (Nasdaq: CYCCP) today reported financial and operating results for the third quarter 2006. The company had a net loss in the quarter of $5.4 million. At the end of the third quarter 2006, the company had $59.7 million in cash, cash equivalents and marketable securities.

“The progress of our lead clinical candidates, seliciclib and sapacitabine, remained in line with our key development milestones, and we strengthened our management team with the addition of John Womelsdorf as Vice President, Business Development,” said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. “We achieved important progress in this quarter with seliciclib, our lead drug, by initiating the APPRAISE randomized, double-blinded Phase IIb study in patients with Non-Small Cell Lung Cancer or NSCLC. Data from APPRAISE is anticipated in late 2007. In addition, we are considering expanding the range of indications addressed by seliciclib by assessing the feasibility of developing the drug as a treatment for nasopharyngeal cancer, or NPC. At present there are no approved medicines for the treatment of NPC and our evaluation suggests that this is an area of great medical need. Current treatments, principally chemotherapy combined with radiotherapy, produce high initial response rates, but there is a high mortality rate after relapse. We expect to provide more details on our plans for NPC in the coming months.”

“We have also been making steady progress with sapacitabine, our second drug. We have been conducting Phase I studies in patients with solid tumors as well as advanced leukemias and myelodysplastic syndromes. Data from both of these studies will be reported in the fourth quarter. Our plan is to enter into Phase II clinical development with this compound in one or more cancer indications in 2007,” noted Mr. Rombotis. “Finally, CYC116, our Aurora kinase and VEGFR2 inhibitor, remains on track for an IND filing before the end of the year.”

Other key highlights from the quarter include:

- In October, the Company strengthened its management team with the appointment of John Womelsdorf, Ph.D., to the position of Vice President, Business Development. Dr. Womelsdorf has more than 20 years of experience in business development roles at Baxter International, Hoffmann-La Roche, and, most recently, Johnson & Johnson (J&J), where he served as Executive Director, Licensing and New Business Development of the Pharmaceuticals Group.
- The Company remains on track with enrollment of the Phase IIb, multi-center, randomized, double-blinded APPRAISE trial which is evaluating the efficacy and safety of the investigational drug seliciclib (CYC202), an orally-available molecule that targets cyclin dependent kinases (CDKs), as a third-line treatment in patients with non-small cell lung cancer (NSCLC).
- The study is co-chaired by Chandra P. Belani, M.D., Professor of Medicine and Co-Director of the Lung and Thoracic Program at the University of Pittsburgh Cancer Institute in Pittsburgh, PA and Alan B. Sandler, M.D., Associate Professor of Medicine at the Vanderbilt-Ingram Cancer Center in Nashville, TN. Approximately 160 patients from 20 centers in the United States will participate in the study. The trial’s primary efficacy endpoint is progression free survival. Secondary endpoints include overall survival, response rate, response duration, safety and tolerability. The study employs a randomized discontinuation design. All patients will receive seliciclib for at least three treatment cycles. Patients who achieve stable disease after three cycles will be randomized to continue on seliciclib or receive placebo with best supportive care. Patients in the placebo group whose disease progresses will be given the option to cross-over and receive seliciclib treatment again.
- The Company has also reported that the Phase I clinical trial of sapacitabine (CYC682), an orally available nucleoside analog, in patients with advanced leukemias or myelodysplastic syndromes (MDS) continues on schedule. The study is being led by Dr. Hagop Kantarjian, Chairman of the Department of Leukemia at The University of Texas M. D. Anderson Cancer Center (UTMDACC) in Houston. The study’s primary objective is to determine the maximum tolerated dose of sapacitabine in patients with advanced leukemias or MDS. The study’s secondary objectives are to characterize the pharmacodynamic effects of sapacitabine in tumor cells, evaluate the relationship between pharmacokinetics and pharmacodynamics, and correlate the pharmacodynamic effects of sapacitabine with anti-cancer activity. The pharmacologic part of the study is led by Dr. William Plunkett, Chief of Cellular and Molecular Pharmacology at UTMDACC. The trial will involve approximately 30 patients. Update on the progress of this trial will be reported in the 4th quarter of 2006.

Key Financials

The net loss applicable to ordinary shareholders according to U.S. generally accepted accounting principles (GAAP) for the quarter ended September 30, 2006 was $5.4 million, or $0.34 per share (including $0.3 million, or $0.016 per share of non-cash stock-based compensation expense) as compared to $5.9 million, or $0.77 per share in the third quarter of 2005.

Research and development (R&D) expenses were $4.1 million in the third quarter of 2006, which included $0.2 million of non-cash stock-based compensation expense, as compared to $2.9 million in the third quarter of 2005, which included a credit of $0.7 million of non-cash stock-based compensation. The $0.3 million increase in R&D expenses, excluding stock-based compensation, was primarily due to activities related to the IND-directed studies for CYC116.

About seliciclib and sapacitabine.

Seliciclib is an orally available cyclin dependent kinase (CDK) inhibitor that selectively inhibits multiple enzyme targets that are central to the process of cell division and cell cycle control. Seliciclib has been administered to more than 200 patients to date, and it is currently being evaluated in a Phase IIb randomized discontinuation trial (APPRAISE) as a third-line treatment in patients with non-small cell lung cancer (NSCLC).

Sapacitabine is an oral nucleoside analog prodrug that acts through a dual mechanism that is unique among nucleoside analogs. It interferes with DNA synthesis by causing single-strand DNA breaks and induces arrest of the cell cycle. Sapacitabine has been administered to approximately 144 patients to date. It has undergone three Phase I studies in patients with solid tumors and lymphomas, and is currently being evaluated in a Phase I clinical trial in patients with advanced leukemias or myelodysplastic syndromes (MDS).

About Cyclacel Pharmaceuticals, Inc.

Cyclacel is a clinical-stage biopharmaceutical company dedicated to the discovery, development and commercialization of novel, mechanism-targeted drugs to treat human cancers and other serious disorders. The Company is currently evaluating seliciclib (CYC202), an orally-available cyclin dependent kinase inhibitor, in Phase II clinical trials for the treatment of lung cancer. Sapacitabine (CYC682) is an orally-available, cell cycle modulating nucleoside analog in Phase I clinical trials for the treatment of cancer. CYC116 is an orally-available, Aurora kinase inhibitor in IND-directed preclinical development. Several additional programs are at an earlier stage.

Risk Factors
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. These factors and others are more fully discussed under "Risk Factors" in the registration statement on Forms S-3 (File No. 333-134945) and S-4 (File No. 333-131225) and in the other reports of Cyclacel filed with the SEC.

Contacts for Cyclacel:

For Investors:
TS Communications Group, LLC (914) 921-5900
Tara Spiess / Andrea Romstad

For Media:
Feinstein Kean Healthcare (617) 577-8110
Kate Weiss