CYCLACEL announces recommendations of data review committee for seliciclib Phase 2b non-small cell lung cancer APPRAISE trial

-- Conference call scheduled for Thursday, August 28 at 4:30 p.m. EDT --

BERKELEY HEIGHTS, NJ - August 28, 2008 – Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP) announced today that an independent data review committee (IDRC) has completed a review of the first interim analysis data from the Phase 2b seliciclib APPRAISE study. The IDRC assessed the safety profile of seliciclib and recommended that the study continue after reviewing data from 173 patients with previously-treated non-small cell lung cancer (NSCLC), of whom 45 proceeded into the blinded portion of the study and were randomized to receive either seliciclib or best supportive care.

Based on the interim data, the IDRC reached the following principal conclusions:

- There were no safety concerns that would warrant stopping the study;
- The study would probably not demonstrate an improvement in progression-free survival as there was no trend favoring the seliciclib treatment arm;
- As a definitive conclusion could not be reached because of the low number of events, it was recommended that the study be continued.

“After analyzing the committee’s conclusions and weighing costs with expected benefits, we have decided not to enroll additional patients in APPRAISE,” said Dr. Judy Chiao, Vice President of Clinical Development and Regulatory Affairs of Cyclacel. “The trial will continue with patients already enrolled until the last enrolled patient has completed follow-up. In accordance with the protocol, the Company will remain blinded until that time. We are notifying participating investigators and wish to thank them, their colleagues and patients for their contributions to and support of this trial.”

“We are pleased that seliciclib’s safety profile was confirmed in a difficult-to-treat patient group. We believe that our original objective of learning the activity of single agent seliciclib in this patient group can be met with the currently enrolled number of patients after the data is unblinded,” said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. “Based on the low randomization rate and the IDRC’s conclusions, we are convinced that we can best serve the interests of our shareholders by concentrating our resources on other development strategies for seliciclib and also on sapacitabine, which have clearer pathways to registration.”

Study Design

APPRAISE is a double-blinded, randomized study of single agent seliciclib versus best supportive care in patients with NSCLC treated with at least two prior systemic therapies. The study design is randomized discontinuation. In the study’s lead-in open label portion, 173 patients were enrolled at 21 US hospitals and treated with seliciclib (1200 mg twice a day for three days) for at least three cycles of two weeks each. Of the 173 patients, 45 achieved stable disease for six weeks and were randomized to continue on seliciclib or receive placebo with best supportive care. Patients in the control arm who progressed will be given the option to cross-over and again receive seliciclib. The primary efficacy endpoint is progression free survival (PFS) measured in the randomized portion of the study. To detect a 100% increase in PFS from approximately two to four months, 80 randomized patients are required. Secondary efficacy endpoints are overall survival and response rate.

Conference Call and Webcast Information:

Cyclacel management will conduct a conference call on August 28, 2008 at 4:30 p.m. Eastern to review this announcement. 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: 62342947

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 Seliciclib

Seliciclib is an orally available molecule that selectively inhibits multiple enzyme targets, CDK2/E, CDK2/A, CDK7 and CDK9, that are central to the process of cell division and cell cycle control. Seliciclib has been evaluated to date in approximately 380 patients and is currently being evaluated in a randomized Phase 2 trial in patients with previously treated nasopharyngeal cancer.

About Cyclacel Pharmaceuticals, Inc.

Cyclacel is a biopharmaceutical company dedicated to the discovery, development and commercialization of novel, mechanism-targeted drugs to treat human cancers and other serious disorders. Three orally-available Cyclacel drugs 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 and cutaneous T-cell lymphoma. Seliciclib (CYC202 or R-roscovitine), a CDK (cyclin dependent kinase) inhibitor, is in Phase 2 for the treatment of lung cancer and nasopharyngeal cancer. CYC116, an Aurora kinase and VEGFR2 inhibitor, is in Phase 1 in patients with solid tumors. Several additional programs are at an earlier stage. 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, oncology and other therapeutic areas based on a portfolio of commercial products and a development pipeline of novel drug candidates.

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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 Annual Report on Form 10-K for the year ended December 31, 2007, as supplemented by the interim quarterly reports, filed with the SEC.

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