



Cyclacel Begins A Phase IIb Randomized Trial Of Seliciclib For Previously Treated Non-Small Cell Lung Cancer

SHORT HILLS, NJ, June 29, 2006 – Cyclacel Pharmaceuticals, Inc. (Nasdaq: CYCC) announced today that the company is beginning a Phase IIb, multi-center, randomized, double-blinded trial to evaluate 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 trial is being initiated following Food and Drug Administration (FDA) and central Institutional Review Board (IRB) approval of the trial protocol. The APPRAISE study builds on the observation of prolonged stable disease experienced by heavily-pretreated NSCLC patients enrolled in a Phase I study of single agent seliciclib.

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.

Seliciclib is an orally available cyclin dependent kinase (CDK) inhibitor 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 240 patients, including patients with advanced NSCLC in two Phase IIa studies in which seliciclib was administered in combination with gemcitabine and cisplatin as first-line treatment and with docetaxel as second-line treatment.

"We have been interested in evaluating seliciclib, our lead cell cycle inhibitor, as a treatment for lung cancer for some time. The APPRAISE study is a key next step in our program to assess the antitumor activity of seliciclib as a monotherapy for lung cancer," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "We are also interested in evaluating seliciclib in other types of cancer, such as nasopharyngeal cancer. The seliciclib program is part of Cyclacel's strategy to develop a portfolio of cell cycle inhibitor drugs for the treatment of cancer. Our pipeline also includes sapacitabine (CYC682), an orally-available, cell cycle modulating nucleoside analog in Phase I clinical trials for the treatment of solid and hematologic cancers, and CYC116, an orally-available, Aurora kinase inhibitor in IND-directed preclinical development."

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.

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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 registration statement on Form S-4 (File No. 333-131225) and in the other reports of Cyclacel filed with the SEC.

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