Cyclacel Pharmaceuticals announces results of Phase II Seliciclib combination studies

BERKELEY HEIGHTS, NJ, June 28, 2007 –– Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP) announced today the results from two Phase II non-randomized studies of seliciclib fixed dose combinations. In one study seliciclib was given in combination with gemcitabine and cisplatin and in another with docetaxel in patients with advanced non-small cell lung cancer (NSCLC).

The primary objectives of the studies were to assess the safety and efficacy of the two combinations. In the first study, 45 patients with advanced NSCLC, who were previously untreated or treated with no more than one prior chemotherapy, were enrolled and treated with the combination of seliciclib plus gemcitabine and cisplatin. Seliciclib was administered twice daily (b.i.d.) by mouth for 4 days every week. Gemcitabine was administered once a week for two weeks followed by one week of rest. Cisplatin was administered once every three weeks. Patients were entered into 3 seliciclib cohorts dosed at 400 mg b.i.d. (n=3), 800 mg b.i.d. (n=36) and 1200 mg b.i.d. (n=6). In the second study, 7 patients with advanced NSCLC who have had one prior chemotherapy were enrolled and treated with the combination of seliciclib plus docetaxel. Seliciclib was administered at 1600 mg b.i.d. for 3 days every 3 weeks. Docetaxel was administered once every three weeks. The combination study with docetaxel was discontinued early due to slow accrual.

The best response by investigator assessment consisted of 9 patients with partial response and 21 with stable disease in patients treated with the combination of seliciclib plus gemcitabine/cisplatin and 2 with partial response and 1 with stable disease in the combination of seliciclib plus docetaxel. The major dose-limiting toxicities were nausea, vomiting, fatigue, hypokalemia and elevation in liver enzymes which were primarily attributed to seliciclib. There were no unexpected toxicities.

“The results of these combination studies demonstrated that seliciclib could be safely combined with gemcitabine/cisplatin or docetaxel with evidence of anti-tumor activity. However the contribution of seliciclib to the anti-tumor activity of the combinations could not be adequately evaluated in a non-randomized study. To assess the anti-tumor activity of seliciclib as a single agent, we are currently conducting a double-blinded, randomized, Phase II study of single agent seliciclib versus best supportive care in patients with advanced NSCLC who have had at least two prior systemic therapies (the APPRAISE study). In addition, we are currently planning a randomized Phase II study of single agent seliciclib in patients with previously treated nasopharyngeal cancer (NPC)”, commented Dr. Judy Chiao, Vice President of Clinical Development and Regulatory Affairs of Cyclacel.

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. Two Cyclacel drugs are in Phase II trials: sapacitabine (CYC682), an orally-available, cell cycle modulating nucleoside analog, for the treatment of cutaneous T-cell lymphoma (CTCL) and seliciclib (CYC202), an orally-available CDK (cyclin dependent kinase) inhibitor, for the treatment of lung cancer. Sapacitabine is also in Phase I trials in patients with hematologic malignancies. CYC116, an orally-available, Aurora kinase and VEGFR2 inhibitor, is at the IND stage. Several additional programs are at an earlier stage.

Please visit http://www.cyclacel.com/cyc/investors/news/pressreleases for additional information.

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.

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