Cyclacel Pharmaceuticals provides year end 2007 pipeline update and outlines 2008 Key Business Objectives

Conference Call Today at 10:30 AM ET

BERKELEY HEIGHTS, NJ, November 26, 2007 — Cyclacel Pharmaceuticals, Inc. (Nasdaq: CYCC) (Nasdaq: CYCCP) today provided an overview of recent advances in its clinical development stage programs and announced its 2008 key business objectives for these programs.

“Our progress against Cyclacel’s business objectives over the past year demonstrates our commitment to building a diversified biopharmaceutical business focused in oncology and hematology,” said Spiro Rombotis, President and CEO of Cyclacel. “From advancing multiple clinical programs, to diversifying our business with the acquisition of Align Pharmaceuticals, to nurturing our early stage pipeline, we are pursuing key elements that we believe position Cyclacel for success in developing and commercializing novel, mechanism-targeted drugs to treat cancer.”

Pipeline Update

Seliciclib Phase IIb APPRAISE in Non-Small Cell Lung Cancer (NSCLC)

Seliciclib, Cyclacel’s orally available cyclin dependent kinase (CDK) inhibitor, is being investigated in the Phase II APPRAISE study as a treatment for patients with advanced NSCLC. 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’s main objective is to learn the anti-tumor activity of seliciclib as a single agent in refractory NSCLC and help determine further development strategies. The study design is randomized discontinuation. All patients receive seliciclib (1200 mg twice a day for three days) for at least three cycles of two weeks each. 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 arm who progress will be given the option to cross-over and again receive seliciclib. The primary efficacy endpoint of APPRAISE is progression free survival (PFS) which will be measured in the randomized portion of the study. To detect a 100% increase in PFS from two to four months 80 randomized patients are required. An interim assessment of safety and efficacy will be performed after approximately 40 patients have been randomized. Approximately 160 patients will be enrolled. Calculation of the sample size was based on the assumption that approximately 50% will achieve stable disease during the initial six week treatment and undergo randomization.

According to recently available and preliminarily analyzed data 120 patients have been enrolled and 26 randomized. The major reason for discontinuation prior to randomization is progression of disease. In particular, 76% of enrolled patients have failed at least three prior treatment regimens and 75% progressed on the last treatment immediately prior to enrollment. A likely cause of the lower than assumed randomization rate may be that seliciclib does not have a high level of activity as a single agent in this population of patients with refractory NSCLC. Following consultation with the chair and co-chair of the study, Cyclacel intends to continue enrollment until 160 patients are enrolled or approximately 40 are randomized, whichever occurs first. A committee of independent experts will then be convened to review the blinded data and recommend whether the study should be continued in order to adequately assess the antitumor effect of seliciclib in this patient population. This will allow the Company to make an informed decision based on the study’s objectives and available data.

Seliciclib Phase II in Nasopharyngeal Cancer (NPC)

Cyclacel recently commenced a Phase II multicenter, international, blinded randomized study of oral seliciclib as a single agent in patients with NPC. The primary objective is to evaluate 6 month progression-free survival (PFS) of two dosing schedules of seliciclib in approximately 75 patients with previously treated nasopharyngeal carcinoma. Secondary objectives are overall survival, response rate, response duration, safety and tolerability. The first part of the study is designed to confirm safety and tolerability of 400 mg twice a day for four days per week or 800 mg once a day for four days per week of seliciclib. It is open to approximately 12 to 24 patients with advanced solid tumors as well as patients with NPC. The second part of the study is designed to detect major differences between the two dosing schedules of seliciclib and a placebo group in terms of 6 month PFS in approximately 51 patients. The study uses a selection design to choose an optimal dosing schedule if both seliciclib dosing schedules are active versus placebo.

Initiation of Phase II development in NPC is based on data from an investigator-sponsored Phase I study. In this study single agent seliciclib was administered to treatment naïve NPC patients at the 400 mg twice a day dose for three to five days over

two weeks with good tolerability and evidence of anti-tumor activity.

2008 Seliciclib Objectives

- Complete enrollment in Phase IIb APPRAISE trial in NSCLC (1H08)
- Update progress with first part of Phase II randomized trial of seliciclib in NPC (1H08)
- Initiate clinical development of seliciclib in combination with targeted therapies (1H08)

Sapacitabine Phase II in Cutaneous T-Cell Lymphoma (CTCL)

Sapacitabine, Cyclacel's orally available nucleoside analogue, is being investigated in a Phase II study as a treatment for patients with cutaneous T-cell lymphoma (CTCL). CTCL is a cancer of T-lymphocytes, or white blood cells, which causes disfiguring skin lesions and severe itching. The primary objective of the study is to evaluate tolerability and response rate of 50 mg and 100 mg regimens (both twice a day for three days per week for two weeks in a three week cycle) in approximately 32 patients with progressive, recurrent, or persistent CTCL on or following two systemic therapies. The study uses a selection design to choose an optimal dose if both are active. Secondary objectives are to assess response duration, time to response, time to progression and relief of pruritus or itching.

This study has enrolled five patients to date at two hospital centers. According to recently available and preliminarily analyzed data, the best response by investigator assessment is partial response in one and stable disease in four patients. The partial response patient was crossed over from the 50 mg to the 100 mg regimen. As both regimens are well tolerated with no grade 2 toxicities, the protocol is being amended to increase dosing to 100 mg and 200 mg respectively using the same schedule as that used previously. The study is being expanded to include additional centers.

Sapacitabine Phase I in Hematological Malignancies

Updated data from the ongoing Phase I trial of oral sapacitabine in patients with advanced acute myelogenous leukemias (AML) or myelodysplastic syndromes (MDS) will be reported by the principal investigator on December 8, 2007 in a presentation at the 2007 Annual Meeting of the American Society of Hematology (ASH). The presentation is entitled "Phase I Study of Sapacitabine, an Oral Nucleoside Analogue, in Patients with Advanced Leukemias or Myelodysplastic Syndromes" (*Blood*, Volume 110, Issue 11, November 16, 2007, Abstract #884). Cyclacel will announce at the same time plans for Phase II development of sapacitabine in hematological malignancies.

2008 Sapacitabine Objectives

- Initiate Phase II trial of sapacitabine in hematological malignancies (1H08)
- Report Phase II progress in CTCL (2H08)
- Initiate additional clinical studies of sapacitabine as a single agent or combination therapy (2H08)

CYC116 Phase I in Advanced Solid Tumors

Fifteen patients have been enrolled in the multicenter Phase I pharmacologic study of CYC116, an orally-available inhibitor of Aurora kinases A and B and VEGFR2, in patients with advanced solid tumors. The primary objective of the study is to determine the maximum tolerated dose. Secondary objectives are to evaluate the pharmacokinetic and pharmacodynamic effects of the drug and to document anti-tumor activity. The maximum tolerated dose has not been reached. According to recently available and preliminarily analyzed data, one patient experienced a grade 3 headache with no other grade 3 toxicities reported. Best responses by investigator assessment were stable disease observed in 3 patients. Of these, one was in a patient with ovarian cancer and was associated with a reduction in the CA-125 tumor marker, one in a patient with peritoneal carcinoma and one in a patient with mesothelioma.

2008 CYC116 Objectives

- Report topline Phase I data of CYC116 in solid tumors (1H08)
- Initiate Phase I trial of CYC116 in hematological cancers (1H08)

Conference call and webcast information: 10:30 AM ET, Monday, November 26

- U.S./Canada call: 888-243-1152, conference ID: 9504867.
- International call: 973-582-2868, conference ID: 9504867.
- Webcast: http://w.on24.com/r.htm?e=98702&s=1&k=166C0D04231BBC47E7E3182E58AB3E7A or via Cyclacel Pharmaceuticals' website at www.cyclacel.com.
- The webcast will be archived for 90 days and the audio replay will be archived for seven days.
- Access numbers for the audio replay are U.S./Canada: 877-519-4471; International: 973-341-3080; conference ID:

9504867.

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. Cyclacel's ALIGN Pharmaceuticals subsidiary markets directly in the U.S. Xclair® Cream for radiation dermatitis, Numoisyn® Liquid and Numoisyn® Lozenges for xerostomia. Three Cyclacel drugs are in clinical development. Sapacitabine (CYC682), an orally-available, cell cycle modulating nucleoside analog, is in Phase II for the treatment of cutaneous T-cell lymphoma (CTCL) and in Phase I in patients with hematologic malignancies. Seliciclib (CYC202), an orally-available CDK (cyclin dependent kinase) inhibitor, is in Phase II for the treatment of lung cancer and is also being evaluated for nasopharyngeal cancer. CYC116, an orally-available, Aurora kinase and VEGFR2 inhibitor, is in Phase I in patients with solid tumors. Several additional programs are at an earlier stage. Cyclacel's strategy is to build a diversified biopharmaceutical business focused in oncology, hematology and other therapeutic areas based on a portfolio of commercial products and a development pipeline of novel drug candidates.

Please visit http://www.cyclacel.com/cyc/investors/news/pressreleases for additional information. Note: The Cyclacel logo and Cyclacel® are trademarks of Cyclacel Pharmaceuticals, Inc. Numoisyn® and Xclair® are trademarks of Sinclair Pharma plc.

Forward-Looking Statements & 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, 2006, as supplemented bythe interim quarterly reports, filed with the SEC.

Contacts for Cyclacel:

For Investors:
Cyclacel Pharmaceuticals, Inc.
Corey Sohmer (908) 517-7330

For Media:
WeissComm Partners
Aline Schimmel (312) 654-6763

View the full press release in PDF format (48 KB)