Cyclacel provides update on meeting with FDA to discuss pivotal study design for sapacitabine

- Special Protocol Assessment Submission Planned for First Quarter of 2010 -

Berkeley Heights, NJ, December 15, 2009 - Cyclacel Pharmaceuticals, Inc. (Nasdaq: CYCC) (Nasdaq: CYCCP) ("Cyclacel" or the "Company") announced today that the Company recently held a Type A meeting with the U.S. Food and Drug Administration (FDA) to discuss a randomized Phase 3 study design for Cyclacel's oral sapacitabine capsules in acute myeloid leukemia (AML) and separately in myelodysplastic syndromes (MDS).

Based on the FDA's confirmation that the proposed study design would be acceptable for a Special Protocol Assessment (SPA), Cyclacel plans to submit a SPA request during the first quarter of 2010.

"We appreciate the considerable time and effort devoted by FDA staff to evaluate our proposed study designs and their guidance in establishing a registration pathway for sapacitabine," said Judy H. Chiao, M.D., Cyclacel's Vice President, Clinical Development & Regulatory Affairs.

Phase 2 data

At the 51st Annual Meeting of the American Society of Hematology (ASH), the Company reported data from a randomized Phase 2 study including promising 1-year survival in a difficult to treat population of elderly patients with AML aged 70 years and activity in older patients with MDS refractory to hypomethylating agents.

AML

The study uses a selection design with the objective of identifying a dosing schedule which produces a better 1-year survival rate in the event that all three dosing schedules are active. The study enrolled 60 patients aged 70 or older with either untreated AML (80%) or AML in first relapse (20%) randomized across three dosing schedules of sapacitabine (Arm A, a 7-day low dose regimen; Arm B, a 7-day high dose regimen and Arm C, a 3-day high dose regimen). Each arm enrolled and treated 20 patients. Approximately 55% of patients had AML de novo and the rest had AML preceded by antecedent hematological disorder (AHD), such as MDS or myeloproliferative disease.

The primary endpoint of 1-year survival was 35% on Arm A, 30% on Arm C and 10% on Arm B. The median overall survival was 212 days on Arm C (range of 13 to over 654 days), 197 days on Arm A (range of 26 to over 610 days) and 100 days on Arm B (range of 6 to over 646 days). Overall response rate (ORR), a secondary endpoint, was 45% on Arm A, 35% on Arm C and 25% on Arm B with CR rate of 25% on Arm C and 10% on Arms A and B. Thirty-day mortality was 10.0% on Arm C and Arm A and 20.0% on Arm B. Approximately 30% of all patients received sapacitabine for at least 6 cycles. Fifteen patients who survived one year or more received an average of 12 treatment cycles and 7 patients are still on study receiving sapacitabine.

Exploratory subgroup analysis suggests that (i) Arm C may be more effective for de novo AML and (ii) Arm A may be more effective for AML preceded by AHD, such as MDS.

The 3-day dosing schedule in Arm C was selected for further clinical development in elderly patients with de novo AML based on a 1-year survival rate of 30%, ORR of 35% with durable CRs. The 7-day dosing schedule in Arm A was selected for further clinical development in elderly patients with AML preceded by AHD based on a 1-year survival rate of 35%, ORR of 45% with durable hematological improvement.

MDS

Cyclacel also reported interim response data for the ongoing Phase 2 clinical trial of sapacitabine in older patients with MDS.

The study has recently completed enrollment of 60 patients aged 60 or older with MDS who were previously treated with azacitidine and/or decitabine. Each arm enrolled 20 patients randomized across the same three dosing schedules of sapacitabine (Arms A, B and C) tested in the AML stratum of the study. Forty-nine of the patients enrolled have been followed-up for more than 30 days. Approximately 46% of the 49 patients had baseline bone marrow blast counts above 10%.

Based on interim data, the highest number of responses was observed on Arm B, the 7-day high dose schedule. Thirty-day mortality from all-causes is 8.2%. Approximately 30% of the patients received 4 or more cycles of sapacitabine.

About Special Protocol Assessment (SPA)

The Special Protocol Assessment process allows for official FDA evaluation of clinical protocols of a Phase 3 clinical trial intended to form the primary basis for an efficacy claim. A SPA provides trial sponsors with a binding FDA agreement that the design and analysis of the trial adequately address objectives in support of a submission for a marketing application if the trial is performed according to the SPA. The SPA agreement may only be changed through a written agreement between the sponsor and the FDA or if the FDA becomes aware of a substantial scientific issue essential to product efficacy or safety.

About sapacitabine

Sapacitabine capsules (CYC682), an orally available nucleoside analogue, is currently being evaluated in Phase 2 trials in hematological and solid tumors. Sapacitabine acts through a dual mechanism, interfering with DNA synthesis by causing single-strand DNA breaks and inducing arrest of cell cycle progression mainly at G2/M-Phase. Both sapacitabine and CNDAC, its major metabolite, have demonstrated potent anti-tumor activity in preclinical studies.

Over 180 patients have received sapacitabine in Phase 2 studies in AML, MDS, advanced cutaneous T cell lymphoma (CTCL) and non-small cell lung cancer (NSCLC). Sapacitabine has been administered to approximately 170 patients in five Phase 1 studies with both hematologic malignancies and solid tumors. In the solid tumor studies, 20 patients experienced prolonged stable disease and remained on study for four months or longer, five with NSCLC, one with small cell lung cancer, four with colorectal, two with bladder, two with gastrointestinal stromal tumors, two with ovarian, one with breast, one with renal, one with parotid and one with an unknown primary tumor. Sapacitabine is part of Cyclacel's pipeline of small molecule drugs designed to target and stop uncontrolled cell division.

About Cyclacel Pharmaceuticals, Inc.

Cyclacel is a diversified biopharmaceutical company dedicated to the discovery, development and commercialization of novel, mechanism-targeted drugs to treat human cancers and other serious disorders. Sapacitabine, a cell cycle modulating nucleoside analog, is in Phase 2 studies for the treatment of acute myeloid leukemia in the elderly, myelodysplastic syndromes, advanced CTCL and lung cancer and in Phase 1 in combination with seliciclib. Seliciclib, a CDK (cyclin dependent kinase) inhibitor, is in Phase 2 for the treatment of lung and nasopharyngeal cancer. CYC116, an Aurora kinase and VEGFR2 inhibitor, is in Phase 1 in patients with solid tumors. 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 and oncology based on a portfolio of commercial products and a development pipeline of novel drug candidates. Please visit www.cyclacel.com 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 Annual Report on Form 10-K for the year ended December 31, 2008, as supplemented by the interim quarterly reports, filed with the SEC.

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