Cyclacel reports Phase 2 sapacitabine data in acute myeloid leukemia and myelodysplastic syndromes at 2009 ASH annual meeting

- Planning underway for a pivotal trial to start in 2010 -
- Conference call scheduled for Monday December 7th at 9:30 AM Eastern -

Berkeley Heights, NJ, December 5, 2009 – Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP; "Cyclacel" or the "Company") announced today 1-year survival data from a Phase 2 randomized trial of oral sapacitabine capsules, a novel nucleoside analogue, in elderly patients with acute myeloid leukemia (AML) and separately interim response data in myelodysplastic syndromes (MDS). The data were reported in two poster presentations at the 51st Annual Meeting of the American Society of Hematology (ASH) in New Orleans.

"Sapacitabine has demonstrated promising 1-year survival in a difficult to treat population of elderly patients with AML and is active in patients with MDS refractory to hypomethylating agents," said Hagop M. Kantarjian, M.D., Chairman and Professor, Department of Leukemia, The University of Texas M. D. Anderson Cancer Center, Houston, Texas and study chair of the sapacitabine Phase 2 study. "Effective therapies are urgently needed to address the unmet medical needs of both diseases. Sapacitabine may emerge as an important treatment option for older patients who are suffering from AML or MDS. We look forward to participating in late-stage development of sapacitabine both as a single agent and in combinations."

"We are deeply grateful to our investigators and their patients for helping us to reach this milestone in the development of sapacitabine in AML and MDS," said Judy H. Chiao, M.D., Cyclacel's Vice President, Clinical Development & Regulatory Affairs. "We look forward to discussing with the FDA our Phase 3 registration strategy for sapacitabine in patients with hematological malignancies. We recently completed enrollment of 60 patients in the MDS stratum of the Phase 2 study. We are also exploring sapacitabine's safety and efficacy in solid tumors both as a single agent and in combination with seliciclib, our investigational cyclin-dependent kinase inhibitor. If Phase 3 trials are successful, sapacitabine could emerge as the first oral drug for the treatment of older patients with AML and MDS."

AML Phase 2 data

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, 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 Phase 2 data

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.

Conference call and webcast information

Cyclacel management will host a conference call featuring Dr. Hagop Kantarjian, M.D. to review Phase 2 sapacitabine data reported at the meeting of the American Society of Hematology (ASH) on Monday December 7 at 9:30 AM Eastern, and comment on the current therapeutic landscape for patients with AML and MDS.

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: 44436396

Webcast: 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 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 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, myelodysplastic syndromes and lung cancer. Seliciclib (CYC202 or R-roscovitine), a CDK (cyclin dependent kinase) inhibitor, is in Phase 2 studies for the treatment of lung cancer and nasopharyngeal cancer and in a Phase 1 trial in combination with sapacitabine. CYC116, an Aurora kinase and VEGFR2 inhibitor, is in a Phase 1 trial 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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A randomized Phase 2 study of sapacitabine, an oral nucleoside analogue, in elderly patients with AML previously untreated or in first relapse