Cyclacel Reports phase 2 sapacitabine data in patients with acute myeloid leukemia and myelodysplastic syndromes at 2009 Asco Annual Meeting

-Emerging sapacitabine data paving the way for a pivotal trial to start in 2009-
-Conference call scheduled for Wednesday June 3rd at 4:30 ET-

ORLANDO, FL May 29, 2009 – Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP) today announced interim data from a Phase 2 randomized clinical trial of oral sapacitabine (CYC682), a novel nucleoside analog, in elderly patients with acute myeloid leukemia (AML) or myelodysplastic syndromes (MDS) at the 45th annual meeting of the American Society of Clinical Oncology (ASCO) (Abstract 7021). The data demonstrated that oral sapacitabine is active in AML across all three dosing schedules tested and that prolonged administration is feasible in the outpatient setting. Activity was also observed in the ongoing MDS stratum of the study. Based on the data, Cyclacel intends to use the 3-day dosing schedule for further clinical development in elderly AML and will discuss with the FDA the design of a pivotal study in elderly patients with AML expected to commence in 2009.

"I am encouraged by these Phase 2 results, which demonstrate that oral sapacitabine produced durable clinical benefit in elderly patients with AML with low extramedullary toxicity," said Dr. Hagop Kantarjian, Professor of Medicine and Chairman of the Leukemia Department at The University of Texas M. D. Anderson Cancer Center and Principal Investigator of the trial. "AML in elderly patients is a challenging disease because elderly patients often experience increased induction mortality and toxicities from conventional chemotherapy because of advanced age and pre-existing comorbid conditions. Sapacitabine has the potential to be a safe and effective treatment for elderly patients with untreated or relapsed AML."

The 3-day dosing schedule demonstrated:

- overall response rate in AML of 35%, including complete remission (CR) of 25%,
- median treatment in patients with CR exceeding 9 cycles and
- all-cause 30-day mortality of 9.4%.

"We are pleased with the interim Phase 2 results, which support our decision to advance sapacitabine to a pivotal study in AML later this year," said Judy Chiao, M.D., Vice President, Clinical Development and Regulatory Affairs of Cyclacel. “We are grateful for the enthusiasm and contributions of our investigators, their colleagues and patients who helped us achieve this important milestone. We look forward to reporting one year survival data in AML from this Phase 2 study in the second half of 2009.”

Phase 2 Study Details

The Phase 2 study rapidly enrolled during 2008 a total of 60 patients aged 70 years or above with untreated or first relapse AML and randomized them to one of three dosing schedules. In the 3-day dosing schedule, a response rate of 35% (7/20 patients) was observed of which 25% (5/20 patients) achieved CR. The median number of treatment cycles in responders currently exceeds nine (range of 3 to over 18 cycles) with 5 of 7 responders still on treatment. The majority of the responders had unfavorable cytogenetics.

In early 2009 an expanded population of 45 additional AML patients was treated in two of the three arms (25 in the 3-day arm) for a total of 105 AML patients. The purpose of the expansion was to further confirm safety and tolerability of these two arms.

In the ongoing MDS stratum thus far 31 patients aged above 60 years have been treated with sapacitabine as second line therapy following treatment with hypomethylating agents. Complete remission and hematological improvement have been observed in 7 patients.

The most common grade 3 or 4 adverse events regardless of causality were anemia, neutropenia, febrile neutropenia and thrombocytopenia. Death within 30 days of beginning treatment from all causes in the 45 AML and 9 MDS patients treated with the 3-day arm was 9.4% (5/53 patients). The results of the trial will be submitted for publication in a peer-reviewed journal.

Study Reference

G. Garcia-Manero, et al, A randomized phase II study of sapacitabine, an oral nucleoside analogue, in elderly patients with AML

previously untreated or in first relapse or previously treated MDS, *J Clin Oncol* 27:15s, 2009 (suppl; abstr 7021).

For definitions of response in hematological malignancies please refer to:

Cheson B et al, Revised recommendation of the International Working Group for diagnosis, standardization of response criteria, treatment outcomes and reporting standards for therapeutic trials in acute myeloid leukemia. *J Clin Oncol* 21: 4642-4649, 2003.

Cheson B et al, Clinical application and proposal for modification of the International Working Group (IWG) response criteria in myelodysplasia. *Blood* 108(2):419-25, 2006.

Conference call and Webcast Information:

Cyclacel management will review the data presented at ASCO 2009 and discuss the progress of its pipeline on a conference call scheduled for Wednesday June 3rd at 4:30 p.m. Eastern. Conference call and webcast details are as follows:

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 is 12669776

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 appears to act through a dual mechanism. It interferes with DNA synthesis by causing single-strand DNA breaks and also induces arrest of cell cycle progression at G2/M-Phase. Both sapacitabine and CNDAC, its major metabolite or a substance into which the drugs converts after ingestion by patients, have demonstrated potent anti-tumor activity in preclinical studies. Sapacitabine was shown to be superior in preclinical models to either gemcitabine (Gemzar®; Lilly) or ara-C, two widely used nucleoside analogs. Gemcitabine is indicated for the palliative treatment of breast, lung, pancreatic and ovarian cancer, but it has not been reported to be active in leukemias or MDS. Ara-C is indicated for the treatment of AML but it is typically not tolerated by elderly patients. A Phase 2 trial of sapacitabine in patients with non-small cell lung cancer is currently in progress. Sapacitabine is part of a deep 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 and in Phase1 in combination with seliciclib. Seliciclib (CYC202 or R-roscovitine), a CDK (cyclin dependent kinase) inhibitor, is in Phase 2 for the treatment of lung cancer 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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