



Sapacitabine phase 1 data published in acute leukemia and myelodysplastic syndromes

- Phase 2 data to be presented at the ASH Conference on Saturday -

Berkeley Heights, NJ, November 30, 2009 - Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP; "Cyclacel" or the "Company") announced publication in the Journal of Clinical Oncology of a Phase 1 study evaluating clinical and pharmacokinetic effects of sapacitabine, an orally available nucleoside analog, in 47 patients with refractory or relapsed acute leukemias and myelodysplastic syndromes (MDS). The study was led by Hagop Kantarjian, MD and colleagues at The University of Texas M. D. Anderson Cancer Center, Houston, Texas.

"We are pleased to see sapacitabine Phase 1 data published in a prestigious peer-reviewed journal. The encouraging anti-leukemic activity and good tolerability support the continued development of this novel agent with a differentiated mechanism of action for the treatment of AML and MDS," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "We recently reported topline 1-year survival of approximately 30% each on two out of three schedules tested in our Phase 2 elderly AML study of sapacitabine. We will be shortly meeting with the FDA to discuss a Phase 3 registration study for sapacitabine in patients with hematological malignancies. In addition we are exploring sapacitabine's potential 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 AML and MDS.

The objective of the study was to define the dose-limiting toxicities and maximum-tolerated dose of sapacitabine given by mouth twice a day for either 7 days every three to four weeks or 3 days for two weeks every three to four weeks. The dose-limiting toxicities with both schedules were gastrointestinal. Maximum-tolerated doses were 375 mg twice a day in the 7-day and 425 mg twice a day in the 3-day schedule. Median age was 65 years (range 35-90). Approximately 68% of patients had received two or more salvage therapies. Responses were observed in 13 patients (28%) with acute myeloid leukemia (AML) or MDS of which four were complete remissions or CRs, two were complete remissions with incomplete platelet count recovery or CRps and seven were marrow complete responses or CRis. In addition, twenty patients (43%) had at least 1-log reduction of peripheral blasts (n=12) and/or at least 50% reduction of marrow blasts (n=8). The estimated 4-week mortality for all patients was 4%.

The data were published ahead of print in the online edition of the Journal of Clinical Oncology (<http://jco.ascopubs.org/cgi/doi/10.1200/JCO.2009.25.0209>).

One-year survival data from the Phase 2 AML study stratum and interim response data from the Phase 2 MDS stratum will be reported at the upcoming meeting of the American Society of Hematology (ASH) this coming Saturday.

About sapacitabine

Sapacitabine, an orally available nucleoside analogue, is currently being evaluated in three 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 150 patients have received sapacitabine in Phase 2 studies in AML, MDS, advanced cutaneous T cell lymphoma or CTCL and non-small cell lung cancer or NSCLC. Sapacitabine has been administered to approximately 170 patients in four 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 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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