



Cyclacel reports interim Phase 2 sapacitabine data in myelodysplastic syndromes at 2010 ASCO annual meeting

Berkeley Heights, NJ, June 7, 2010 – Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP; “Cyclacel” or the “Company”) announced today interim response data from a Phase 2 randomized trial of oral sapacitabine capsules, a novel nucleoside analogue, in older patients with myelodysplastic syndromes (MDS) that have failed hypomethylating agents. The data were presented at an oral poster discussion session at the 2010 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, Illinois.

“There are no effective therapies for MDS after treatment failures of hypomethylating agents. Sapacitabine has demonstrated promising activity in this difficult to treat population which warrants further clinical development in MDS,” 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.

“We are encouraged by the interim response data which indicates that sapacitabine is active in MDS patients after treatment with hypomethylating agents such as azacitidine or decitabine,” said Judy H. Chiao, M.D., Cyclacel’s Vice President, Clinical Development & Regulatory Affairs. “The primary efficacy endpoint of the study is 1-year survival. We look forward to reporting 1-year survival data toward the end of 2010.”

MDS Phase 2 data

Based on interim data, the overall response rate is 24% on Arm A, the 7-day low dose schedule, 35% on Arm B, the 7-day high dose schedule, and 10% on Arm C, the 3-day high dose schedule. Two patients achieved complete remission and both were treated on Arm A. Thirty-day mortality from all-causes is 4.8% on Arm A, 0% on Arm B and 15% on Arm C. Approximately 34% of the patients received 4 or more cycles of sapacitabine.

The study has completed treatment of 61 patients aged 60 or older with MDS who were previously treated with azacitidine or decitabine or both. Patients were randomized across three dosing schedules of sapacitabine (Arms A, B and C). All patients have received at least one hypomethylating agent and 15 patients (25%) have received two hypomethylating agents, i.e., azacitidine and decitabine. Approximately 51% of the 61 patients had baseline bone marrow blast counts above 10%.

The poster presentation (abstract number 6528) will take place today between 2:00 PM – 6:00 PM Central Time and the oral poster discussion between 5:00 PM – 6:00 PM Central Time.

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 200 patients have received sapacitabine in Phase 2 studies in acute myeloid leukemia (AML), MDS, 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. The company expects to report interim Phase 2 data with sapacitabine in NSCLC during the second half of 2010.

In December 2009 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 or older. During the first quarter of 2010, the Company submitted a Special Protocol Assessment (SPA) request to the FDA for a randomized Phase 3 registration study of sapacitabine in elderly patients with AML. 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 developing oral therapies that target the various phases of cell cycle control for the treatment of cancer and other serious diseases. Sapacitabine (CYC682), a cell cycle modulating nucleoside analog, is in Phase 3 development for the treatment of acute myeloid leukemia in the elderly under a Special Protocol Assessment agreement with the U.S. Food and Drug Administration, and in Phase 2 studies for 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. 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.

Forward-looking Statements

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. For a further list and description of the risks and uncertainties the Company faces, please refer to our most recent Annual Report on Form 10-K and other periodic and current filings that have been filed with the Securities and Exchange Commission and are available at www.sec.gov. Such forward-looking statements are current only as of the date they are made, and we assume no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

Contact for Cyclacel Pharmaceuticals, Inc.

Investors/Media:
Corey Sohmer,
(908) 517-7330
csohmer@cyclacel.com

[View the full press release in PDF format](#) (192KB)

To read the PDF documents on this page you may need to download the free [Adobe Reader](#) or you can use the [free online conversion tools](#).

© Copyright 2011 Cyclacel Pharmaceuticals, Inc. All Rights Reserved. The Cyclacel logo and Cyclacel® are trademarks of Cyclacel Pharmaceuticals, Inc. Numoisyn® and Xclair® are trademarks of Sinclair Pharma plc.