Cyclacel reports Phase 2 survival data with sapacitabine in myelodysplastic syndromes at 2010 ASH annual meeting

Berkeley Heights, NJ, December 4, 2010 – Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP; "Cyclacel") announced today 1-year survival data from a Phase 2 randomized trial of oral sapacitabine capsules, a novel nucleoside analogue, in older patients with myelodysplastic syndromes (MDS) refractory to hypomethylating agents, such as azacitidine and decitabine. The data were reported at a poster presentation at the 52nd Annual Meeting of the American Society of Hematology (ASH) in Orlando, Florida.

"MDS patients have a poor outcome after treatment failures of hypomethylating agents. Effective therapies are urgently needed to improve the survival of these patients," said Hagop M. Kantarjian, M.D., Chairman and Professor, Department of Leukemia, The University of Texas MD Anderson Cancer Center, Houston, Texas and study chair of the sapacitabine Phase 2 study. "The survival data of sapacitabine in this study are promising and warrant further clinical development in this patient population."

"We are deeply grateful to our investigators and their patients for helping us to reach this milestone in the development of sapacitabine in MDS," said Judy H. Chiao, M.D., Cyclacel's Vice President, Clinical Development & Regulatory Affairs. "We plan to initiate discussions with the FDA regarding potential registration pathways in MDS patients refractory to hypomethylating agents. We are also looking forward to opening enrollment in "SEAMLESS", our pivotal Phase 3 study of sapacitabine in elderly patients with acute myeloid leukemia (AML). If Phase 3 trials are successful, sapacitabine could emerge as the first oral drug for the treatment of AML and MDS as chronic diseases."

MDS Phase 2 survival 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 61 patients aged 60 or older with MDS refractory to hypomethylating agents randomized across three dosing schedules of sapacitabine: 21 patients in Arm A, a 7-day low dose regimen (200 mg b.i.d.); 20 patients in Arm B, a 7-day high dose regimen (300 mg b.i.d.) and 20 patients in Arm C, a 3-day high dose regimen (400 mg b.i.d.). Approximately 77% of patients were aged 70 years or older and 84% were scored as intermediate-2 or high risk by IPSS, the International Prognostic Scoring System. Baseline blast counts were between 11% and 29% in 51% of the patients. All patients were previously treated with hypomethylating agents: 43% with azacitidine, 34% with decitabine and 23% were double refractory patients as they were treated with both azacitidine and decitabine (7 on Arm A, 4 on Arm B and 3 on Arm C). Approximately 16% were previously treated with lenalidomide in addition to hypomethylating agents.

The primary endpoint of 1-year survival was achieved in 29% of the patients on Arm A, 30% of the patients on Arm B and 35% of the patients on Arm C. The median overall survival was 217 days on Arm A (range of 15 to 663 days), 232 days on Arm B (range of 37 to over 811 days) and 236 days on Arm C (range of 16 to over 672 days). Overall response rate, a secondary endpoint consisting of the rate of CR, CRp, PR, CRi or hematological improvement, was 24% for patients on Arm A, 35% for patients on Arm B and 15% for patients on Arm C. Two patients achieved a CR both on Arm A. Approximately 20% of all patients received sapacitabine for 4 to 6 cycles and 15% for 7 or more cycles. The mortality rate from all causes within thirty days of randomization was 6.6%.

Publication details

52nd Annual Meeting of the American Society of Hematology (ASH)

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	Hall A3/A4 (Orange County Convention Center)
Session:	Myelodysplastic Syndromes: Poster I
Poster board:	I-837

The abstract is available online at http://ash.confex.com/ash/2010/webprogram/start.html.

About MDS

MDS is a family of clonal myeloid neoplasms, or malignancies of the blood, caused by the failure of blood cells in the bone marrow to develop into mature cells. Patients with MDS typically suffer from bone marrow failure and cytopenias, or reduced counts of platelets, red and white blood cells.

The exact incidence and prevalence of MDS are unknown because it can go undiagnosed and a national survey has not been completed. Some estimates place MDS incidence at 15,000 to 20,000 new cases each year in the US alone with some authors estimating incidence as high as 46,000. Literature evidence suggests that there is a rising incidence of MDS as the age of the population increases with the majority of patients aged above 60 years.

Most patients with high risk disease, as defined by IPSS, die from their disease within one year of diagnosis with reported mean survival rates of six to nine months. Patients with high IPSS scores, such as intermediate-2 and high risk, have a high probability of experiencing transformation of their MDS into acute myeloid leukemia (AML), an aggressive form of blood cancer with typically poor survival.

About sapacitabine

Sapacitabine (CYC682), an orally-available nucleoside analog, will be entering Phase 3 development for the treatment of acute myeloid leukemia (AML) in the elderly under a Special Protocol Assessment agreement with the U.S. Food and Drug Administration, and is in Phase 2 studies for myelodysplastic syndromes (MDS) and lung cancer. 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-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 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 hematological malignancies and solid tumors. In December 2009 at the 51st Annual Meeting of the American Society of Hematology (ASH), Cyclacel reported data from a randomized Phase 2 study including 1-year survival in elderly patients with AML aged 70 years or older. 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. Three product candidates are in clinical development. Sapacitabine (CYC682), a cell cycle modulating nucleoside analog, will be entering 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 is 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. 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.

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 Cyclacel 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.

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