Cyclacel Provides Update on Clinical Progress With Sapacitabine as Second Line Therapy in Older Patients With Myelodysplastic Syndromes

Complete Remissions and Major Hematological Improvements in MDS After Treatment Failure of Hypomethylating Agents

BERKELEY HEIGHTS, N.J., Feb. 13, 2012 (GLOBE NEWSWIRE) -- Cyclacel Pharmaceuticals, Inc. (Nasdaq:CYCC) (Nasdaq:CYCCP) (Cyclacel or the Company), announced today new topline response data from an ongoing, multicenter, Phase 2 randomized trial of oral sapacitabine capsules, a novel nucleoside analogue, in older patients with myelodysplastic syndromes (MDS) after treatment failure of hypomethylating agents, such as azacitidine and/or decitabine. Eight patients responded with 2 complete remissions (CR), 2 complete remissions with incomplete platelet count recovery (CRp) and 4 major hematological improvements of platelet counts or neutrophils. More than 50% of the patients are still alive and longer follow-up is needed to assess 1-year survival and overall survival.

"MDS patients have poor outcome after treatment failures of front-line hypomethylating agents. The interim response data indicates that sapacitabine is active in this patient population," said Hagop Kantarjian, M.D., Chairman & Professor, Department of Leukemia, The University of Texas MD Anderson Cancer Center and principal investigator for the study. "Front line treatment of MDS with hypomethylating agents results in a CR rate ranging from 5.6% to 17%. It is encouraging to observe CRs in MDS patients treated with sapacitabine as a single agent after failures of hypomethylating agents."

"We are encouraged by these interim results with sapacitabine as a second line treatment of older patients with myelodysplastic syndromes (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 after treatment failure of hypomethylating agents. We are also looking forward to continue enrollment in 'SEAMLESS', our pivotal Phase 3 study of sapacitabine in elderly patients with acute myeloid leukemia (AML). Sapacitabine may emerge as the first oral drug that could address the unmet medical need in both AML and MDS patients."

Interim Data from Ongoing Phase 2 Study in Patients with MDS

The study randomized 61 patients aged 60 years or older with IPSS score 2 or higher risk MDS to receive sapacitabine every 4 weeks on one of the 3 dosing schedules: 200 mg twice daily for 7 days, 300 mg once daily for 7 days, or 100 mg once daily for 5 days per week for 2 weeks. Among 56 patients who have had at least 30 days of follow-up, the thirty-day mortality from all causes is 5.4%. Eight patients responded with 2 complete remissions (CR), 2 complete remissions with incomplete platelet count recovery (CRp) and 4 major hematological improvements of platelet counts or neutrophils. Responses occurred on all 3 dosing schedules. More than 50% of the patients are still alive and longer follow-up is needed to assess 1-year survival and overall survival.

MDS Phase 2 Study Objective & Previously Reported Interim 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. Updated results will be reported at an upcoming medical conference.

At the 2010 annual meeting of the American Society of Hematology Cyclacel reported interim data from three schedules of sapacitabine administered as single-agent treatment over a 4-week cycle in 61 patients with IPSS intermediate — 2 or higher risk MDS after treatment failure of hypomethylating agents: 200 mg twice daily for 7 days, 300 mg twice daily for 7 days, or 400 mg twice daily for 3 days per week for 2 weeks. The primary endpoint of 1-year survival was achieved in 29%, 30% and 35% of the patients respectively among the 3 schedules tested. Median overall survival was 217, 232 and 236 days respectively. Two patients achieved a CR. The mortality rate from all causes within 30 days of randomization was 6.6%.

About Myelodysplastic Syndromes (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 canvassing both hospitals and office practitioners 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 or the International Prognostic Scoring System,[1] 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.

[1]Greenberg P, et al, International scoring system for evaluating prognosis in myelodysplastic syndromes. Blood 1997;86:2079.

About sapacitabine

Sapacitabine (CYC682), an orally-available nucleoside analogue, is currently being evaluated in a registration-directed, Phase 3 trial in elderly patients with newly diagnosed acute myeloid leukemia (AML), Phase 2 trials in patients with hematological malignancies, including myelodysplastic syndromes (MDS), cutaneous T-cell lymphoma (CTCL), chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL), and non-small cell lung cancer (NSCLC) and in a Phase 1 trial in combination with seliciclib in patients with advanced solid tumors. Sapacitabine acts through a novel DNA single-strand breaking mechanism, leading to production of DNA double strand breaks (DSBs) and/or checkpoint activation. Unrepaired DSBs cause cell death. Repair of sapacitabine-induced DSBs is dependent on the homologous recombination DNA repair (HRR) pathway. Both sapacitabine and CNDAC, its major metabolite, have demonstrated potent anti-tumor activity in preclinical studies.

Over 350 patients have received sapacitabine in Phase 2 studies in AML, MDS, CTCL and NSCLC. Sapacitabine has been administered to approximately 600 patients in Phase 1 and Phase 2 studies with both hematological malignancies and solid tumors. In December 2011 at the Annual Meeting of the American Society of Hematology (ASH), Cyclacel reported median overall survival of approximately 8 months from a pilot Phase 1/2 study of elderly patients with AML aged 70 years or older receiving sapacitabine alternating with decitabine. In December 2011 Cyclacel reported that sapacitabine demonstrates anti-tumor activities as measured by partial response and stable disease, in Phase 2 patients with Non-Small Cell Lung Cancer and also in Phase 1 patients with various solid tumors who are carriers of BRCA mutations. The FDA and the European Medicines Agency have designated sapacitabine as an orphan drug for the treatment of both AML and MDS. 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), an orally-available, cell cycle modulating, nucleoside analogue, is in a Phase 3 trial being conducted under a SPA with the U.S. FDA for the front-line treatment of acute myeloid leukemia in the elderly and Phase 2 studies for myelodysplastic syndromes, lung cancer and chronic lymphocytic leukemia. Seliciclib (CYC202 or R-roscovitine), an orally-available, 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, trials may have difficulty enrolling, Cyclacel may 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.

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