June 1, 2012

Cyclacel Presents New Phase 2 Data of Sapacitabine for MDS at ASCO Annual Meeting

Results Highlight Sapacitabine's Activity in MDS and Potential Role as Second-Line Therapy After Treatment Failure of Hypomethylating Agents

BERKELEY HEIGHTS, N.J., June 1, 2012 (GLOBE NEWSWIRE) -- Cyclacel Pharmaceuticals, Inc. (Nasdaq:CYCC) (Nasdaq:CYCCP) (Cyclacel or the Company), today announced new data from an ongoing, multicenter, Phase 2 randomized trial of oral sapacitabine capsules, the Company's lead product candidate, in older patients with myelodysplastic syndromes (MDS) after treatment failure of front-line hypomethylating agents, such as azacitidine (Vidaza®) and/or decitabine (Dacogen®). Median overall survival to date for all patients is 252 days or approximately 8.4 months. Data were presented as a poster during the 2012 American Society of Clinical Oncology (ASCO) Annual Meeting being held June 1-5, 2012, in Chicago, Illinois.

"MDS patients have a poor outcome after treatment failures with front-line therapies and the interim data reported at ASCO 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. "Median survival for patients with intermediate-2 or high-risk MDS following treatment failures of hypomethylating agents is 4.3 to 5.6 months.[1, 2] Effective therapies are urgently needed for these patients."

Study Design

The open-label, multi-center, Phase 2 study randomized 63 patients aged 60 years or older with MDS of intermediate-2 (n=52) or high-risk (n=11) classification by the International Prognostic Scoring System (IPSS) at study entry to receive sapacitabine every 4 weeks on one of the 3 dosing schedules: 200 mg twice daily for 7 days (Arm G), 300 mg once daily for 7 days (Arm H), or 100 mg once daily for 5 days per week for 2 weeks (Arm I). The primary efficacy endpoint of the study is 1-year survival with the objective of identifying a dosing schedule that produces a better 1-year survival rate in the event that all three dosing schedules are active. All patients in the study progressed after receiving azacitidine, decitabine, or both agents.

Results

At ASCO, the median overall survival for each arm was reported as follows: 240 days (approx. 8 months) for Arm G, 290 days (approx. 10 months) for Arm H, and 153 days (approx. 5 months) for Arm I. The median overall survival for all three arms is 252 days (approx. 8 months). Complete remissions (CRs) and major hematologic improvement (HI) in platelet counts or neutrophils, secondary efficacy endpoints in the study, were observed on all 3 dosing schedules as follows: 1 CR and 3 HI's in Arm G, 1 CR and 2 HI's in Arm H, and 2 CRs and 1 HI in Arm I. The thirty-day mortality from all causes is 5%. Forty-one percent of all patients received 4 or more cycles. More than 34% of the patients are still alive and longer follow-up is needed to assess 1-year survival and overall survival.

"As we continue patient enrollment in SEAMLESS, our pivotal Phase 3 study of sapacitabine in elderly patients with acute myeloid leukemia (AML), we are encouraged by the interim results of sapacitabine as a second line treatment of older patients with MDS," said Judy H. Chiao, M.D., Cyclacel's Vice President, Clinical Development and Regulatory Affairs. "Sapacitabine may emerge as the first oral drug that could address the unmet medical need in both AML and MDS patients."

The abstract can be accessed through the ASCO website, www.asco.org:

"A randomized phase 2 study of sapacitabine in MDS refractory to hypomethylating agents"

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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.

Median survival for patients with intermediate-2 or high-risk disease, as defined by the International Prognostic Scoring System (IPSS), is 4.3 to 5.6 months.[1, 2] Patients with high IPSS scores also have a high probability of experiencing transformation of their MDS into AML, an aggressive form of blood cancer with typically poor survival.

[1] Prebet T, Gore S, et al, Outcome of High-Risk Myelodysplastic Syndrome After Azacitidine Treatment Failure, Journal of Clinical Oncology 2011, 10.1200/JCO.2011.35.8135.

[2] Jabbour E, Garcia-Manero G, et al, Outcome of Patients With Myelodysplastic Syndrome After Failure of Decitabine Therapy, Cancer 2010, 10.1002/cncr.25247.

About sapacitabine

Sapacitabine (CYC682), an orally-available nucleoside analogue, is in the SEAMLESS, 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), a Phase 1 trial in combination with seliciclib in patients with advanced solid tumors and an investigator-led, Phase 2/3 study comparing sapacitabine to low dose cytarabine as front-line treatment of elderly patients with AML or high risk MDS unfit for intensive chemotherapy. 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 and over 170 patients in five Phase 1 studies with both hematological malignancies and solid tumors. In June 2009 at the Annual Meeting of the American Society of Hematology (ASH), Cyclacel reported data from a randomized Phase 2, single-agent study of sapacitabine including promising 1-year survival in elderly patients with AML aged 70 years or older. In June 2011 at the Annual Meeting of the American Society of Clinical Oncology (ASCO), Cyclacel reported data from a pilot Phase 1/2 study including promising response rate, low 4-week and 8-week mortality in elderly patients with AML aged 70 years or older receiving sapacitabine alternating with decitabine. 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.

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-1 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 and 13 achieved major hematologic improvement. The mortality rate from all causes within 30 days of randomization was 6.6%.

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 oral capsules is in the SEAMLESS Phase 3 trial being conducted under an SPA with the FDA as front-line treatment of acute myeloid leukemia (AML) in the elderly, Phase 2 studies for AML, myelodysplastic syndromes (MDS), solid tumors including lung cancer, chronic lymphocytic leukemia and an investigator-led, Phase 2/3 study comparing sapacitabine to low dose cytarabine as front-line treatment of elderly patients with AML or high risk MDS unfit for intensive chemotherapy. Cyclacel's pipeline includes seliciclib oral capsules 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 product candidates, 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 other filings we file 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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