



December 9, 2013

Cyclacel Reports New Phase 2 Data of Sapacitabine for MDS at ASH

- Nearly Doubles Expected Median Survival of Older Patients with MDS after Treatment Failure of Hypomethylating Agents -

- Data Presented at 2013 American Society of Hematology (ASH) Meeting and Exposition -

BERKELEY HEIGHTS, N.J., Dec. 9, 2013 (GLOBE NEWSWIRE) -- Cyclacel Pharmaceuticals, Inc. (Nasdaq:CYCC) (Nasdaq:CYCCP) (Cyclacel or the Company), today announced new, primary endpoint data from an ongoing, open-label, multicenter, randomized Phase 2 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 and/or decitabine. The 7-day dose regimen of 200 mg twice daily (Arm G), appears to be a better schedule with a one-year survival rate of 38%, median overall survival of approximately 10 months and response rate of 19%. The 30-day mortality from all causes for all patients is 5%. Data were presented at a poster on December 8, 2013 during the 2013 American Society of Hematology (ASH) Meeting and Exposition held in New Orleans, LA.

"The survival data from this study in MDS patients after treatment failures of hypomethylating agents continue to be impressive based on our experience with investigational agents and justify further clinical evaluation of sapacitabine," said Guillermo Garcia-Manero, M.D., Chief of the Section of Myelodysplastic Syndromes and Professor, Department of Leukemia, The University of Texas MD Anderson Cancer Center and an investigator for the study.

"We are very interested in novel treatment options for MDS patients following failure of front-line therapies. The survival data with sapacitabine in this population confirm our previous experience with the drug," 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 with investigational agents is 4.3 to 5.6 months and with best supportive care 4.1 months. We urgently need new therapeutics for these patients with the potential of controlling the disease and offering high quality of life."

"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 promising survival data of sapacitabine as a treatment of older patients with MDS after failure of front line hypomethylating agents," added Judy H. Chiao, M.D., Vice President, Clinical Development and Regulatory Affairs of Cyclacel. "Sapacitabine may emerge as the first oral drug that could potentially address the unmet medical needs of both AML and MDS patients."

Results

At ASH, the median overall survival for each arm was approximately 9.7 months for Arm G, 9.7 months for Arm H and 7.6 months for Arm I. The median overall survival for all three arms is approximately 8.6 months. One-year survival is 38% for Arm G, 24% for Arm H, and 33% for Arm I. To date, 9 patients have responded (2 CRs, 2 CRp, and 5 major HIs): 19% for Arm G, 10% for Arm H and 14% for Arm I. Time to response is 1 to 4 cycles. Median number of cycles was 3 with a range of 1 to over 23 and 30 patients received 4 or more cycles. Additionally, 23 patients achieved stable disease lasting longer than 16 weeks. The thirty-day mortality from all causes is 5% in each of the three arms. Ten patients (approximately 16%) are still alive.

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 four weeks on one of 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 two weeks (Arm I). Eligible patients must be aged 60 years or older with intermediate-2 or high-risk MDS previously treated with hypomethylating agents and 6%-19% blasts in their bone marrow, ECOG performance status 0-2, and adequate renal and hepatic function. The primary efficacy endpoint 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. Median age was 73. Forty-one patients had 10-19% blasts in their bone marrow. All patients in the study progressed after receiving either azacitidine and/or decitabine. Eighteen patients were double refractory as they had received both agents.

Abstract Information

The sapacitabine abstract can be accessed through the following link on the ASH website:
<https://ash.confex.com/ash/2013/webprogram/Paper63484.html>. Abstract information is as follows:

Session Name: 633. Myelodysplastic Syndromes: Poster II

Abstract 2752: "A Randomized Phase II Study Of Sapacitabine In MDS Refractory To Hypomethylating Agents" Garcia-Manero, et al.

Date: Sunday, December 8, 2013

Presentation Time: 6:30 PM - 8:30 PM

Location: Ernest N. Morial Convention Center, Hall E

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 30,000 to 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 with investigational agents and 4.1 months with best supportive care.^{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 being studied in SEAMLESS, an ongoing, Phase 3, registration-directed trial in elderly patients aged 70 years or older with newly diagnosed AML who are not candidates for or have refused induction chemotherapy. Sapacitabine is in Phase 2 trials in patients with hematological malignancies, including AML, myelodysplastic syndromes (MDS), cutaneous T-cell lymphoma (CTCL), chronic lymphocytic leukemia, small lymphocytic lymphoma, and also non-small cell lung cancer (NSCLC), and a Phase 1 trial 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 (HR) DNA repair pathway. Both sapacitabine and CNDAC, its major metabolite, have demonstrated potent anti-tumor activity in preclinical studies.

Over 800 patients have received sapacitabine in clinical studies in patients with AML, MDS, CTCL, NSCLC, hematological malignancies and solid tumors. At the 2012 American Society of Hematology (ASH) Annual Meeting, data from the pilot study and lead-in phase of SEAMLESS showed promising response rate, overall survival and low 30-day and 60-day mortality in elderly patients with AML aged 70 years or older receiving sapacitabine alternating with decitabine. Results 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 were published in *The Lancet Oncology* in November 2012.

At the 2013 American Association of Cancer Research (AACR) Annual Meeting data, from a Phase 1 study of sapacitabine in combination with Cyclacel's oral seliciclib, which showed antitumor activity in cancer patients found to be carriers of gBRCA mutations was highlighted by the AACR Annual Meeting Program Committee.

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, Cyclacel's most advanced product candidate, is the subject of SEAMLESS, a Phase 3 trial being conducted under an SPA with the FDA as front-line treatment for acute myeloid leukemia (AML) in the elderly, and other studies for myelodysplastic syndromes (MDS), chronic lymphocytic leukemia (CLL) and solid tumors including breast, lung, ovarian and pancreatic cancer and in particular those carrying gBRCA mutations. Cyclacel's strategy is to build a diversified biopharmaceutical business focused in hematology and oncology based on 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 the Company's most recent Annual Report on Form 10-K and other periodic and other filings Cyclacel files 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 Cyclacel assumes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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