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Cyclacel's Sapacitabine Nearly Doubles Expected Survival of Elderly Patients With MDS After Front-Line Therapy Failure

Conference Call Today at 3:30 PM ET With Leading Physicians to Review Results

BERKELEY HEIGHTS, N.J., Oct. 15, 2012 (GLOBE NEWSWIRE) -- Cyclacel Pharmaceuticals, Inc. (Nasdaq:CYCC) (Nasdaq:CYCCP) (Cyclacel or the Company), will host a conference call today to discuss updated data from an ongoing, multicenter, Phase 2 randomized trial of oral sapacitabine capsules, the Company's lead product candidate, in older patients with intermediate-2 or high-risk myelodysplastic syndromes (MDS) after treatment failure of front-line hypomethylating agents, such as azacitidine (Vidaza®) and/or decitabine (Dacogen®).

The data were recently discussed at two separate sessions at The Eighth Annual Hematologic Malignancies 2012 Conference being held on October 10-14, 2012, in Houston, Texas. Median overall survival to date for all 63 patients in the Phase 2 study is 252 days or approximately 8 months. Median overall survival for 41 out of 63 patients with 10% or more blasts in their bone marrow is 274 days or approximately 9 months.

In addition to Cyclacel senior management, Guillermo Garcia-Manero, M.D., Chief of the Section of Myelodysplastic Syndromes and Professor, Department of Leukemia and Hagop Kantarjian, M.D., Chairman & Professor, Department of Leukemia, both with The University of Texas MD Anderson Cancer Center, will review and discuss the findings from the Phase 2 trial. The call is scheduled for Monday, October 15, 2012, starting at 3:30 p.m. (ET) and can be accessed by dialing (877) 493-9121 (domestic) or (973) 582-2750 (international) and providing the pass code 44048598. A replay of the call will be available approximately two hours after completion of the call and will be archived for three weeks.

Study Results

Updated median survival for all three arms is 252 days (approximately 8 months). The median survival for each arm is 291 days (approximately 10 months) for Arm G, 274 days (approximately 9 months) for Arm H, and 227 days (approximately 8 months) for Arm I. Twenty-seven percent of all patients received 6 or more cycles. Twenty-two percent of patients are still alive and longer follow-up is needed to assess 1-year survival and overall survival of each arm.

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 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.

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), and in the investigator-led, Phase 2/3 LI-1 Trial in patients aged 60 years or older with previously untreated AML or high risk MDS who are unfit for intensive chemotherapy. Sapacitabine is in 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 500 patients have received sapacitabine in Phase 2 studies in AML, MDS, CTCL and NSCLC and Phase 1 studies in both hematological malignancies and solid tumors. At the 2009 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. At the 2011 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. Cyclacel is currently enrolling patients in the SEAMLESS, Phase 3, randomized, registration-directed study of sapacitabine in elderly patients with acute myeloid leukemia (AML). 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 sapacitabine in MDS

A total of 124 patients aged 60 years or older with MDS previously treated with hypomethylating agents (HMA) were treated in a Cyclacel Phase 2 study. Initially 61 patients were randomized across 3 dosing schedules of sapacitabine. Mature survival data from this cohort were presented at the 2010 Annual Meeting of the American Society of Hematology (ASH) on the basis of which the study was subsequently expanded to compare additional dosing schedules. Interim data on a further 63 patients were presented at the 2012 Annual Meeting of the American Society of Clinical Oncology (ASCO), with median survival of 8.4 months. This survival level is considered clinically significant by MDS experts in light of historical control expectations of 4 to 5 months. At the time of ASCO 2012 over 34% of the patients were still alive and longer follow-up is needed to assess 1-year survival and overall survival. Updated mature survival data will be reported in late 2012 or early 2013. Cyclacel is developing a pivotal development plan for the indication of second-line MDS to present to regulatory authorities.

At ASCO 2012 Cyclacel reported interim data from three schedules of sapacitabine administered as single-agent treatment over a 4-week cycle in 63 patients with IPSS intermediate-1 or higher risk MDS after treatment failure of hypomethylating agents: 200 mg twice daily for 7 days as Arm G, 300 mg once daily for 7 days as Arm H, or 100 mg once daily for 5 days per week for 2 weeks as Arm I. Median overall survival was 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. Median overall survival for all three arms is 252 days (approx. 8 months). In terms of secondary efficacy endpoints complete remissions (CRs) and major hematologic improvement (HI) in platelet counts or neutrophils, were observed on all 3 dosing schedules: 1 CR and 3 HIs in Arm G, 1 CR and 2 HIs in Arm H, and 2 CRs and 1 HI in Arm I. The 30-day mortality from all causes is 5%. Forty-one percent of all patients received 4 or more cycles. At the time of ASCO 2012 more than 34% of the patients were still alive and longer follow-up is needed to assess 1-year survival and overall survival.

At ASH 2010 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 as Arm A, 300 mg twice daily for 7 days as Arm B, or 400 mg twice daily for 3 days per week for 2 weeks as Arm C. 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 days (approx. 7 months), 232 days (approx. 8 months) and 236 days (approx. 8 months) respectively. Two patients achieved a CR and 13 achieved major hematologic improvement. The 30-day mortality from all causes 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) and solid tumors including lung cancer and in investigator-led studies including a 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 and a Phase 2 study in chronic lymphocytic leukemia. 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 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 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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