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Cyclacel Reports Updated Phase 2 Survival Data of Sapacitabine for MDS

Nearly Doubles Expected Median Survival of Older Patients With MDS Who Failed Front-Line Therapies

BERKELEY HEIGHTS, N.J., April 30, 2013 (GLOBE NEWSWIRE) -- Cyclacel Pharmaceuticals, Inc. (Nasdaq:CYCC) (Nasdaq:CYCCP) (Cyclacel or the Company), announced updated median overall survival 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®). Median overall survival to date for all 63 patients treated is approximately 9 months. Median overall survival for each of the three randomization schedules is approximately 10 months for Arm G, 10 months for Arm H and 8 months for Arm I. The 30-day mortality for all patients is 5%.

"The updated survival data from this study in MDS patients after treatment failures of hypomethylating agents continue to be impressive based on our experience," 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. "Sapacitabine's oral administration and low 30-day mortality suggest that it may become a new treatment standard for older patients with MDS."

"There is a dearth of treatment options for MDS patients after failing front-line therapies. The updated survival data with sapacitabine as a single agent in MDS 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 is 4.3 to 5.6 months. We urgently need new therapeutics for these patients with the potential of controlling the disease and offering high quality of life."

Results

The updated median overall survival for all three arms is 259 days or approximately 9 months. The median overall survival for each arm was 291 days or approximately 10 months for Arm G, 290 days or approximately 10 months for Arm H, and 227 days or approximately 8 months for Arm I. Median number of cycles was 3. Approximately 43% of patients received 4 or more cycles. Median follow-up is 524 days and 13 patients are still alive. Longer follow-up is needed to assess 1-year survival and overall survival of each arm.

Topline median survival data were previously reported at two separate sessions at The Eighth Annual Hematologic Malignancies 2012 Conference held on October 10-14, 2012, in Houston, Texas.

Study Design

The open-label, multi-center, Phase 2 study randomized 63 patients aged 60 years or older with MDS of intermediate-2 (n=50) or high-risk (n=13) 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). 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, 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. Thirty-nine 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.

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. 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.

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 Cyclacel's oral 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 650 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- and 60-day mortality in elderly patients with AML aged 70 years or older receiving sapacitabine alternating with decitabine. Data, presented at The Eighth Annual Hematologic Malignancies 2012 Conference, from an ongoing, multicenter, Phase 2 randomized trial of single-agent oral sapacitabine capsules in older patients with intermediate-2 or high-risk myelodysplastic syndromes (MDS) after treatment failure of front-line hypomethylating agents, such as azacitidine and/or decitabine, showed sapacitabine nearly doubled expected median survival of elderly patients with MDS after front-line therapy failure. Cyclacel is developing a pivotal trial plan for sapacitabine in the MDS indication. 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. In a Phase 1 study, sapacitabine, in combination with Cyclacel's seliciclib, showed antitumor activity in cancer patients with HR pathway defects including 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, 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 BRCA 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 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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CONTACT: Contact for Cyclacel Pharmaceuticals, Inc.

Investors/Media: Corey Sohmer,

(908) 517-7330, csohmer@cyclacel.com