



November 7, 2013

Researchers to Present New Phase 2 Data on Sapacitabine as a Treatment for Patients With MDS at ASH Annual Meeting

- Including Primary Endpoint of One Year Survival to Select a Dosing Schedule for Phase 3 Study -

BERKELEY HEIGHTS, N.J., Nov. 7, 2013 (GLOBE NEWSWIRE) -- Cyclacel Pharmaceuticals, Inc. (Nasdaq:CYCC) (Nasdaq:CYCCP) (Cyclacel or the Company), today announced that researchers will present new 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 and/or decitabine, at the 55th Annual Meeting of the American Society of Hematology (ASH). The data include the primary endpoint of one year survival which will enable selection of a dosing schedule for a Phase 3 study.

An abstract summarizing the data is published on the ASH website (<https://ash.confex.com/ash/2013/webprogram/Paper63484.html>). The ASH annual meeting will be held December 7-10, 2013 in New Orleans, LA. Further information related to the data is embargoed until the time of presentation in accordance with the meeting's embargo policy.

Abstract Information

The sapacitabine 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. 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 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.

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.

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