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Cyclacel Announces Publication of Phase 2 Results for Sapacitabine in Elderly AML Patients in the Lancet Oncology

Study Provides Support for SEAMLESS, an Ongoing, Phase 3, Registration-Directed Trial in Elderly Patients With Newly Diagnosed AML

Updated Survival Data From a Pilot Study and Lead-In Phase of SEAMLESS to be Presented at the 2012 Annual Meeting of the American Society of Hematology

BERKELEY HEIGHTS, N.J., Nov. 1, 2012 (GLOBE NEWSWIRE) -- Cyclacel Pharmaceuticals, Inc. (Nasdaq:CYCC) (Nasdaq:CYCCP) (Cyclacel or the Company), today announced the publication of results from a Phase 2 randomized trial of single-agent sapacitabine in elderly patients aged 70 years or older with newly diagnosed acute myeloid leukemia (AML) or AML in first relapse. The study, published in *The Lancet Oncology*, demonstrates the safety and efficacy of sapacitabine in this patient population.

"We are pleased to report that Phase 2 data for sapacitabine in AML has been published in a prestigious peer-reviewed journal," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "The data provide support for SEAMLESS, our ongoing, Phase 3, registration-directed study in elderly patients with newly diagnosed AML. We will provide an update on patient enrollment in SEAMLESS during our third quarter conference call and present updated survival data from the pilot study and lead-in phase of SEAMLESS at the upcoming American Society of Hematology 2012 annual meeting in December. We also look forward to reaching the second planned periodic safety review of SEAMLESS in the near future. In addition to our AML programs, we are committed to exploring with the FDA next steps for sapacitabine in older patients with intermediate-2 or high-risk myelodysplastic syndromes (MDS) after failure of front-line therapy based on encouraging survival demonstrated in recently disclosed Phase 2 data. If Phase 3 trials are successful, sapacitabine could emerge as the first oral drug for the treatment of AML, and possibly, MDS."

The Phase 2 study enrolled and treated between December 27, 2007 and April 21, 2009, a total of 105 patients aged 70 years or above with untreated or first relapse AML. The median age of patients was 77 years (range 70—91). The group was comprised of a randomized cohort of 60 patients and an expanded, non-randomly assigned cohort enrolling a further 45 patients. Of the 105 patients, 86 were previously untreated and 19 in first relapse. Approximately 50% of patients had AML *de novo* and 50% had AML preceded by antecedent hematological disorder (AHD), such as MDS or myeloproliferative disease, or treatment-related AML. All but one enrolled patients had intermediate or unfavorable cytogenetics. The randomized cohort of patients were randomly assigned to one of three dosing schedules: 200 mg twice a day for 7 days (group A); 300 mg twice a day for 7 days (group B); and 400 mg twice a day for 3 days each week for 2 weeks (group C). All schedules were given in 28 day cycles.

The 3-day dosing schedule in group C was selected for further clinical development in elderly patients with untreated AML. This decision was based on the schedule's overall efficacy profile, which included a 1-year survival rate of 30%, median overall survival of 213 days and durable complete remissions (CRs) in 25% of patients. The median overall survival of patients from all groups who achieved CR was 525 days (95% C.I. 192—798).

The most common grade 3—4 adverse events regardless of causality were anemia, neutropenia, thrombocytopenia, febrile neutropenia and pneumonia. Seven deaths were thought to be probably or possibly related to sapacitabine treatment. Approximately 31% of all patients received sapacitabine for at least 4 cycles.

Journal Citation

Hagop Kantarjian, Stefan Faderl, Guillermo Garcia-Manero, Selina Luger, Parameswaran Venugopal, Lori Maness, Meir Wetzler, Steven Coutre, Wendy Stock, David Claxton, Stuart L Goldberg, Martha Arellano, Stephen A Strickland, Karen Seiter, Gary Schiller, Elias Jabbour, Judy Chiao, William Plunkett, Oral sapacitabine for the treatment of acute myeloid leukaemia in elderly patients: a randomised phase 2 study, The Lancet Oncology, Volume 13, Issue 11, Pages 1096 - 1104, November 2012.

The journal paper can be accessed at: http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045%2812%2970436-9/fulltext or by using doi:10.1016/S1470-2045(12)70436-9.

About Acute Myeloid Leukemia (AML)

AML is a cancer of the blood cells that progresses rapidly and if not treated, could be fatal in a few months. AML is generally a disease of older people and is uncommon before the age of 40. The average age of a patient with AML is about 67 years. There are more than 12,300 new cases of AML, of which about half are elderly aged 70 years or older. Nearly 9,000 deaths are caused by this cancer each year in the United States. A review of The University of Texas MD Anderson Cancer Center's historical experience with front-line intensive induction chemotherapy for AML patients aged 70 years or older demonstrated that while 45% achieved a complete remission, median overall survival was only 4.6 months and was associated with a 4-week death rate of 26% and a 8-week death rate of 36% (Kantarjian, H, et al, Blood, doi:10.1182/blood-2010-03-276485).

About sapacitabine and SEAMLESS

Sapacitabine (CYC682), an orally-available nucleoside analogue, is currently being studied in 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. SEAMLESS is being conducted under a Special Protocol Assessment (SPA) agreement that Cyclacel reached with the US Food and Drug Administration (FDA). Sapacitabine is also the subject of Phase 2 trials in patients with hematological malignancies, including MDS, cutaneous T-cell lymphoma, chronic lymphocytic leukemia and small lymphocytic lymphoma, and non-small cell lung cancer, a Phase 1 trial in combination with seliciclib in patients with advanced solid tumors, and an investigator-led, Phase 2/3 study ("LI-1 Trial") 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 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. 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 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 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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