



Cyclacel announces commencement of investigator-initiated phase 2 trial of sapacitabine in patients with CLL or SLL hematological malignancies and 11q22-23 deletion

- Novel gene-based, personalized medicine approach based on previously published DNA-repair mechanism -

Berkeley Heights, NJ, August 30, 2011 – Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP; Cyclacel or the Company), today announced that the first patient has been dosed in an investigator-initiated, translational, Phase 2 clinical study at The University of Texas MD Anderson Cancer Center. The objective of the study is to learn if oral sapacitabine capsules given in combination with two standard injectable drugs, cyclophosphamide and rituximab, or the “SCR regimen”, can help control chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL) in up to 40 relapsed patients with leukemia cells containing the 11q22-23 chromosome deletion. Deletion at chromosome 11q22-23 is associated with deletion of the Ataxia Telangiectasia Mutated (ATM) gene, an important element of the homologous recombination DNA repair (HRR) pathway. Previous findings show that cells with HRR pathway defects are particularly sensitive to sapacitabine. Sapacitabine may therefore be of particular benefit to patients with ATM-defective blood cancers.

The study is led by William G. Wierda, M.D., Ph.D., Associate Professor of Medicine, Leukemia Department, Division of Cancer Medicine, and is based on translational work published by a group led by William Plunkett, Ph.D., Professor and Deputy Chair, Department of Experimental Therapeutics, both of MD Anderson. The trial is being funded by MD Anderson’s Leukemia Department with Cyclacel contributing sapacitabine and a small grant to support the performance of certain exploratory diagnostic tests.

“As gene-based, personalized medicine approaches have in certain cases been developed and approved faster than traditional methods, we are encouraged by the prospect of tailoring treatment with sapacitabine to the genetic profile of an individual’s cancer cells,” said Spiro Rombotis, President and CEO of Cyclacel. “We have collaborated with Dr. Wierda, Dr. Plunkett and their teams for several years to study sapacitabine’s effects on the DNA repair pathway. We thus welcome the opportunity to explore the hypothesis that the presence of 11q22-23 deletion may translate into clinical benefit for patients treated with the sapacitabine-based SCR regimen, while doing so in a fiscally responsible and collaborative manner. We look forward to the eventual outcome of this unique study and building our value proposition on data from Cyclacel’s ongoing studies in both hematological malignancies and solid tumors, with emphasis on our SEAMLESS Phase 3 pivotal trial in patients with front-line acute myeloid leukemia (AML).”

The translational Phase 2 study is a single institution, single arm, trial of the SCR regimen in previously treated patients with CLL or SLL. The primary objective is to evaluate the overall response rate of the regimen based on the 2008 International Workshop on Chronic Lymphocytic Leukemia (IWCLL) criteria. Up to 40 patients will be enrolled at different dosing schedules under evaluation. Secondary endpoints include the evaluation of tolerability and toxicities, determination of duration of response, disease-free survival and overall survival. In addition the study will evaluate the association between response to the SCR regimen and ATM gene function in previously treated patients with CLL who have chromosomal deletion 11q22-23 by the fluorescence in-situ hybridization or FISH technique. The study will also evaluate other clinically-correlated pretreatment indicators with response and time-to-event outcomes.

Patients enrolled in the study will be 18 years and older and have a diagnosis of CLL or SLL with leukemia cells containing the 11q22-23 deletion, have been previously treated with at least one prior regimen and have undergone FISH-evaluation within 3 months without intervening treatment. The latest previous dose of chemotherapy must have been administered at least 30 days prior to receiving treatment on this study.

About Chronic Lymphocytic Leukemia (CLL), Small Lymphocytic Lymphoma (SLL) and Deletion 11q22-23

According to the American Cancer Society, CLL is a very common adult leukemia, accounting for one-third of all leukemias in the United States. Nearly 94,000 Americans are living with CLL, which mainly affects the elderly with an average age at the time of diagnosis around 72 years. The American Cancer Society projects 14,570 new cases of CLL and about 4,380 deaths from the disease in 2011. CLL is a type of cancer that starts from white blood cells (called lymphocytes) in the bone marrow and can spread through the blood to the lymph nodes, spleen, liver and other parts of the body. SLL, a subset of Non-Hodgkins Lymphoma (NHL) accounting for 5-10% of NHL cases, is a type of blood cancer that also starts from lymphocytes. In SLL, however, cancer cells are mainly located in the lymph nodes.

The presence of deletion 11q22-23 measured by fluorescence in-situ hybridization (FISH) occurs in approximately 18% of CLL

cases and is associated with high-risk disease with a poor prognosis. Deletion at chromosome 11q22-23 is associated with deletion of the Ataxia Telangiectasia Mutated (ATM) gene. ATM, an element of the homologous recombination DNA repair pathway, plays an important role in cellular responses to double strand DNA breaks. Previous findings show that cells with defects in this chromosome region, such as inactivation of ATM, are particularly sensitive to sapacitabine (Liu, X, et al, Blood, 9 September 2010, Vol. 116, No. 10, 1737-46). In addition to ATM deletions, mutations of ATM are also common in CLL with deletion 11q22-23. Sapacitabine may be of particular benefit to patients with ATM-defective leukemia cells.

About sapacitabine

Sapacitabine (CYC682), an orally-available nucleoside analogue, is currently being evaluated in a registration-directed, Phase 3 trial in front-line elderly AML and Phase 2 trials in patients with hematological malignancies and solid tumors. Sapacitabine acts through a dual mechanism, interfering with DNA synthesis by causing single-strand DNA breaks and inducing arrest of cell cycle progression mainly at G2-Phase. Both sapacitabine and CNDAC, its major metabolite, have demonstrated potent anti-tumor activity in preclinical studies. Over 300 patients have received sapacitabine in Phase 2 studies in AML, MDS, cutaneous T cell lymphoma (CTCL) and NSCLC. Sapacitabine has been administered to approximately 170 patients in five Phase 1 studies with both hematological malignancies and solid tumors. In December 2009 at the 51st Annual Meeting of the American Society of Hematology (ASH), Cyclacel reported data from a randomized Phase 2 study including promising 1-year survival in elderly patients with AML aged 70 years or older. 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 (CYC682), a cell cycle modulating nucleoside analog, is in Phase 3 development for the front-line treatment of acute myeloid leukemia in the elderly and Phase 2 studies for myelodysplastic syndromes, lung cancer and chronic lymphocytic leukemia. Seliciclib (CYC202 or R-roscovitine), a CDK (cyclin dependent kinase) inhibitor, is 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 ALIGN Pharmaceuticals subsidiary markets directly in the U.S. Xclair[®] Cream for radiation dermatitis, Numoisyn[®] Liquid and Numoisyn[®] Lozenges for xerostomia. Cyclacel's strategy is to build a diversified biopharmaceutical business focused in hematology and oncology based on a portfolio of commercial products and 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 products, 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 current filings that have been filed 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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