



Publications highlight novel combinations of sapacitabine with targeted agents for the treatment of cancer

Synergy Demonstrated in Preclinical Studies with HDAC Inhibitors and ATM, BRCA1/2, PARP Inhibitors

BERKELEY HEIGHTS, NJ – November 10, 2010 – Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP), a biopharmaceutical company developing oral therapies that target the various phases of cell cycle control for the treatment of cancer and other serious diseases, announced today publication of data demonstrating that its sapacitabine oral nucleoside analog works synergistically with histone deacetylase (HDAC) inhibitors to induce significant reductions in tumor cell growth in both *in vitro* and *in vivo* preclinical models. Further evidence of promising combinations of sapacitabine with targeted agents was recently published by independent investigators demonstrating synergy of sapacitabine with agents interfering with DNA repair, such as inhibitors of the function of ATM, BRCA1/2 and PARP. Taken together the publications suggest promising combination treatment strategies for future clinical evaluation in a rational and targeted manner, in addition to clinical trials currently evaluating sapacitabine and the planned SEAMLESS Phase 3 pivotal trial in acute myeloid leukemia (AML).

The data in the publication in the *British Journal of Cancer* suggest that sapacitabine given in combination with HDAC inhibitors, such as vorinostat or sodium valproate, results in significantly enhanced cell death in AML cells and cell lines derived from other tumor tissues, including cutaneous T-cell lymphoma (CTCL), non-Hodgkins lymphoma (NHL) and non-small cell lung cancer (NSCLC). In an AML xenograft model combined treatment with low doses of sapacitabine and the HDAC inhibitor vorinostat resulted in tumor regression with no apparent toxicity associated with the treatment regimen.

A second publication recently published in the journal *Blood* demonstrated that CNDAC, the major metabolite of sapacitabine, induces DNA damage that is repaired by the homologous recombination pathway. The publication describes how defects in proteins involved in the homologous recombination DNA damage pathway, such as ATM, BRCA2 and XRCC3, result in significantly increased sensitivity to CNDAC as a consequence of the cells reduced capacity to repair DNA. Patients with cancers known to have defects in the homologous recombination pathway may benefit by treatment with sapacitabine as a single agent or in combination with targeted agents interfering with DNA repair or targeting components of the homologous recombination pathway, such as PARP inhibitors or ATM inhibitors. Examples of such cancers include triple negative breast cancer and ovarian cancer, both of which have a high incidence of defects in BRCA 1/2 genes, and B-cell chronic lymphocytic leukemia (CLL), a leukemia frequently associated with a high level of ATM chromosomal deletions.

The publications support and extend data previously published by Cyclacel scientists evaluating combinations of sapacitabine with agents involved in the DNA damage pathway at the 2009 Congress of the European Hematology Association and assessing determinants of sapacitabine sensitivity at the 2010 Annual Meeting of the American Association for Cancer Research.

Publication Citations

Green, S, et al, *British Journal of Cancer*, 26 October 2010, Vol. 103, No. 9, 1391-9.
Liu, X, et al, *Blood*, 9 September 2010, Vol. 116, No. 10, 1737-46.

About sapacitabine

Sapacitabine (CYC682), an orally-available nucleoside analog, will be entering Phase 3 development for the treatment of Acute Myeloid Leukemia (AML) in the elderly under a Special Protocol Assessment agreement with the U.S. Food and Drug Administration, and is in Phase 2 studies for myelodysplastic syndromes (MDS) and lung cancer. 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 200 patients have received sapacitabine in Phase 2 studies in AML, MDS, cutaneous T cell lymphoma (CTCL) and non-small cell lung cancer (NSCLC). Sapacitabine has been administered to approximately 170 patients in five Phase 1 studies with both hematologic 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 disorders. Three product candidates are in clinical development. Sapacitabine (CYC682), a cell cycle modulating nucleoside analog, will be entering Phase 3 development for the treatment of Acute Myeloid Leukemia in the elderly under a Special Protocol Assessment agreement with the U.S. Food and Drug Administration, and is in Phase 2 studies for myelodysplastic syndromes and lung cancer. 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. CYC116, an Aurora kinase and VEGFR2 inhibitor, is in a Phase 1 trial in patients with solid tumors. 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, the risk that Cyclacel will 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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