Sapacitabine has anti-cancer activity in combination with targeted agents & other nucleoside analogs

- Preclinical data reported at European Hematology Association congress -

BERKELEY HEIGHTS, NJ – June 8, 2009 – Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP) announced that Cyclacel scientists reported preclinical data supporting potential combinations of sapacitabine, a novel nucleoside analog, with novel targeted agents and other nucleoside analogs for the treatment of cancer. The combinations exploit sapacitabine's unique mechanism of action and were shown to be effective in models of leukemia and solid tumors. The data were presented at a poster presentation on Saturday, June 6 at the 14th Congress of the European Hematology Association (EHA) in Berlin, Germany.

"We are encouraged by the wide spectrum of anti-cancer agents that result in synergy when combined with sapacitabine. The EHA data extend previously reported data and support clinical evaluation of sapacitabine given with various anti-cancer agents as combination treatment for leukemia and other cancers," said Spiro Rombotis, President and CEO. "A week ago at the ASCO conference we reported interim Phase 2 data that pave the way for a pivotal trial of sapacitabine as a single agent in elderly patients with leukemia. We look forward to developing the broad therapeutic potential of sapacitabine to benefit patients in need of new treatment options."

The results, arising from a combination screen of over 30 compounds from several chemical families, showed robust synergy when sapacitabine was combined with inhibitors of cell cycle checkpoints, cell survival, and DNA repair, including targeted inhibitors of ATM, BCL2, CHK1, DNA-PK and PARP.

In addition, increased apoptosis or cancer cell death was observed when sapacitabine was administered in combination with other nucleoside analogs which inhibit ribonucleotide reductase, such as clofarabine and gemcitabine.

The findings extend previously reported data supporting the combination of sapacitabine with demethylating agents or HDAC inhibitors.

Specific targeted molecules presented in the abstract, inducing synergy when given in combination with sapacitabine, included: ABT-888 (PARP inhibitor), ABT-737 (BCL-2 inhibitor), KU55933 (ATM inhibitor), IC86621 and NU7026 (both DNA-PK inhibitors), PF-0477736 and SB218078 (both CHK1 inhibitors).

Study reference

S Frame, RH MacKay, M Hogben, C Connolly, S Anderson, IN Fleming, S Davis, D Blake, S Green, Exploiting the unique mechanism of action of sapacitabine (CYC682) to obtain synergy with other therapeutic agents for clinical use in Acute Myeloid Leukemia, 14th Congress of the European Hematology Association (EHA), June 4-7, 2009, Berlin, Germany, Abstract 0761.

The poster is available from the Cyclacel website www.cyclacel.com and the abstract is available at http://www.eventure-online.com/eventure/publicAbstractView.do?id=102037.

About sapacitabine

Sapacitabine is an orally-available, investigational, nucleoside analog drug that acts through a dual mechanism. It interferes with DNA synthesis by causing single-strand DNA breaks and also induces arrest of cell cycle progression at G2/M-Phase. Both sapacitabine and CNDAC, its major metabolite or a substance into which the drug converts after ingestion by patients, have demonstrated potent anti-tumor activity in preclinical studies. Sapacitabine was shown to be superior in preclinical models to either gemcitabine (Gemzar®; Lilly) or ara-C, two widely used nucleoside analogs. Gemcitabine is indicated for the palliative treatment of breast, lung, pancreatic and ovarian cancer, but it has not been reported to be active in leukemias or myelodysplastic syndromes or MDS. Ara-C is indicated for the treatment of acute myeloid leukemia or AML but is typically not tolerated by elderly patients. Phase 2 trials of sapacitabine in patients with AML, MDS and non-small cell lung cancer are in progress. Sapacitabine is part of Cyclacel's deep pipeline of small molecule drugs designed to target and stop uncontrolled cell division.

About Cyclacel Pharmaceuticals, Inc.

Cyclacel is a biopharmaceutical company dedicated to the discovery, development and commercialization of novel, mechanism-targeted drugs to treat human cancers and other serious disorders. Three orally-available Cyclacel drugs are in clinical development. Sapacitabine (CYC682), a cell cycle modulating nucleoside analog, is in Phase 2 studies for the treatment of acute myeloid leukemia in the elderly, myelodysplastic syndromes and lung cancer and in Phase 1 in combination with seliciclib. Seliciclib (CYC202 or R-roscovitine), a CDK (cyclin dependent kinase) inhibitor, is in Phase 2 for the treatment of lung cancer and nasopharyngeal cancer. CYC116, an Aurora kinase and VEGFR2 inhibitor, is in Phase 1 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.

Risk factors

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. These factors and others are more fully discussed under "Risk Factors" in the Annual Report on Form 10-K for the year ended December 31, 2008, as supplemented by the interim quarterly reports, filed with the SEC.

Contacts for Cyclacel Pharmaceuticals, Inc.
Investors/Media:
Corey Sohmer, (908) 517-7330
csohmer@cyclacel.com

SOURCE: Cyclacel Pharmaceuticals, Inc.