Cyclacel's Sapacitabine receives orphan designation for AML & MDS from EU regulators

BERKELEY HEIGHTS, NJ – May 27, 2008 – Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP) announced that the European Medicines Evaluation Agency (EMEA) designated sapacitabine as an orphan medicine in two separate indications: Acute Myeloid Leukemia (AML) and Myelodysplastic Syndromes (MDS).

Specifically the EMEA's Committee for Orphan Medicinal Products (COMP) adopted a positive opinion on the company's application to designate sapacitabine as an orphan medicinal product for the indications of AML and MDS. The objective of European orphan medicines legislation is to stimulate research and development of medicinal products for rare diseases by providing incentives to industry.

An orphan designation in the European Union confers a range of benefits to sponsor companies including market exclusivity for a period of 10 years, EMEA scientific advice on protocol development, direct access to the centralized procedure for review of marketing authorizations, EMEA fee reductions and eligibility for grant support from European agencies.

Cyclacel is currently enrolling patients in an open-label, U.S. multicenter, randomized Phase 2 trial of oral sapacitabine in elderly patients with AML who are previously untreated or in first relapse.

About sapacitabine

Sapacitabine appears to act through a dual mechanism. It interferes with DNA synthesis by causing single-strand DNA breaks and also induces arrest of cell cycle progression mainly at G2/M-Phase. Both sapacitabine and CNDAC, its major metabolite or a substance into which the drugs converts after ingestion by patients, have demonstrated potent anti-tumor activity in preclinical studies. In addition, in a mouse model of liver metastasis, sapacitabine was shown to be superior in terms of delaying the onset and growth of liver metastasis to either gemcitabine (Gemzar®; Lilly) or 5-FU, two widely used nucleoside analogs. Gemcitabine is indicated for the palliative treatment of breast, lung, ovarian and pancreatic cancer, but it has not been reported to be active in leukemias or MDS.

The ongoing Phase 2 study in AML in the elderly follows three Phase 1 trials in solid tumors or lymphomas involving over 120 patients which evaluated safety and pharmacokinetics of a variety of dosing schedules. A fourth Phase 1 trial evaluated two treatment schedules of sapacitabine in 47 patients with advanced leukemias or myelodysplastic syndromes (MDS) in which previously treated patients with AML or MDS achieved complete remission (CR) or complete remission without platelet count recovery. In addition to the Phase 2 study in elderly AML patients, a further Phase 2 study of sapacitabine is currently ongoing in patients with advanced cutaneous T cell lymphoma.

Sapacitabine is part of a deep pipeline of small molecule drugs designed to target and stop uncontrolled cell division. Cyclacel's other development programs include seliciclib, a CDK (cyclin dependent kinase) inhibitor in two randomized Phase 2 clinical trials for non-small cell lung cancer and nasopharyngeal cancer, and CYC116, an Aurora kinase and VEGFR2 inhibitor in Phase 1 development in patients with solid tumors.

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 Cyclacel drugs are in clinical development. Sapacitabine (CYC682), an orally-available cell cycle modulating nucleoside analog, is in Phase 2 studies for the treatment of acute myeloid leukemia in the elderly and cutaneous T-cell lymphoma (CTCL). Seliciclib (CYC202), an orally-available CDK (cyclin dependent kinase) inhibitor, is in Phase 2 for the treatment of lung cancer and nasopharyngeal cancer. CYC116, an orally-available, Aurora kinase and VEGFR2 inhibitor, is in Phase 1 in patients with solid tumors. Several additional programs are at an earlier stage. 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, oncology and other therapeutic areas based on a portfolio of commercial products and a development pipeline of novel drug candidates.

Please visit www.cyclacel.com for additional information. Note: The Cyclacel logo and Cyclacel® are trademarks of Cyclacel Pharmaceuticals, Inc. Numoisyn™ and Xclair™ are trademarks of Sinclair Pharma plc.

For more information on the EMEA's Committee for Orphan Medicinal Products (COMP) please visit:

http://www.emea.europa.eu/htms/human/orphans/intro.htm.

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, 2007, as supplemented by the interim quarterly reports, filed with the SEC.

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