



Cyclacel Pharmaceuticals announces FDA orphan drug designation for sapacitabine in both AML and MDS

BERKELEY HEIGHTS, NJ – July 1, 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 disorders, today announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation to the company's sapacitabine (CYC682) product candidate for the treatment of both acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS).

"Orphan drug designation for both AML and MDS significantly strengthens the value proposition represented by sapacitabine and enhances our opportunity to advance this promising product candidate to late stage clinical development and commercialization," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel.

Sapacitabine, a cell cycle modulating nucleoside analogue, is in Phase 2 studies for the treatment of AML in the elderly, MDS and lung cancer. Cyclacel has reported Phase 2 results from ongoing studies in AML and MDS. The company plans to advance sapacitabine into pivotal Phase 3 development in 2010. During the first quarter of 2010, the company submitted a Special Protocol Assessment (SPA) request to the FDA for a randomized Phase 3 study of sapacitabine in elderly patients with AML.

Orphan drug designation entitles Cyclacel Pharmaceuticals to seven years of marketing exclusivity for sapacitabine upon regulatory approval, as well as the opportunity to apply for grant funding from the U.S. government to defray costs of clinical trial expenses, tax credits for clinical research expenses and a potential waiver of the FDA's application user fee. Orphan status is granted by the FDA to promote the development of new drug therapies for the treatment of diseases that affect fewer than 200,000 individuals in the United States.

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, is in Phase 2 studies for the treatment of acute myeloid leukemia in the elderly, 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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