Cyclacel's second-generation cyclin-dependent kinase inhibitor CYC065 demonstrates activity in multiple myeloma

Berkeley Heights, NJ, December 5, 2010 – Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP; "Cyclacel" or the "Company"), 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 the presentation of new preclinical data for CYC065, a novel, orally-available, cell cycle kinase inhibitor. The data were reported at a poster presentation at the 52nd Annual Meeting of the American Society of Hematology (ASH) in Orlando, Florida.

"We are encouraged by the prospects of new multiple myeloma treatments, such as CYC065, that may act by modulation of cell cycle mechanisms, potentially expanding the range of therapeutic alternatives available to patients," said Noopur Raje, M.D., Director of the Center for Multiple Myeloma at Massachusetts General Hospital Cancer Center in Boston and Associate Professor of Medicine at Harvard Medical School.

"For over a decade Cyclacel has emerged as a leader in the study of cell cycle biology and the identification of novel anticancer drugs that exploit mechanisms of cell cycle control. We are excited about CYC065's promising anticancer activity in preclinical models of multiple myeloma," said Spiro Rombotis, Cyclacel's President & Chief Executive Officer. "CYC065 is part of Cyclacel's broad pipeline of novel drugs which may prove useful in treating hematological malignancies, including acute myeloid leukemia (AML), myelodysplastic syndromes (MDS) and multiple myeloma."

At ASH Dr. Raje and colleagues presented results of a study entitled, "CYC065, a Potent Derivative of Seliciclib Is Active In Multiple Myeloma In Preclinical Studies". The data demonstrate that CYC065 is cytotoxic at sub-micromolar concentrations against myeloma cell lines and CD138+ myeloma cells derived from patients. CYC065 demonstrated antiproliferative activity even in the presence of the growth stimulatory effects of both cytokines and stromal cells in the bone marrow. CYC065 induced apoptosis in myeloma cells as evidenced by the appearance of cleaved PARP.

Cyclacel discovered CYC065 and other novel CDK inhibitors in collaboration with the Cancer Research UK Centre for Cancer Therapeutics at The Institute of Cancer Research (ICR), London, UK. CYC065 and other compounds in a related series target the same key CDK/cyclin complexes which are targeted by seliciclib. CYC065 retains the specificity and mechanism of action of seliciclib, but has increased anti-proliferative potency and improved pharmaceutical properties. Investigational new drug (IND)-enabling studies with CYC065 are in progress.

About CDKs and Cyclins

Cyclin-dependent kinases (CDKs) are a group of signaling molecules that play a direct role in the regulation and progression of the cell cycle. CDK activity is dependent on the availability of their regulatory subunits called cyclins. Production and destruction of cyclins are tightly regulated in coordination with cell cycle progression. Targeting CDK/cyclin macromolecular complexes is an attractive strategy for the design of novel anticancer drugs.

In 2001, the Nobel Prize in Physiology and Medicine was awarded for the discovery of cyclins and CDKs, key regulators of the cell cycle. By selectively modulating cell cycle regulation in cancer cells, inhibition of CDK/cyclin complexes represents a promising strategy for cancer therapy. For example Cyclacel's seliciclib (CYC202, R-roscovitine), a novel, first-in-class, orally available CDK inhibitor, currently in Phase 2 clinical trials, selectively targets multiple CDK/cyclin complexes, in particular CDK2/Cyclin E, CDK2/Cyclin A, CDK5, CDK7 and CDK9. Seliciclib also induces apoptosis in neutrophil granulocytes that mediate inflammation, indicating that CDK inhibitors may also hold promise in applications outside oncology, such as the treatment of chronic autoimmune and inflammatory diseases, such as arthritis or asthma.

About CYC065

CYC065 is a novel, orally available, cell cycle kinase inhibitor currently in IND-directed development. CYC065 and other compounds in a related series target the same key CDK/cyclin complexes which are targeted by seliciclib. CYC065 retains the specificity and mechanism of action of seliciclib, but has increased anti-proliferative potency and improved pharmaceutical properties.

Publication details

52nd Annual Meeting of the American Society of Hematology (ASH)

Abstract:	2999
Title:	CYC065, a Potent Derivative of Seliciclib is Active in Multiple Myeloma in Preclinical Studies
Date/Time:	Sunday, December 5, 2010, 6:00 PM – 8:00 PM Eastern Time
	Hall A3/A4 (Orange County Convention Center)
Session:	Myelodysplastic Syndromes: Poster I
Poster board:	II-879

The abstract is available online at http://ash.confex.com/ash/2010/webprogram/start.html.

About Multiple Myeloma

In 2010, the American Cancer Society expects that more than 20,000 new cases of multiple myeloma will be diagnosed and more than 10,000 deaths will result from the disease. Average five-year survival is estimated at 35%.

Multiple myeloma is characterized by malignant plasma cells that form tumors in the bone marrow. These plasma cell tumors can spread throughout the bone marrow, thereby disrupting the production of red blood cells and platelets, which normally occur in the bone marrow. Excessive amounts of malignant plasma cells may also decrease the number of white blood cells, which are important in fighting off infections.

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. 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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View the poster in PDF format (480KB)