

# Cyclacel reports survival data from phase 2 sapacitabine study in elderly patients with acute myeloid leukemia

**BERKELEY HEIGHTS, NJ** – **October 28, 2009** – Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP) announced today topline survival data for the primary endpoint of the Phase 2 study of sapacitabine as a treatment for elderly patients aged 70 or older with either newly diagnosed acute myeloid leukemia (AML) or AML in first relapse. The study was a three-arm randomized trial evaluating three dosing schedules of sapacitabine. The primary endpoint of 1-year survival is approximately 30% each on two out of the three schedules tested. Details of the results from this study will be presented at an upcoming medical conference.

"We are pleased to report such encouraging survival data from our Phase 2 study. The data provide a strong rationale supporting the continued development of this novel agent with a differentiated mechanism of action," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "We are currently working with the FDA to design a Phase 3 registration study for sapacitabine in patients with hematological malignancies. We are concentrating our efforts on advancing sapacitabine into late stage development. In addition we are exploring its potential in solid tumors both as a single agent and in combinations. If Phase 3 trials are successful, sapacitabine could emerge as the first oral drug for the treatment of AML and MDS."

Survival in elderly patients aged 70 or older with newly diagnosed AML remains poor. A recent, randomized study comparing tipifarnib, an investigational drug with a different mechanism to sapacitabine, with best supportive care in this population reported 1-year survival of 15% for the tipifarnib arm and 18% for the best supportive care arm (Harousseau JL, et al, Blood, 2009 01:19:8093).

#### Conference Call to Discuss Data & Third Quarter 2009 Financial Results - November 3

Cyclacel will discuss the survival data during its third quarter 2009 financial results conference call and live webcast to be held on Tuesday, November 3, 2009 at 4:30 p.m. Eastern.

Conference call information:

US/Canada call: (877) 493-9121/ international call: (973) 582-2750 US/Canada archive: (800) 642-1687 / international archive: (706) 645-9291

Code for live and archived conference call is 37927625.

For the live and archived webcast, please visit the Corporate Presentations page on the Cyclacel website at <a href="https://www.cyclacel.com">www.cyclacel.com</a>. The webcast will be archived for 90 days and the audio replay for 7 days.

## **About Cyclacel Pharmaceuticals, Inc.**

Cyclacel is a diversified biopharmaceutical company dedicated to the discovery, development and commercialization of novel, mechanism-targeted drugs to treat human cancers and other serious disorders. Sapacitabine, 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, a CDK (cyclin dependent kinase) inhibitor, is in Phase 2 for the treatment of lung 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 <a href="https://www.cyclacel.com">www.cyclacel.com</a> 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.

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