



## Cyclacel reviews 2010 achievements and key clinical development objectives for 2011

### Company to Present at the OneMedForum Conference on Tuesday, January 11 at 11:30 am PT

**Berkeley Heights, NJ, January 6, 2011** - Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP; "Cyclacel" or the "Company") today reviewed 2010 achievements and outlined the Company's key clinical development objectives for 2011, which will be highlighted at the Company's presentation during the 4th Annual OneMedForum Business Development and Investment Conference at 11:30 am Pacific Time on January 11, 2011, at the Sir Francis Drake Hotel in San Francisco.

"We have demonstrated sapacitabine's single-agent potential when administered as a front-line therapy to elderly patients with acute myeloid leukemia (AML) and older patients with myelodysplastic syndromes (MDS) refractory to the hypomethylating agents, azacitidine and/or decitabine. We are looking forward to the initiation of our pivotal Phase 3 "SEAMLESS" trial in AML being conducted under a Special Protocol Assessment (SPA)," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "During 2010 numerous publications and presentations highlighted Cyclacel's innovative and diverse oncology targeted pipeline. We will continue to work diligently in 2011 to achieve our key clinical development objectives."

### Review of 2010 Accomplishments

#### *Sapacitabine*

- Cyclacel reached agreement with the FDA regarding a SPA for a pivotal Phase 3 trial for oral sapacitabine capsules, Cyclacel's lead product candidate, as a front-line treatment in elderly patients aged 70 years or older with newly diagnosed AML who are not candidates for intensive induction chemotherapy.
- Interim response data from a Phase 2 randomized trial of sapacitabine in older patients with MDS refractory to the hypomethylating agents, azacitidine and/or decitabine, were presented at the 46th Annual Meeting of the American Society of Clinical Oncology (ASCO).
- One-year survival data from a Phase 2 randomized trial of sapacitabine in older patients with MDS refractory to the hypomethylating agents, azacitidine and/or decitabine, were presented at the 52nd Annual Meeting of the American Society of Hematology (ASH).
- The U.S. Food and Drug Administration (FDA) granted orphan drug designation to sapacitabine for the treatment of both AML and MDS.
- Publication of preclinical model data demonstrating sapacitabine works synergistically with histone deacetylase (HDAC) inhibitors to induce significant reductions in tumor cell growth *in vitro* and *in vivo*.

#### *Selaciclib and Second Generation CDK Inhibitors*

- Cyclacel announced topline data from the "APPRAISE", Phase 2b, randomized discontinuation, double-blinded, placebo-controlled, study of oral selaciclib capsules as a third or more line treatment in patients with non-small cell lung cancer (NSCLC) showing no difference in median progression free survival (PFS) between the selaciclib and placebo arms (48 versus 53 days respectively), but an increase in median overall survival (OS) favoring selaciclib over placebo (388 versus 218 days respectively).
- Publication of a peer-reviewed journal article demonstrating that selaciclib was effective against lung cancer cell lines, and in particular those with activating mutations in K-RAS and N-RAS proteins.
- Publication of a peer-reviewed journal article demonstrating that selaciclib reversed resistance to the aromatase inhibitor letrozole (Femara®) and killed hormone receptor positive breast cancer cells that had become insensitive to the effects of letrozole.
- Oral presentation of a preclinical study at the 101st Annual Meeting of the American Association of Cancer Research (AACR) introducing CYC065, Cyclacel's oral CDK inhibitor with the same targeted profile as selaciclib, and showing that CYC065 induced apoptosis in HER2 positive breast cancer cell lines refractory to trastuzumab (Herceptin®). CYC065 was also shown in preclinical studies to have anticancer activity in AML, chronic lymphocytic leukemia (CLL) and human mixed-lineage leukemia (MLL).
- Preclinical data demonstrating that CYC065 has anticancer activity and induced apoptosis at sub-micromolar concentrations against myeloma cell lines and CD138+ myeloma cells derived from patients, even in the presence of growth stimulatory effects of both cytokines and stromal cells in the bone marrow, were presented at the 52nd ASH Annual Meeting.

### Corporate Developments

- Cyclacel raised in the aggregate approximately \$36.0 million in gross proceeds through the sale of common stock, warrants and units, before deducting placement agent fees and offering expenses.
- Cyclacel filed its Answer and Counterclaims to the declaratory judgment complaint filed by Celgene Corporation and filed counterclaims charging Celgene with infringement of each of four Cyclacel-owned patents that claim the use and administration of Celgene's romidepsin for injection (ISTODAX®) in T-cell lymphomas, including cutaneous T-cell lymphoma (CTCL) and peripheral T-cell lymphoma (PTCL).
- Cyclacel was added to the Russell Microcap® Index.

### **Key 2011 Clinical Development Objectives**

- Initiation of the SEAMLESS pivotal Phase 3 study of sapacitabine in AML.
- Presentation of additional sapacitabine data in hematological malignancies both as a single agent and in combination with other anticancer agents.
- Presentation of Phase 2 sapacitabine data in NSCLC.
- Patient biomarker analysis from the APPRAISE Phase 2b randomized discontinuation study of seliciclib in patients with NSCLC.

### **Financial information**

As of September 30, 2010, the Company had \$18.5 million in cash, cash equivalents and short-term investments, compared to \$11.5 million as of December 31, 2009. Cash, cash equivalents and short-term investments do not include \$14.1 million in net proceeds received from the private placement completed in October 2010.

For the live and archived webcast, please visit the Corporate Presentations page on the Cyclacel website at [www.cyclacel.com](http://www.cyclacel.com). The webcast will be archived for 90 days and the audio replay for 7 days.

### **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](http://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](http://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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