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Cyclacel Announces Grants of New U.S. & European Patents Covering Sapacitabine Used in Combination With HDAC Inhibitors

Granted Patents Provide Exclusivity for Potential Uses of Sapacitabine in Hematological Malignancies and Solid Tumors

BERKELEY HEIGHTS, N.J., Feb. 12, 2013 (GLOBE NEWSWIRE) -- 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 disorders, today announced the issuance of U.S. Patent No. US 8,349,792 ('792) and European Patent No 2,101,790 ('790). Both patents include claims to combination treatment of sapacitabine, the Company's lead product candidate, with HDAC (histone deacetylase) inhibitors. The patents provide exclusivity until June 2029 and December 2027 respectively.

"The grants of the '792 and '790 patents are important enhancements of sapacitabine's intellectual property estate. They supplement sapacitabine's existing composition of matter, dosing regimen and combination treatment patent protection and support US and EU market exclusivity toward the end of the next decade," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "We are pursuing a broad intellectual property strategy providing us with a strong foundation to achieve our clinical and commercial objectives for sapacitabine and our other assets. As we continue to enroll SEAMLESS, our pivotal Phase 3 trial of sapacitabine as front-line treatment in elderly patients with acute myeloid leukemia (AML), we look forward to providing additional updates for sapacitabine this year, including Phase 2 data in myelodysplastic syndromes (MDS), AML preceded by MDS, and solid tumors."

The two patents include claims to combinations of sapacitabine and HDAC inhibitors, pharmaceutical compositions comprising sapacitabine and HDAC inhibitors, and methods of treatment using such compositions of proliferative disorders including leukemias, lymphomas, and lung cancer. HDAC inhibitors specifically claimed include belinostat (PXD101), dacinostat (LAQ824), entinostat (MS-275), mocetinostat (MGCD0103), pracinostat (SB939), romidepsin (depsipeptide), sodium butyrate, sodium valproate, tacedinaline (CI-994, PD-123654, GOE-5549, acetyldinaline), trichostatin A, vorinostat (SAHA or suberoylanilide hydramic acid), and valproic acid. Cyclacel published preclinical model data in 2010 demonstrating that sapacitabine works synergistically with histone deacetylase (HDAC) inhibitors to induce significant reductions in tumor cell growth in vitro and in vivo.

The claims and specifications of the '792 and '790 patents are unrelated to the claims and specifications of the four Cyclacel-owned patents that are the subject of Cyclacel's intellectual property litigation with Celgene Corporation (Celgene) regarding Celgene's drug romidepsin (depsipeptide, Istodax®).

About sapacitabine

Sapacitabine (CYC682), an orally-available nucleoside analogue, is currently being studied in an ongoing, Phase 3, registration-directed trial in elderly patients aged 70 years or older with newly diagnosed AML who are not candidates for or have refused induction chemotherapy. Sapacitabine is also the subject of Phase 2 trials in patients with hematological malignancies, including AML, myelodysplastic syndromes (MDS), cutaneous T-cell lymphoma (CTCL), chronic lymphocytic leukemia and small lymphocytic lymphoma, and non-small cell lung cancer (NSCLC), and a Phase 1 trial in combination with seliciclib in patients with advanced solid tumors. Sapacitabine acts through a novel DNA single-strand breaking mechanism, leading to production of DNA double strand breaks (DSBs) and/or checkpoint activation. Unrepaired DSBs cause cell death. Repair of sapacitabine-induced DSBs is dependent on the homologous recombination DNA repair (HRR) pathway. Both sapacitabine and CNDAC, its major metabolite, have demonstrated potent anti-tumor activity in preclinical studies.

Over 500 patients have received sapacitabine in Phase 2 studies in AML, MDS, CTCL and NSCLC and Phase 1 studies in hematological malignancies and solid tumors. Data, discussed at two separate sessions at The Eighth Annual Hematologic Malignancies 2012 Conference, from an ongoing, multicenter, phase 2 randomized trial of single-agent oral sapacitabine capsules in older patients with intermediate-2 or high-risk myelodysplastic syndromes (MDS) after treatment failure of front-line hypomethylating agents, such as azacitidine (Vidaza®) and/or decitabine (Dacogen®), showed sapacitabine nearly doubles expected survival of elderly patients with MDS after front-line therapy failure. Results from a randomized Phase 2, single-agent study of sapacitabine, including promising 1-year survival in elderly patients with AML aged 70 years or older, were published in *The Lancet Oncology* in November 2012. At the 2012 ASH Annual Meeting, Cyclacel reported data from the pilot study and lead-in phase of SEAMLESS including promising response rate, overall survival and low 30-day and 60-day mortality in elderly

patients with AML aged 70 years or older receiving sapacitabine alternating with decitabine. The FDA and the European Medicines Agency have designated sapacitabine as an orphan drug for the treatment of both AML and MDS. Sapacitabine is part of Cyclacel's pipeline of small molecule drugs designed to target and stop uncontrolled cell division.

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. The Company's most advanced oral product candidate, sapacitabine, is the subject of SEAMLESS, a Phase 3 trial being conducted under an SPA with the FDA as front-line treatment of acute myeloid leukemia (AML) in the elderly and Phase 2 studies for AML, myelodysplastic syndromes (MDS), chronic lymphocytic leukemia (CLL) and solid tumors including breast, lung, ovarian and pancreatic cancer. Cyclacel's pipeline includes seliciclib, a CDK inhibitor, in Phase 2 for lung and nasopharyngeal cancer and in Phase 1 in combination with sapacitabine; and CYC065, a second generation CDK inhibitor, in IND-directed development. Cyclacel's strategy is to build a diversified biopharmaceutical business focused in hematology and oncology based on 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, trials may have difficulty enrolling, Cyclacel may not obtain approval to market its product candidates, 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 other filings we file 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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