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New US Patents Issued Covering Sapacitabine Use With Hypomethylating Agents and Sapacitabine Dosing Regimens

Extend Exclusivity for Dosing Regimens Intended for Commercialization

BERKELEY HEIGHTS, N.J., Nov. 5, 2013 (GLOBE NEWSWIRE) -- Cyclacel Pharmaceuticals, Inc. (Nasdaq:CYCC) (Nasdaq:CYCCP) (Cyclacel or the Company), today announced that the US Patent and Trademark Office (USPTO) issued two patents extending the exclusivity of sapacitabine, the Company's lead clinical candidate. The first patent claims, among others, methods of treating cancer comprising sapacitabine together with DNA methyltransferase inhibitors, including azacitidine and decitabine. The second patent claims methods of use for sapacitabine for the treatment of acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS), including the dosing regimen used in SEAMLESS, the Company's ongoing, pivotal, registration-directed, Phase 3 study in front-line elderly AML.

"The two new US patents are important enhancements to the sapacitabine intellectual property estate extending existing patent protection, including composition of matter, dosing regimen and combination treatment," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "We are executing on our patent lifecycle strategy for the treatment of AML and MDS with the goal of extending sapacitabine's exclusivity through 2030 and potentially building long-term commercial value for our stockholders. We look forward to providing additional updates for sapacitabine, including progress in SEAMLESS, our pivotal Phase 3 trial in front-line elderly AML, the primary outcome in our Phase 2 study of sapacitabine in MDS after front-line treatment failure, and our other programs."

In particular, the USPTO issued US Patent No. US 8,530,445 ('445) which includes claims to combinations of sapacitabine and DNA methyltransferase inhibitors, pharmaceutical compositions comprising sapacitabine and DNA methyltransferase inhibitors, and methods of using sapacitabine and DNA methyltransferase inhibitors in the simultaneous, sequential or separate treatment of proliferative disorders including cancer. Specifically claimed DNA methyltransferase inhibitors include azacitidine and decitabine. The '445 patent provides exclusivity until 2029, excluding any patent term adjustments which may extend its coverage. An equivalent European patent, EP 2307002, was granted earlier in 2013 with the corresponding national European patents expiring in 2029.

The USPTO also issued US Patent No. 8,536,188 ('188) which includes claims to methods of treatment of AML or MDS using sapacitabine dosing regimens. The sapacitabine regimen used in Cyclacel's SEAMLESS pivotal Phase 3 study of sapacitabine alternating with decitabine versus decitabine as a frontline treatment of elderly patients with AML who are unfit or have refused intensive chemotherapy is specifically claimed. The '188 patent provides exclusivity until 2028, excluding any patent term adjustments which may extend its coverage.

About sapacitabine

Sapacitabine (CYC682), an orally-available nucleoside analogue, is being studied in SEAMLESS, 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 in Phase 2 trials in patients with hematological malignancies, including AML, myelodysplastic syndromes (MDS), cutaneous T-cell lymphoma (CTCL), chronic lymphocytic leukemia, small lymphocytic lymphoma, and also non-small cell lung cancer (NSCLC), and a Phase 1 trial 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 (HR) DNA repair pathway. Both sapacitabine and CNDAC, its major metabolite, have demonstrated potent anti-tumor activity in preclinical studies.

Over 800 patients have received sapacitabine in clinical studies in patients with AML, MDS, CTCL, NSCLC, hematological malignancies and solid tumors. At the 2012 American Society of Hematology (ASH) Annual Meeting, data from the pilot study and lead-in phase of SEAMLESS showed 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. 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.

Data, presented 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 and/or decitabine, showed sapacitabine nearly doubled expected median survival of elderly patients with MDS after front-line therapy failure.

At the 2013 American Association of Cancer Research (AACR) Annual Meeting data, from a Phase 1 study of sapacitabine in combination with Cyclacel's seliciclib, which showed antitumor activity in cancer patients found to be carriers of gBRCA mutations was highlighted by the Annual Meeting Program Committee.

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. Sapacitabine, Cyclacel's most advanced product candidate, is the subject of SEAMLESS, a Phase 3 trial being conducted under an SPA with the FDA as front-line treatment for acute myeloid leukemia (AML) in the elderly, and other studies for myelodysplastic syndromes (MDS), chronic lymphocytic leukemia (CLL) and solid tumors including breast, lung, ovarian and pancreatic cancer, and in particular those carrying gBRCA mutations. 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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