September 19, 2013

Cyclacel's Sapacitabine Reported to Have Anti-Tumor Activity Against Ovarian Cancer

75% of Ovarian Cancer Patient Samples Highly Sensitive to Sapacitabine Including Those Resistant to Therapy

BERKELEY HEIGHTS, N.J., Sept. 19, 2013 (GLOBE NEWSWIRE) -- Cyclacel Pharmaceuticals, Inc. (Nasdaq:CYCC) (Nasdaq:CYCCP) ("Cyclacel" or the "Company") today announced updated data showing that sapacitabine has activity against a majority of ovarian cancer samples taken from patients, including resistant tumors. The data were reported at a poster presentation during the American Association of Cancer Research (AACR) conference "Advances in Ovarian Cancer: from concept to clinic" being held September 18-21, 2013, in Miami, FL.

"We are encouraged by the activity signal of sapacitabine in ovarian cancer samples," said Judy Chiao, M.D., Vice President, Clinical Development and Regulatory Affairs of Cyclacel. "This observation may be directly related to the drug's mechanism which is enhanced in cancer cells with reduced capacity for DNA repair through the homologous recombination repair or HR pathway. In addition to our ongoing Phase 3 registration trial of sapacitabine in acute myeloid leukemia and Phase 2 studies in myelodysplastic syndromes, we are continuing to evaluate sapacitabine as a potential treatment for patients with solid tumors, and in particular those with BRCA-deficient cancers."

Cyclacel collaborators from the Northern Institute for Cancer Research, Newcastle University, UK led by Nicola Curtin, Professor of Experimental Therapeutics and Richard Edmondson, Professor of Gynaecological Oncology reported that CNDAC, the active metabolite of sapacitabine, was active against 75% (30 of 40) of primary ovarian cancer (POC) samples isolated from patients. In contrast cisplatin was active in less than half of the samples. Over half of the cisplatin-resistant samples were sensitive to CNDAC, indicating that sapacitabine has potential utility for treatment of ovarian cancers, including platinum-resistant disease. The majority, but not all, of the samples tested were from high grade serous ovarian cancers.

The HR activity of the ovarian samples was determined as HR deficient or HR proficient by a functional assay. Sensitivity to sapacitabine was substantially greater in HR deficient than HR proficient samples (mean GI_{50} values of 135 nM versus 477 nM, respectively). This difference suggests that HR status, or other surrogate markers such as BRCA mutation status, could be used to enrich for potential responders in stratified clinical trials of sapacitabine in patients with solid tumors.

Sapacitabine activity has been shown to be substantially enhanced in cell lines with defects or mutations in the HR pathway, including mutations in ATM, BRCA1, BRCA2, RAD51 and XRCC3. The reported data further support the potential for sapacitabine to be used as a treatment for HR defective cancers, such as ATM- or BRCA-defective tumors. Clinical trials examining the activity of sapacitabine in ATM-defective CLL, and of sapacitabine in combination with Cyclacel's seliciclib in cancer patients with BRCA1 or BRCA2 mutations, are currently in progress.

Poster Details:

"Therapeutic potential of sapacitabine in ovarian cancers defective in homologous recombination"

Poster Number: A33. Thursday September 19, 2013, 4:30 p.m. - 6:30 p.m. Eastern.

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 BRCA mutations was highlighted by the AACR's 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 Homologous Recombination Repair, BRCA Genes and Mutations

Breast cancer susceptibility proteins BRCA1 and BRCA2 are tumor suppressors that ensure DNA stability and prevent uncontrolled cell growth in normal cells. BRCA gene mutations are common in breast and ovarian cancer, but other defects including suppression of BRCA1/2 expression by promoter hypermethylation can produce HR defects in these and other tumors, including NSCLC and AML. Although BRCA1/2 mutations are found in approximately 20% of high grade serous ovarian cancers, around 50% are reported to be HR-defective due to these and other modifications of HR components.

Genetic testing for BRCA status is routinely available and reimbursed by payors. BRCA mutation has been linked to predisposition to breast and ovarian cancer. According to the US National Cancer Institute, during her life time a woman has a 60% chance of developing breast cancer and 15-40% chance of developing ovarian cancer if she inherits a harmful BRCA mutation. These risks are 5 times and over 10 times more likely respectively than for women without the mutation. Risks are highest with a family history of multiple cases of breast cancer; cases of both breast and ovarian cancer; one or more family members with two primary cancers; Norwegian, Dutch, or Icelandic heritage; or Ashkenazi (Central and Eastern European) Jewish background. Harmful BRCA1 mutations may additionally increase a woman's risk of developing triple-negative breast, cervical, colon, pancreatic and uterine cancer. Harmful BRCA2 mutations may increase a woman's risk of bile duct, gallbladder, stomach, pancreatic cancer and melanoma. Men with harmful BRCA1 mutations have an increased risk of male breast cancer and possibly pancreatic, early-onset prostate, and testicular cancer. Harmful BRCA2 mutations may increase a man's risk of developing male breast, pancreatic and prostate cancer.

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. 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.

CONTACT: Cyclacel Pharmaceuticals, Inc.

Investors/Media:

Paul McBarron

(908) 517-7330

pmcbarron@cyclacel.com