Cyclacel Pharmaceuticals Announces Initiation of Phase 1b/2 Clinical Trial of Sapacitabine With Olaparib in BRCA Mutant Breast Cancer

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BERKELEY HEIGHTS, N.J., Sept. 10, 2018 (GLOBE NEWSWIRE) -- Cyclacel Pharmaceuticals, Inc. (Nasdaq:CYCC, Nasdaq:CYCCP) ("Cyclacel" or the "Company"), a biopharmaceutical company developing innovative medicines based on cancer biology, announced the initiation of a Phase 1b/2 investigator-sponsored clinical trial to evaluate the safety and effectiveness of sapacitabine in combination with olaparib in patients with BRCA mutant breast cancer. The trial will be conducted at the Dana-Farber Cancer Institute with collaborators Cyclacel and AstraZeneca providing sapacitabine investigational drug and the approved PARP-inhibitor olaparib (Lynparza™), respectively.

“Despite advancements in the treatment of BRCA positive breast cancer, we are continually searching for ways to improve on the standard of care for this disease which carries a poor prognosis for the majority of individuals,” said Sara M. Tolaney, MD, MPH, instructor of medicine, Harvard Medical School, attending physician of medical oncology, Dana-Farber Cancer Institute and Principal Investigator of the study. “PARP inhibitor monotherapy is the current standard of care for breast and ovarian cancers with homologous recombination deficient (HRD) cancers, which include those positive for BRCA mutations. The study will help determine if the all-oral combination of sapacitabine and olaparib could provide additional benefit to these patients for whom limited treatment options exist.”

“Preclinical data support additivity or synergy of sapacitabine with PARP inhibitors. We believe that dual targeting of the DNA damage response pathway with the addition of sapacitabine to olaparib may enhance the efficacy of the current standard of care for patients with BRCA positive breast cancer,” said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. “We are excited about this collaboration and the potential to improve outcomes for a difficult to treat patient population with a convenient, orally administered drug combination.”

The investigator-sponsored Phase 1b/2 study will enroll approximately 64 patients with breast cancer and BRCA1 or BRCA2 mutation. The primary endpoints are to determine maximum tolerated dose, recommended Phase 2 dose and objective response rate. Progression-free survival will be assessed as a secondary endpoint. The first of two parts of the study will assess safety and tolerability of escalating doses of the combination. The second part will assess efficacy of the recommended Phase 2 dose in 18 patients. If a prespecified number of these patients achieve a complete or partial response per RECIST 1.1 criteria, the study will be expanded to a further 28 patients (www.clinicaltrials.gov, NCT03641755).

About Cyclacel Pharmaceuticals, Inc.

Cyclacel Pharmaceuticals is a clinical-stage biopharmaceutical company using cell cycle, transcriptional regulation and DNA damage response biology to develop innovative medicines based on cancer biology. Cyclacel's transcriptional regulation program is evaluating CYC065, a CDK inhibitor, in patients with advanced cancers. The DNA damage response program is evaluating a sequential regimen of sapacitabine and seliciclib, a CDK inhibitor, in patients with BRCA positive, advanced solid cancers. Cyclacel's strategy is to build a diversified biopharmaceutical business focused in hematology and oncology based on a pipeline of novel drug candidates. For additional information, please visit www.cyclacel.com.

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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