Cyclacel Announces Notice of Grant of New European Patent Covering Sapacitabine Pharmaceutical Formulations

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Granted Patent Broadens Exclusivity of Sapacitabine

BERKELEY HEIGHTS, N.J., Feb. 21, 2018 (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 receipt of a notice from the European Patent Office of the intention to grant a patent (EP1962814) including claims to novel pharmaceutical formulations of sapacitabine. The European patent will provide exclusivity until December 2026 excluding any extensions. Equivalent patents have been granted in the United States (US 8,497,291 expiring in January 2030) and other countries.

"This European notice of grant enhances the intellectual property estate related to sapacitabine. The relevant patent family is an important layer of our strategy of building on sapacitabine's exclusivity. It supplements existing composition of matter, dosing regimen and combination treatment patent protection in major global markets extending into 2030," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "We look forward to providing updates on our progress with sapacitabine, in terms of regulatory discussions regarding the data from our SEAMLESS study in acute myeloid leukemia and updates from our ongoing Phase 1 extension study evaluating the sequential regimen of sapacitabine and seliciclib in patients with BRCA positive, breast, ovarian and pancreatic cancers."

About sapacitabine

Sapacitabine (CYC682), an orally-available nucleoside analogue, is currently being studied in an ongoing, Phase 1 study evaluating a sequential regimen of sapacitabine and seliciclib, a first generation CDK inhibitor. Parts 1 and 2 of the study evaluated an enriched population of approximately 76 patients with advanced cancers and were reported at ASCO 2016. The ongoing extension of part 1 enrolled 20 patients with BRCA positive advanced breast cancers and is in the follow-up stage. Part 3 of the study has been opened for enrolment with the objective of testing a revised dosing schedule in additional patients, including BRCA positive patients with advanced ovarian and pancreatic cancers.

Sapacitabine is also the subject of the Phase 3 SEAMLESS study of elderly patients with acute myeloid leukemia, or AML. Data from this completed study were reported on December 11, 2017 in an oral presentation at the 59th ASH Annual Meeting. Sapacitabine has been evaluated in both hematological cancers and solid tumors. Over 1,000 patients have received sapacitabine in Phase 1, 2 and 3 studies.

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, targeted medicines for cancer and other proliferative diseases. 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 BRCA positive patients with 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.

Contacts

Company:
Paul McBarron, (908) 517-7330, pmcbarron@cyclacel.com

Investor Relations:
Russo Partners LLC, Alexander Fudukidis, (646) 942-5632,

alex.fudukidis@russopartnersllc.com

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