Cyclacel Announces Notice of Intention to Grant New European Patent Covering Plogosertib Pharmaceutical Compositions

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Lengthens Patent Exclusivity of Plogosertib until August 2040

BERKELEY HEIGHTS, N.J., June 26, 2024 (GLOBE NEWSWIRE) -- Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP; "Cyclacel" or the "Company"), a biopharmaceutical company developing innovative medicines based on cancer cell biology, today announced the receipt of a notice from the European Patent Office of the intention to grant a patent which includes claims to novel pharmaceutical compositions of plogosertib, a PLK1 inhibitor. Once granted, the European patent will provide exclusivity until August 2040 not including any extensions. The Company is prosecuting patent applications from the same family in other jurisdictions.

"The notice further strengthens the Company's patent portfolio and attests to the novelty of Cyclacel's clinical pipeline, which includes plogosertib and fadraciclib, both of which were discovered in house," said Spiro Rombotis, President and Chief Executive Officer of Cyclacel. "The patent supports our switch to a new oral formulation of plogosertib with improved bioavailability. Our strategy is to test in the clinic whether certain ARID1A- and/or SMARCA-mutated cancers may benefit from treatment with plogosertib. We are also following a precision medicine approach with our lead drug candidate, fadraciclib, a CDK2/9 inhibitor, which is being evaluated in a proof of concept study initially in patients with solid tumors prospectively selected for CDKN2A/CDKN2B alterations, followed by patients with T-cell lymphoma, with initial proof of concept data expected in the second half of 2024."

About Polo-like Kinase and Plogosertib

Polo-like kinase 1 (PLK1) is a serine/threonine kinase that plays a central role in cell division or mitosis. PLK1 is an important regulator of the DNA damage cell cycle checkpoint, mitotic entry and exit, spindle formation and cytokinesis, or cell separation into daughter cells. Cancer cells in general, and in particular KRAS mutated and p53(-) cells, are very sensitive to PLK1 depletion. In contrast normal cells with intact cell cycle checkpoints are less sensitive. Pharmacological inhibition of PLK1 in cancer cells blocks proliferation by prolonged mitotic arrest and induces onset of apoptotic death of such cells.

Plogosertib (formerly CYC140) is a novel, small molecule, selective and potent PLK1 inhibitor. It has demonstrated impressive efficacy in human tumor xenografts at nontoxic doses. Cyclacel's translational biology program supports the development of plogosertib in solid tumors and leukemias. Preclinical data from independent groups have shown that certain ARID1A- and/or SMARCA-mutated cancers may benefit from treatment with plogosertib. Additionally, recent data suggest that PLK1 inhibition may be effective in KRAS-mutated metastatic colorectal cancer. PLK1 overexpression correlates with poor patient prognosis in several tumors, including esophageal, gastric, leukemia, lung, ovarian, and squamous cell cancers, as well as MYC-amplified cancers.

Initial dose escalation data from a Phase 1 clinical study of oral plogosertib suggest that the compound is well tolerated with no dose limiting toxicity observed in five dosing schedules. Clinical benefit was observed in patients with adenoid cystic, biliary tract, ovarian, and squamous cell sinus cancers.

About Cyclacel Pharmaceuticals, Inc.

Cyclacel is a clinical-stage, biopharmaceutical company developing innovative cancer medicines based on cell cycle, transcriptional regulation and mitosis biology. The transcriptional regulation program is evaluating fadraciclib, a CDK2/9 inhibitor, and the anti-mitotic program plogosertib, a PLK1 inhibitor, in patients with both solid tumors and hematological malignancies. Cyclacel's strategy is to build a diversified biopharmaceutical business based on a pipeline of novel drug candidates addressing oncology and hematology indications. 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, statements related to the intended use of proceeds from the private placement, 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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