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Cyclacel & ManRos Therapeutics Announce Licensing & Supply Agreement Regarding Development of Seliciclib in Cystic Fibrosis

Novel CDK Inhibitor-Based Approach to Treat Cystic Fibrosis

DUNDEE, UK and ROSCOFF, France, June 29, 2015 (GLOBE NEWSWIRE) -- Cyclacel Ltd, a wholly owned subsidiary of Cyclacel Pharmaceuticals, Inc. (NASDAQ:CYCC) (NASDAQ:CYCCP) ("Cyclacel") and ManRos Therapeutics SA ("ManRos") announced the execution of a collaboration, licensing and supply agreement for the exclusive development and commercialisation of Cyclacel's oral seliciclib capsules by ManRos as a treatment for cystic fibrosis (CF). Among other terms of the agreement ManRos licensed rights to Cyclacel's proprietary clinical data to enable clinical development of seliciclib for cystic fibrosis indications. The agreement provides for Cyclacel supply of seliciclib investigational product for initial and later stage clinical trials of seliciclib in CF and technical assistance related to Cyclacel's know-how to facilitate these trials. Cyclacel will receive an up-front payment, milestone payments and tiered royalties, if seliciclib is commercialized for the treatment of CF. Financial details were not disclosed.

"Treatment of lung disease associated with CF represents a major unmet medical need, in particular, with regard to reducing dysregulated innate immunity, chronic infections, inflammation and subsequent lung injury," said Dr. Laurent Meijer, President of ManRos. "Seliciclib is a well-studied, orally-available, investigational medicinal product. We have shown that seliciclib acts through multiple mechanisms and may confer therapeutic benefits to CF patients. With this agreement we are leveraging Cyclacel's extensive clinical experience with seliciclib in hundreds of cancer patients to offer patients with CF a differentiated treatment alternative. Following receipt of regulatory authorisations, we expect that proof-of-concept clinical trials in CF patients will begin in the near term."

"The CDK field is experiencing a resurgence and CDK inhibitors are receiving a lot of attention as novel treatments in oncology and other proliferative diseases," said Spiro Rombotis, Chief Executive Officer of Cyclacel. "Like Cyclacel, the founders of ManRos have been studying CDK inhibitors for many years and will be evaluating an innovative application of a CDK inhibitor to potentially help patients with CF. The agreement with ManRos illustrates our commitment to generate value from our portfolio of CDK inhibitors and deliver on our science-driven business strategy."

Seliciclib Mechanism of Action in CF

Patients with CF suffer from extensive inflammatory and chronic infectious injury to the lung airway. It was recently recognized that immune system defects, and in particular macrophage function, play a key role in disease initiation. It has also been reported that impairment of the CFTR gene is associated with modification of macrophage function resulting in reduced bactericidal activity (Di et al., 2006) and disease progression. ManRos and academic collaborators have discovered that seliciclib may restore the defective bactericidal activity of macrophages in CF (publication pending). They have also discovered that seliciclib may have "corrector" activity in the most prevalent CF mutation, F508del (Norez 2014). Separately, independent investigators have demonstrated in model systems that seliciclib has anti-inflammatory properties which may also help reduce inflammatory injury in patients with CF (Rossi et al., 2006; Moriceau 2010).

About Cystic Fibrosis

Cystic Fibrosis (CF) is a life-threatening inherited genetic disease that primarily affects the lungs and digestive system. An estimated 70,000 children and adults worldwide (of which an estimated 30,000 in the United States) suffer from CF. In CF patients, a defective gene (CFTR) and its protein product cause the body to produce unusually thick, sticky mucus that clogs the lungs, leads to life-threatening lung infections, obstructs the pancreas and stops natural enzymes from helping the body break down food and absorb vital nutrients. There are more than 1,900 known mutations of the CFTR gene. The most common mutation is F508del and disrupts the function of many organs in the body, most notably the lungs, by perturbing salt and water transport across epithelial surfaces.

About seliciclib (also known as R-roscovitine, CYC202)

Seliciclib is an orally-available CDK2/9 inhibitor. It has been evaluated to date in approximately 450 patients with various cancers. Seliciclib is currently being explored in combination with Cyclacel's sapacitabine in patients with advanced solid tumors as an all oral regimen.

About Cyclacel

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, which has completed enrollment and is being conducted under an SPA with the FDA as front-line treatment for acute myeloid leukemia (AML) in the elderly, and other indications including myelodysplastic syndromes (MDS). Cyclacel's pipeline includes an oral regimen of seliciclib in combination with sapacitabine in a Phase 1 study of patients with Homologous Recombination (HR) repair-deficient breast, ovarian and pancreatic cancers, including gBRCA positive tumors, and CYC065, a novel CDK2/9 inhibitor, with potential utility in both hematological malignancies and solid tumors. 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 more information.

About ManRos

ManRos is a biotechnology company founded by Dr. Laurent Meijer (a former CNRS research director) and Dr. Hervé Galons (Professor of Organic Chemistry at the University Paris-Descartes). Located in Roscoff (Brittany, France), ManRos aims at developing, optimizing and bringing to clinical trials a small selection of specific kinase inhibitors. Its pipeline comprises (1) R-roscovitine (for chronically infected cystic fibrosis patients; phase 2a expected to begin in the near future pending regulatory approval), (2) a family of kinase inhibitors (for autosomal dominant polycystic kidney disease (ADPKD); preclinical stage) and (3) Leucettines, a marine natural product derived alkaloid (for the treatment of cognitive defects in Down syndrome and Alzheimer's disease patients; preclinical stage).

Citations

Di, A. et al., 2006. CFTR regulates phagosome acidification in macrophages and alters bactericidal activity. **Nat. Cell Biol. 8**, 933-944.

Moriceau, S. et al., 2010. In cystic fibrosis homozygotes and heterozygotes, neutrophil apoptosis is delayed and modulated by diamide or roscovitine: evidence for an innate neutrophil disturbance. **J. Innate Immun. 2**, 260-266.

Norez, C. et al., 2014. Roscovitine is a proteostasis regulator that corrects the trafficking defect of F508del-CFTR by a CDK-independent mechanism. **Br. J. Pharmacol. 171**, 4831-4849.

Rossi, A.G. et al., 2006. Cyclin-dependent kinase inhibitors enhance the resolution of inflammation by promoting inflammatory cell apoptosis. **Nat. Med. 12**, 1056-1064. Erratum in: **Nat. Med. 12**, 1434.

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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