



CVie Therapeutics



FOR IMMEDIATE RELEASE

CVieTherapeutics Enrolled the First Patient in Phase 2b Clinical Study of Istaroxime in China

Hong Kong, December 1, 2016—Lee's Pharmaceutical Holdings Limited ("Lee's Pharm" or the "Group", Stock Code: 0950) today announced that its subsidiary, CVie Therapeutics Limited ("CVie" or the "company"), a pharmaceutical/biotechnology company focused on cardiovascular diseases, has successfully enrolled its first patient for its Phase 2b clinical trial (Protocol No. CVT-CV-002) of Istaroxime for acute decompensated heart failure in China.

This is a Phase 2b, multi-center, randomized, double-blinded, parallel and placebo-controlled clinical study targeting a total of 120 patients in Italy (24 patients) and China (96 patients). The Italian arm of the trial has been completed while the Chinese arm is expected to be completed before the end of 2017. The study aims to assess the efficacy, safety and tolerability of two different doses of Istaroxime (0.5 and 1.0 $\mu\text{g}/\text{kg}/\text{min}$) in comparison with placebo through 24 hour intravenous infusion in the treatment of patients with acute decompensated heart failure and a blood pressure between 90 and 125 mmHg.

"Heart failure is a serious life-threatening disease in which 20% of the patients die within the first year of diagnosis and 50% within 5 years. Conventional therapies suffer from various adverse effects from arrhythmia, hypotension to myocardial injuries," said Dr. Lit-Fui Lau, President and Chief Operating Officer of CVie. "Due to its unique dual mechanisms of action and luso-inotropic effects, Istaroxime will be a first-in-class medicine and expected to fill the high unmet medical need of acute heart failure with minimized adverse effects."

About CVie Therapeutics Limited

CVie is a Taiwan-based joint venture founded in 2013 by Lee's Pharmaceutical Holdings Limited and certain reputable venture capital from the US and Taiwan. It is a stand-alone drug development company specialized in cardiovascular diseases. CVie currently owns two Phase 2b assets that target cardiovascular diseases with significant unmet medical need. Rostafuroxin is a novel precision medicine targeting hypertensive patients with certain genetic profiles with better efficacy and safety than conventional therapies. Istaroxime is a first-in-class luso-inotropic medicine for the treatment of acute heart failure and will have fewer adverse effects than conventional inotropes, namely, increased heart rate, arrhythmia, increased oxygen consumption and hypotension.

About Istaroxime

Istaroxime is a first-in-class luso-inotropic agent under development for the treatment of acute decompensated heart failure. It possesses a unique dual mechanism of action: i) inhibition of Na^+/K^+ -ATPase leading to increased myocardial contractility; and ii) activation of the SERCA 2a calcium pump on the sarcoplasmic reticulum leading to reduction in cytoplasmic calcium and improvement in myocardial relaxation. Therefore, Istaroxime exhibits both inotropic (myocyte contraction) and lusotropic (myocyte relaxation) effects. Based on its mechanisms of action, preclinical studies and clinical findings (28 healthy volunteers and 170 heart failure patients), it is anticipated that Istaroxime will have minimal deleterious effects of conventional inotropes, i.e., increased heart rate, increased oxygen consumption, increased risk of arrhythmia and hypotension.

About Rostafuroxin

Rostafuroxin is a novel anti-hypertensive targeting the pathological mechanisms leading to the activation of Na^+/K^+ -ATPase induced by mutated adducin or elevated endogenous ouabain (EO). It does not bind to 35 other proteins involved in the physiological regulation of blood pressure. Rostafuroxin administered in hypertension animal models of either adducin or EO mechanism displays high potency and efficacy. Treatment of hypertension patients who carry genetic profiles linked to adducin or EO-hypertensive mechanisms is efficacious and safe (84 healthy volunteers; 473 hypertensive patients). Rostafuroxin is currently in Phase 2b (280 hypertension patients with specified genetic profiles) and could signify a paradigm shift towards personalized treatment.

About Lee's Pharmaceutical Holdings Limited ("Lee's Pharm")

Lee's Pharm is a research-based Hong Kong biopharmaceutical company listed in Hong Kong with more than 20 years of operation in China's pharmaceutical industry. It is fully integrated with strong infrastructures in drug development, manufacturing, sales and marketing. It has established extensive partnership with more than 20 international companies and currently has 15 products in the market place. Lee's Pharm focuses on several key disease areas such as cardiovascular, oncology, gynecology, dermatology and ophthalmology. The company's development program is lauded with over 40 products stemming from both internal R&D efforts and collaborations with US, European and Japanese companies, including promising compounds to treat diseases such as liver cancer and pulmonary hypertension. The mission of Lee's Pharm is to become a successful biopharmaceutical group in Asia providing innovative products to fight diseases and improve health and quality of life. Additional information about Lee's Pharm is available at www.leespharm.com.

Safe Harbour Statement

The performance and the results of operation of Lee's Pharm during the past years are historical in nature and past performance can be no guarantee of future results of the Lee's Pharm. This news release may contain forward-looking statements and opinions that involve risks and uncertainties. Actual results may differ materially from expectations discussed in such forward-looking statements and opinions. Neither Lee's Pharm nor the Directors, employees or agents of Lee's Pharm assume (a) any obligation to correct or update the forward-looking statements or opinions contained in this news release; and (b) any liability in the event that any of the forward-looking statements or opinions does not materialize or turns out to be incorrect.

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