

FOR IMMEDIATE RELEASE

**Phase III clinical study of L-Carnitine on chronic Heart Failure patients with acute episode meets the primary endpoint**

**Hong Kong, June 28, 2012**—Lee's Pharmaceutical Holdings Limited (Main Board Stock Code: 0950; Website: [www.leespharm.com](http://www.leespharm.com)) today announced the completion of its Phase III clinical study of **Carnitene**<sup>®</sup> (L-Carnitine Injection, "LC") on chronic heart failure patients with acute episode. Preliminary analysis demonstrated that the trial has met its primary endpoint.

This multi-centers, randomized, double-blind, parallel and placebo controlled clinical trial was conducted over 13 clinical centers located in China at Beijing, Shanghai, Jiangsu, Wunan, Nanjing, Heilongjiang and Jiangxi etc; and led by Shanghai Pulmonary Hospital of Tongji University (Ref No. NCT01580553 on ClinicalTrials.gov). The Group initiated this Phase III clinical trial in January 2009, and completed enrollment with total of 268 patients in April 2012. The primary efficacy measure of the study is the improvement of patients' heart function after seven days of treatment according to the New York Heart Association Classification (NYHAC) over the base line. Result of the study shows that the primary endpoint was reached in over 58.7% patients treated with L-Carnitine while only 39.8% of the patients in the control group met the primary endpoint. The difference between two groups is highly statistically significant ( $P=0.0073$ ). Preliminary analysis of other secondary efficacy endpoints such as six minutes walk distance, Acyl-L-CarnitineC/L-Carnitine ratio, NT-proBNP level and Left ventricular ejection fraction shows that L-Carnitine treatment was associated with improved outcome when compared with control group. Among them, six minutes walk distance of the treated group was significantly increased over the control group (61 vs.46,  $P=0.0497$ ). Adverse events observed in the trial included chest distress, nausea and vomit, and the incidence did not differ between the two groups.

"We are thrilled with the results that demonstrate Carnitene's efficacy in treatment of heart failure patients in a placebo-controlled trial," said Dr. Benjamin Li, the Chief Executive Officer of the Company. "Despite the raising awareness of the potential benefit of metabolic intervention in patients suffered from ischemia heart disease and heart failure, lack of clinical data generated from well-controlled trial has hindered the use of compounds such as Carnitine in this era of evidence-based medicine. With the result of this study that we conducted over three years, for the first time in China, we provide strong evidence to support and substantiate the clinical benefit of Carnitine as a metabolic intervention agent in treatment of heart failure. It is our sincere hope that more and more patients could be benefited with Carnitine treatment in the future."

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### **CARNITENE® (L-Carnitine Injection, “LC”)**

**Carnitene®**, was developed and manufactured by Sigma-Tau S.p.A., Italy; and approved in Italy since 1981. From then on, it has been obtained marketing approval over 30 countries, includes Austria , Germany, Greece, Spain, UK, Portugal USA, etc. It is a unique molecule which obtains both amino acid and vitamin properties. Carnitene® improves the efficacy and metabolism of heart from myocardial ischemia. Moreover, in acute myocardial infarction, Carntiene® can reduce arrhythmias and improve shock.

### **About Heart Failure**

Heart failure, which is also defined as chronic heart failure (CHF), is inability of the heart to keep up with the demands on it, with failure of the heart to pump blood with normal efficiency. When this occurs, the heart is unable to provide adequate blood flow to other organs, such as the brain, liver, and kidneys. CHF may be due to failure of the right or left ventricle, or both. The symptoms include shortness of breath (dyspnea), asthma due to the heart (cardiac asthma), pooling of blood (stasis) in the general body (systemic) circulation or in the liver's (portal) circulation, swelling (edema), blueness or duskiness (cyanosis), and enlargement (hypertrophy) of the heart. The many causes of CHF include coronary artery disease leading to heart attacks and heart muscle (myocardium) weakness; primary heart muscle weakness from viral infections or toxins, such as prolonged alcohol exposure; heart valve disease causing heart muscle weakness due to too much leaking of blood or causing heart muscle stiffness from a blocked valve; hyperthyroidism; and high blood pressure.

### **About Sigma-Tau**

Sigma-Tau is a leading, all Italian capital, International pharmaceutical group that invests in the research, development and marketing of innovative and effective treatments to improve human well-being and quality of life. Sigma-Tau Group has headquarters in Pomezia (Rome, Italy), and subsidiaries in France, Switzerland, the Netherlands, Belgium, Portugal, Germany, UK, India, US and Spain, these two latter with a production plant. It has over 2400 employees and an extensive network of licensees worldwide. Sigma-Tau was founded in Italy in 1957 and achieved a global turnover of € 673 million in 2010. Sigma- Tau invests on average 16% of its turnover in R&D, and employs approximately 400 researchers currently working on a significant discovery pipeline, studying, through clinical and pre-clinical trials, 26 different molecules, mostly (11) new and original, and 18 owned by the sigma-tau Group. Therapeutic areas in which the company's research and development are focused include rare and neglected diseases, oncology, immunology and biotech. For further information about Sigma-Tau: Website: [www.sigma-tau.it](http://www.sigma-tau.it)

### **About Lee's Pharmaceutical**



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Lee's Pharmaceutical Holdings Limited ("Lee's") is a research-based Hong Kong biopharmaceutical company with over 18 years 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 20 international companies and currently has 13 products in the market place. Lee's focuses on several key disease areas such as cardiovascular, oncology, gynecology, dermatology and ophthalmology. Lee's development program is lauded with 30 products stemming from both internal R&D efforts and collaborations with US, European and Japanese companies and aspiring to combat diseases such as liver cancer and pulmonary hypertension. The mission of Lee's is to become a successful biopharmaceutical group in Asia providing innovative products to fight diseases and improve health and quality of life. For further information about Lee's Pharmaceutical: Website: [www.leespharm.com](http://www.leespharm.com)

#### **Safe Harbor Statement**

*The statements in this news release, other than the historical financial information, may contain forward-looking statements that involve risks and uncertainties that could cause actual results to differ from anticipated results. Further information on risk factor that could affect, among other things, Lee's financial condition and results of operations is detailed in Lee's IPO prospectus, as filed with the Main Board of the Stock Exchange of Hong Kong Limited.*

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