



FOR IMMEDIATE RELEASE

## Propionyl-L-Carnitine Clinical Study Meets Primary and Secondary Endpoint of Treating Peripheral Arterial Diseases

**Hong Kong, Feb 11, 2011**—Lee's Pharmaceutical Holdings Limited (Main Broad Stock Code: 950; Website: [www.leespharm.com](http://www.leespharm.com)) today announced positive results from its Phase III clinical study of **Dromos**<sup>®</sup> (Propionyl-L-Carnitine hydrochloride tablets, "PLC") on evaluation the effectiveness and safety of treating patients with peripheral arterial diseases (intermittent claudication).

This multi-centers, randomized, double-blind and placebo controlled clinical trial was conducted over 9 clinical centers located in China at Beijing, Shanghai, Tianjin, Nanjing and Wuhan etc; and led by Xuanwu Hospital of Capital Medical University in Beijing (Ref No. NCT00809497 on ClinicalTrials.gov). Both groups received pentoxifylline as basic therapy. The Group initiated this Phase III clinical trial in May 2008, and completed enrollment with total of 239 patients in June 2010. The study is to evaluate the effect of PLC in improving the walking distance of patients suffered from Peripheral Arterial Diseases. The primary endpoint of the study is the Peak Walking Time ("PWT"). The results showed that after 4 months treatment, PLC significantly increased the PWT over the placebo (1.76 min. vs. 0.44 min,  $P < 0.05$ ) and prolonged the claudication onset time ("CT") (0.73 min vs. 0.36 min,  $P < 0.05$ ). PLC has also demonstrated excellent safety profile during the study.

"We are very excited about the positive results of this study. It demonstrates again that PLC is effective and safe in treatment of intermittent claudication," said Dr. Benjamin Li, the Chief Executive Officer of the Company. "I would like to compliment to our clinical development team for a job well done and to thanks Sigma-Tau for its support. We look forward to taking the next step toward filing our application of Imported Drug License ("IDL") before end of coming March."

The review period for an application of Imported Drug License ("IDL") is expected in 9 to 12 months, and the Group will launch the product immediately after obtaining the approval.

### **DROMOS<sup>®</sup> (Propionyl-L-Carnitine hydrochloride tablets, "PLC" )**

Propionyl-L-carnitine is a short-chain fatty ester of carnitine and a naturally occurring substance required in mammalian energy metabolism. The mechanisms by which supervised physical training improves walking ability in patients with intermittent claudication are microcirculatory, rheological, and metabolic. The main mechanism of levo propionyl carnitien is metabolic; it increases the walking ability in claudicants, providing an additional energy to the ischemic muscle by an anaplerotic activity.

## FOR IMMEDIATE RELEASE

### **About Peripheral Arterial Diseases (PAD) and Intermittent Claudication**

Peripheral arterial disease (PAD) is a common circulatory problem in which narrowed arteries reduce blood flow in the limbs. PAD can build up over a lifetime, and the symptoms may not become obvious until later in life. For many people, the outward symptoms of peripheral artery disease will not appear until the artery has narrowed by 60 percent or more.

The first noticeable symptom of peripheral artery disease may be **intermittent claudication** -- leg discomfort, pain or cramping that develops with activity, is relieved with rest, and recurs upon resuming activity. Intermittent claudication symptoms may also include numbness, weakness, heaviness or fatigue in the leg muscles when walking that are relieved at rest.

### **About Sigma-Tau**

**Sigma-tau** is one of the most important Italian pharmaceutical groups, which, with an excellent role internationally and a workforce of 2,439 achieved a corporate turnover of about € 615 million in 2009. The sigma-tau complex in Pomezia, the site of the Group's head office, houses not only the main factory, but also Avantgarde, a company operating in the pharmaceutical field and specializing in dermatology and gynaecology. Ever since its foundation in 1957, sigma-tau has based the various stages of its development on a single common denominator: research. The company's primacy in this field is an indispensable part of its corporate philosophy. A tangible impact on the quality of life can only be attained through constant, top-level research. Sigma-tau employs about 400 researchers, providing them with the means and resources to develop the therapeutic breakthroughs needed to guarantee better health conditions for everyone. For further information about Sigma-Tau: Website: [www.sigma-tau.it](http://www.sigma-tau.it)

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

Lee's Pharmaceutical Holdings Limited is a public biopharmaceutical company with over 15 years operation in China's pharmaceutical industry. It is fully integrated with solid infrastructures in drug development, clinical development, regulatory, manufacturing, sales and marketing in China with global perspectives and currently markets six products. Leespharm focuses on several different areas such as cardiovascular and infectious diseases, dermatology, oncology, gynecology and others. It has more than 20 products under different development stages stemming from both internal R&D as well as from the recent acquisition of licensing and distribution rights from various US and European companies. 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)



---

**FOR IMMEDIATE RELEASE**

**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.*

*For further information, please contact:*

*Vivian Fung*

*Tel: (852)2314-1282*

*Fax: (852)2314-1708*

*Email: [info@leespharm.com](mailto:info@leespharm.com)*