



FOR IMMEDIATE RELEASE

**Patients Enrollment completed in Clinical Study on  
Acetyl L-Carnitine Tablets for treatment of Peripheral Neuropathy**

**Hong Kong, May 9, 2011**—Lee's Pharmaceutical Holdings Limited (Main Broad Stock: 950: Website: [www.leespharm.com](http://www.leespharm.com)) today announced that the Group has successfully completed the patient enrollment for a clinical trial conducted in China on Sigma-Tau's original product, **Nicetile**<sup>®</sup> (Levocarnitine Acetate Hydrochloride Gastro-Resistant Tablets, "ALC"), to evaluate the effectiveness and safety for treatment of chemotherapy-induced peripheral neuropathy ("CIPN").

This multi-centers, randomized, double-blind, placebo-controlled and parallel clinical trial was conducted over 13 major clinical centers located in Beijing, Shanghai, Nanjing, Changzhou and Zhejiang; and led by The 6<sup>th</sup> People's Hospital affiliated to Shanghai Jiao Tong University. The trial has completed enrollment with total of 236 patients to date and the 4-month follow-up period has begun.

"We are pleased to have reached this important milestone in the ALC study. We would like to thank the dedicated clinical investigators, study coordinators and patients who participated in our trial as well as the support from Sigma-Tau Group," said Dr. Benjamin Li, the Chief Executive Officer of the Company. "This is the third completion of enrollment of registration study for the Group's in-licensed products in last six months. With the subsequent filings of registration this year, the Group could see a significant increase in the number of products available in the market place next year which could further fuel the growth momentum of the Group."

Acetyl-L-carnitine, a member of Carnitine family, is a kind of short-chain acyl-L-carnitine. Acetic ester of L-carnitine, as low-molecular-mass water-soluble polymers, is widely distributed in tissues of mammals. Acetyl-L-Carnitine can acetylate different microtubulins in neurons to enhance the stability of microtubules, prevent cytoskeleton damages and nerve fiber denaturation, so as to improve sensory nerve condition. Nicetile<sup>®</sup> has been launched in Italy since July 1984. Registered indications of ALC were mechanical and inflammatory injuries of peripheral nerve trunks or nerve roots.

It is an important milestone to achieve the completion of the ALC trial enrollment in a multi-centers trial focused on Chemotherapy-induced peripheral neuropathy ("CIPN") in China. This is the first attempt for the Group in the oncology area and it has positioned the Group well for further development in this area. The Group is looking forward to having the study report ready to filing to the SFDA the application for marketing authorization in September.

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### **About Chemotherapy-induced Peripheral Neuropathy (CIPN)**

Chemo-induced peripheral neuropathy (CIPN) is caused by the chemotherapy drugs used in cancer treatment. Symptoms are related to the type of nerve that is affected by the chemotherapy. It describes damage to the peripheral nervous system that transmits information between the central nervous system (e.g. the brain and spinal cord) and the rest of the body, caused by some chemotherapy agents. Sensory nerves are at increased risk to chemotherapy associated damage compared to motor nerves. This is because most of the drugs associated with CIPN are not able to enter the well-protected central nervous system, where the cell bodies of motor nerves are located. Therefore, patients often experience sensory symptoms such as numbness, tingling, or burning sensations.

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

Lee's Pharmaceutical Holdings Limited is a public biopharmaceutical company with over 16 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 nine products. Leespharm focuses on several key therapeutic areas such as cardiovascular and infectious diseases, dermatology, oncology, gynecology. It has more than 30 products under different development stages stemming from both internal R&D as well as from the recent acquisition of licensing and distribution rights from 18 US, European and Japanese 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)

### **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. Website: [www.sigma-tau.it](http://www.sigma-tau.it)



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**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 Growth Enterprise Market of the Stock Exchange of Hong Kong Limited.*

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