

FOR IMMEDIATE RELEASE

Clinical Trial Application for Phase III study for Gimatecan was accepted for review by China FDA

Hong Kong, 5 August 2013 - Lee's Pharmaceutical Holdings Limited ("the Group") (Main Board Stock Code: 0950; Website: www.leespharm.com) today announced that the Group has successfully submitted the application to the China FDA for conducting a phase III clinical study for Gimatecan on ovarian cancer in the People's Republic of China.

The clinical study application was submitted with the fast-track designation, and has been accepted for review by the CFDA (Acceptance Notice Nos. CXHL1300756, CXHL1300757, CXHL1300758 & CXHL1300759 for both of its drug substance and drug product). The registration-enabling, Phase III pivotal clinical trial is to test oral Gimatecan versus topotecan in refractory patients with advanced epithelial ovarian, fallopian or peritoneal cancer, resistant or partial sensitive to platinum.

Gimatecan, a novel oral lipophilic camptothecin, has some distinctive features that make it quite unique within the camptothecins. Proposed therapeutic advantages of Gimatecan consist of an improvement of the therapeutic index observed in the treatment of the non-small cell lung carcinoma, NCI-H460, and the glioblastoma, GBM. They relate to the drug efficacy at a large range of doses and different administration schedules, suggesting a lesser dependence on the treatment schedule in comparison with the reference compound TPT. A prospective phase II study was conducted to evaluate the efficacy and toxicity of oral Gimatecan in patients with recurrent epithelial ovarian, fallopian tube or peritoneal cancer. The result shows that the best overall response to study treatment was partial response in 17 patients (24.6%) and disease stabilization in 22 patients (31.9%). The median time to progression and overall survival were 3.8 and 16.2 months, respectively. It is suggested that oral Gimatecan has produced durable disease stabilization and is well tolerated with less than 10% grade 3/4 haematological toxicities.

"We're pleased with the acceptance of review by the CFDA for this important application. Oncology has been one of focused areas of the Group. Today's application underlines our commitment in the area and the advancement in our oncology pipeline," said Dr. Benjamin Li, Chief Executive Officer of the Group. "We are working closely with investigators, study team members on the clinical development plan, aiming for initiation of the study in the second half of next year."



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About Lee's Pharmaceutical

Lee's Pharmaceutical Holdings Limited is a research-based Hong Kong biopharmaceutical company with over 19 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 over 20 international companies and currently has 14 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. Additional information about Lee's Pharmaceutical is available at www.leespharm.com.

Safe Harbor Statement

The performance and the results of operation of Lee's during the past years are historical in nature and past performance can be no guarantee of future results of the Lee's. 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 nor the Directors, employees or agents of Lee's 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 materialise or turns out to be incorrect.

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