

**FOR IMMEDIATE RELEASE**

**Lee's Pharmaceuticals Announces it has  
Obtained the Imported Drug License in China  
for Remodulin (Treprostinil) injection**

Hong Kong, April 9, 2013 – Lee's Pharmaceutical Holdings Limited ("the Group") (Main Board Stock Code: 0950; Website: [www.leespharm.com](http://www.leespharm.com)) today announced that it has successfully obtained the Imported Drug Licenses (IDL Nos. H20130216, H20130217, H20130218, H20130219) from the China Food and Drug Administration ("CFDA") for United Therapeutics Corporation's product, Remodulin® (treprostinil) injection, for the treatment of patients with pulmonary arterial hypertension (PAH).

The application was submitted with the fast-track designation in September 2011. As Remodulin targets a rare disease with unmet medical need, a waiver of registration clinical study was sought in the application in accordance with the relevant registration regulation, and was granted by the CFDA.

Remodulin is a prostacyclin vasodilator that is indicated for treatment of PAH (WHO Group 1) by intravenous and subcutaneous administration, to diminish symptoms associated with exercise.

"This approval is a significant milestone not only for the development of Lee's, but more importantly, for the treatment of pulmonary arterial hypertension patients in China. Remodulin will fill a major void in treatment options that could result in better care for pulmonary arterial hypertension patients in China," said Dr. Benjamin Li, Chief Executive Officer of Lee's Pharmaceutical. "We are thrilled to be part of the effort to make this medicine available in China and look forward to bringing other much-needed drugs to the market."

## About Remodulin (treprostinil) injection

**Indication.** Remodulin is a prostacyclin vasodilator indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to diminish symptoms associated with exercise. Studies establishing effectiveness included patients with NYHA Functional Class II-IV symptoms and etiologies of idiopathic or heritable PAH (58%), PAH associated with congenital systemic-to-pulmonary shunts (23%), or PAH associated with connective tissue diseases (19%). Remodulin may be administered as a continuous subcutaneous infusion or continuous intravenous infusion; however, because of the risks associated with chronic indwelling central venous catheters, including serious blood stream infections, continuous intravenous infusion should be reserved for patients who are intolerant of the subcutaneous route, or in whom these risks are considered warranted.

### Important Safety Information

- ◆ Chronic intravenous infusions of Remodulin are delivered using an indwelling central venous catheter. This route is associated with the risk of blood stream infections (BSI) and sepsis, which may be fatal. Therefore, continuous subcutaneous infusion is the preferred mode of administration.
- ◆ Remodulin should be used only by clinicians experienced in the diagnosis and treatment of PAH. Remodulin is a potent pulmonary and systemic vasodilator. It lowers blood pressure, which may be further lowered by other drugs that also reduce blood pressure. Remodulin inhibits platelet aggregation and therefore, may increase the risk of bleeding, particularly in patients on anticoagulants. Remodulin dosage adjustment may be necessary if inhibitors or inducers of CYP2C8 are added or withdrawn.
- ◆ Initiation of Remodulin must be performed in a setting with adequate personnel and equipment for physiological monitoring and emergency care. Therapy with Remodulin may be used for prolonged periods, and the patient's ability to administer Remodulin and care for an infusion system should be carefully considered.
- ◆ Remodulin dosage should be increased for lack of improvement in, or worsening of, symptoms and it should be decreased for excessive pharmacologic effects or for unacceptable infusion site symptoms.

- ◆ Abrupt withdrawal or sudden large reductions in dosage of Remodulin may result in worsening of PAH symptoms and should be avoided. Caution should be used in patients with hepatic or renal insufficiency.
- ◆ The most common side effects of Remodulin included those related to the method of infusion. For subcutaneous infusion, infusion site pain and infusion site reaction (redness and swelling) occurred in the majority of patients. These symptoms were often severe and could lead to treatment with narcotics or discontinuation of Remodulin. For intravenous infusion, line infections, sepsis, arm swelling, tingling sensations, bruising, and pain were most common. General side effects (>5% more than placebo) were diarrhea, jaw pain, vasodilatation, and edema.

**For full prescribing information for Remodulin in the United States,** please visit [www.Remodulin.com](http://www.Remodulin.com).

### **About United Therapeutics**

United Therapeutics is a biotechnology company focused on the development and commercialization of unique products to address the unmet medical needs of patients with chronic and life-threatening conditions.

### **About Lee's**

Lee's Pharmaceutical Holdings Limited is a research-based biopharmaceutical company listed in Hong Kong 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](http://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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