

FOR IMMEDIATE RELEASE

## U.S. FDA Grants Orphan Drug Designation to Anfibatide for Treatment of Thrombotic Thrombocytopenic Purpura

**Hong Kong, March 24, 2016**—Lee's Pharmaceutical Holdings Limited (Main Board Stock Code: 0950; Website: [www.leespharm.com](http://www.leespharm.com)) today announced that Anfibatide, a new molecular entity discovered and developed by the Group and a first-in-class platelet 1b receptors antagonist, has received orphan drug designation from the U.S. Food and Drug Administration (FDA) for treatment of thrombotic thrombocytopenic purpura (TTP).

TTP is a rare blood disorder characterized by clotting in small blood vessels, resulting in a low platelet count. The clots limit or block the flow of oxygen-rich blood to the body's organs thus TTP can affect any organ system such as brain, heart and kidneys which can ultimately develop serious health problem. If left untreated, TTP has a mortality rate of as high as 90%.

"We are pleased that FDA has granted orphan drug designation for Anfibatide and we are thrilled of reaching this important milestone for Anfibatide development.' said Dr. Benjamin Li, Chief Executive Officer of the Group. "As we understand from the available information, this is the one of the few if not the only molecule originated from China to obtain this designation. This is the validation of our commitment on R&D and orphan disease, for Lee's, no single patient should be left alone. This orphan drug designation should promote the development of Anfibatide and provide an additional new treatment option for patients with TTP."

### About US FDA Orphan Drug Designation Program

The Orphan Drug Designation program provides orphan status to drugs and biologics which are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases/disorders that affect fewer than 200,000 people in the U.S., or that affect more than 200,000 persons but are not expected to recover the costs of developing and marketing a treatment drug.

( source: <http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/ucm2005525.htm> )

U.S. FDA Orphan drug designation from provides incentives such as user fee waivers, tax credits and eligibility for 7-year market exclusivity to assist and encourage the development of drugs for rare diseases.

### About TTP

TTP is a rare disease that causes extensive microscopic thromboses in small blood vessels throughout the body. It is a potentially life-threatening disease characterized by thrombocytopenia, haemolytic anemia and microvascular thrombosis in the organs. There are currently no drugs specifically approved for the treatment of TTP currently, plasma exchange is the only remedy for alleviation of condition. It is required to repeat the plasma

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exchange daily until there is improvement in the blood test. A significant number of patients who survive initial episodes will suffer recurrences. By estimation, there are more than 2,000 TTP-related hospitalizations occurred in the US per year.

**About Anfibatide**

Anfibatide is a new molecular entity discovered and developed by the Group. It is a first-in-class platelet 1b receptors antagonist and is currently undergone Phase IIb clinical study. It is a potent inhibitor of platelet aggregation in healthy volunteer and does not increase the risk of bleeding. Over two hundred healthy volunteers and patients have been treated with Anfibatide so far and the drug has shown a very good safety profile. Animal studies have shown that intravenous injection of Anfibatide effectively abolishes the cyclic flow reduction in canine model of unstable angina with much less prolongation of bleeding time than platelet 2b3a receptors antagonist. Anfibatide represents a novel therapeutic mechanism and may advance the treatment of acute coronary syndrome and percutaneous coronary intervention. It is expected that Anfibatide could have an important role in preventing thrombosis and plaque progression at sites of pathological endothelial injury, contributing to the treatment of unstable angina as well as to reduction of thrombosis in patients undergone PTCA and stenting. The Group has obtained patents in US and China for this product.

**About Lee's Pharmaceutical**

Lee's Pharmaceutical Holdings Limited is a research-based biopharmaceutical company listed in Hong Kong with more than 20 years of operation in China's pharmaceutical industry. It is fully integrated with a strong infrastructure in drug development, manufacturing, sales and marketing. It has established extensive partnerships with more than 20 international companies and currently has 15 products in the market place. Lee's Pharmaceutical focuses on several key disease areas such as cardiovascular, oncology, gynecology, dermatology and ophthalmology. The company's development program is lauded with over 40 product candidates stemming from both internal R&D efforts and collaborations with US, European and Japanese companies, including promising compounds to treat liver cancer and pulmonary hypertension. The mission of Lee's Pharmaceutical is to become a successful biopharmaceutical group in Asia providing innovative products to fight diseases and improve health and quality of life. Additional information is available at <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 materialize or turns out to be incorrect.*

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