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Lee's Pharmaceutical Holdings Limited

李氏大藥廠控股有限公司*

(incorporated in the Cayman Islands with limited liability)

(Stock Code: 950)

VOLUNTARY ANNOUNCEMENT – UPDATE ON AN INVESTIGATIONAL ANESTHESIA PRODUCT

This announcement is made by the board (the “**Board**”) of directors (the “**Directors**”) of Lee’s Pharmaceutical Holdings Limited (the “**Company**” or “**Lee’s Pharm**”, and, together with its subsidiaries, the “**Group**”) on a voluntary basis.

The Board of the Company is pleased to announce that, on 18 August 2023, a phase IIa clinical trial of a fentanyl aerosol for inhalation conducted by Zhaoke Pharmaceutical (Guangzhou) Limited (兆科藥業(廣州)有限公司), a wholly-owned subsidiary of the Company, reached its expected endpoints.

This clinical trial was a phase IIa clinical trial to assess the safety and effectiveness of the fentanyl aerosol for inhalation in Chinese patients with breakthrough cancer pain (“**BTCP**”). The primary endpoint of this trial was to initially assess the dose–response relationship and determine the range of effective dose of fentanyl aerosol in the treatment of BTCP. The secondary endpoint was to verify the safety of fentanyl aerosol and the reliability, dependability and safety of the inhaler. This trial was designed as a multi-center, randomized, double-blinded, self-crossover study. A total of 60 patients were successfully enrolled from 13 participating centers. The results of the treatment demonstrated that the response of the tested group was better than that of the placebo group with statistical significance. This trial also verified the safety and tolerability of the fentanyl aerosol for inhalation. The results of this trial will be used to expedite the review and approval procedures for national new drug approval with the aim of launching the product as soon as possible in order to meet the medical need of patients with BTCP.

ABOUT FENTANYL AEROSOL FOR INHALATION

Fentanyl aerosol for inhalation is a combination drug–device fentanyl delivery product designed for rapid and systemic delivery of aerosolized fentanyl via the lung. One of the advantages of such product is the safety features inherent in its design. Several abuse deterrent and overdose prevention features such as finger print activation, GPS tracking, Cloud data collection and dose limitation have been, or can readily be, incorporated into the device, thereby effectively addressing the abuse and overdose concerns. Since any development work carried out on fentanyl must be pre-approved by the National Medical Products Administration of China, Staccato® Fentanyl for Inhalation as a solution for the unmet medical needs and abuse and overdose prevention had been presented to the regulatory agency and is subject to review by the expert panel. The agency concluded that this unique drug-device system provides an excellent opportunity to address the highly unmet medical needs while drastically improving the control over potential abuse and overdose. As a result, for the first time in the last 25 years, an approval to develop this fast-acting fentanyl product for BTCP in China has been granted to the Group.

ABOUT LEE’S PHARM

Lee’s Pharm is a research-driven and market-oriented biopharmaceutical company with more than 25 years of operation in the pharmaceutical industry in China. The Company is fully integrated with solid infrastructures in drug development, clinical development, regulatory, manufacturing, sales and marketing based in Mainland China with global perspectives. The Company has established extensive partnerships with over 20 international companies and currently markets over 25 proprietary, generic and licensed-in pharmaceutical products in Mainland China, Hong Kong, Macau and Taiwan. The Company focuses on several key disease areas such as cardiovascular, woman health, pediatrics, rare diseases, oncology, dermatology and obstetrics, and has more than 40 products under different development stages stemming from both internal research and development as well as from the licensing of development, commercialisation, and manufacturing rights from various United States, European and Japanese companies. More information is available at www.leespharm.com.

By order of the Board
Lee’s Pharmaceutical Holdings Limited
Lee Siu Fong
Chairman

Hong Kong, 21 August 2023

As at the date of this announcement, Ms. Lee Siu Fong (Chairman) and Ms. Leelalertsuphakun Wanee are executive Directors of the Company, Dr. Li Xiaoyi and Mr. James Charles Gale are non-executive Directors of the Company, and Dr. Chan Yau Ching, Bob, Ms. Cheang Yee Wah, Eva and Dr. Tsim Wah Keung, Karl are independent non-executive Directors of the Company.

* *For identification purpose only*