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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 – INOMAX DSIR PLUS DELIVERY SYSTEM OBTAINS MEDICAL DEVICE REGISTRATION CERTIFICATE

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**”, together with its subsidiaries as the “**Group**”) on a voluntary basis.

Reference is made to the announcement of the Company dated 21 April 2022 in relation to the registration approval of INOmax (nitric oxide for inhalation) (“**INOmax**”) obtained from the China National Medical Products Administration (“**NMPA**”) in March 2022. The Board is pleased to announce that, on 25 May 2023, the Medical Device Registration Certificate for INOmax DS_{IR} Plus Delivery System™ (“**INOmax DS_{IR} Plus**”) was obtained from the NMPA.

INOmax DS_{IR} Plus is a system for the delivery of INOmax for treating term and near-term neonates (>34 weeks) with hypoxic respiratory failure (“**HRF**”) associated with pulmonary hypertension (“**PPHN**”). Following the approval of INOmax DS_{IR} Plus, the Company can now market and distribute this comprehensive solution for the public in Mainland China.

The number of newborns was about 10.62 million in China in 2021. As reported by Liu et al. in *Respiratory Research* (2019) 20:174, the incidence of HRF in China ranges from 2 to 6 per 1,000 newborns and the mortality rate is about 10–20%. The NMPA registration of INOmax DS_{IR} Plus will enable treatment with INOmax in this patient population where clinically appropriate, addressing an unmet medical need in the region.

INOmax and INOmax DS_{IR} Plus are in-licensed products from Mallinckrodt Pharmaceuticals (“**Mallinckrodt**”) for the Mainland China, Hong Kong, Macau and Taiwan.

* *For identification purpose only*

ABOUT INOmax and INOmax DS_{IR} Plus

INOmax is a therapeutic drug approved for the treatment of HRF associated with PPHN in term and near-term infants greater than 34 weeks gestational age, and is used together with the INOmax DS_{IR} Plus. PPHN is a serious condition in which blood vessels in the lungs constrict, making it difficult to oxygenate blood, often resulting in HRF. INOmax is a vasodilator which selectively relaxes pulmonary blood vessels and, in conjunction with ventilatory support and other appropriate agents, improves oxygenation in this fragile newborn population.

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. The approval of INOmax DS_{IR} Plus has brought the total number of product approvals to 12 since 2021. More information available at www.leespharm.com.

ABOUT MALLINCKRODT

Mallinckrodt is a global business consisting of multiple wholly owned subsidiaries that develop, manufacture, market and distribute specialty pharmaceutical products and therapies. The company's Specialty Brands reportable segment's areas of focus include autoimmune and rare diseases in specialty areas like neurology, rheumatology, hepatology, nephrology, pulmonology, ophthalmology, and oncology; immunotherapy and neonatal respiratory critical care therapies; analgesics; cultured skin substitutes and gastrointestinal products. Its Specialty Generics reportable segment includes specialty generic drugs and active pharmaceutical ingredients. To learn more about Mallinckrodt, visit www.mallinckrodt.com.

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

Hong Kong, 9 June 2023

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