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## LUYE PHARMA GROUP LTD.

绿叶制药集团有限公司

(Incorporated in Bermuda with limited liability) (Stock Code: 02186)

## **VOLUNTARY ANNOUNCEMENT**

## RIVASTIGMINE TWICE WEEKLY TRANSDERMAL PATCH APPROVED FOR MARKETING IN CHINA

The board of directors (the "**Board**") of Luye Pharma Group Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") announces that the new central nervous system ("**CNS**") exclusive drug Rivastigmine Twice Weekly Transdermal Patch developed by the Group has been approved by the National Medical Products Administration of China for the symptomatic treatment of mild to moderate Alzheimer's disease ("**AD**"). The commercialization of the product in China is managed via collaboration between the Group and Changchun GeneScience Pharmaceutical Co., Ltd. ("**GENSCI**").

AD has become a major challenge to public healthcare worldwide. It is regarded as one of the most difficult diseases to treat, and the development of new drugs is relatively slow and existing drugs are limited. Moreover, the treatment of older patients is often challenging due to the prevalence of AD-associated conditions such as dysmnesia and cognitive disorders. In clinical practice, patient outcomes are significantly compromised due to issues such as poor patient compliance, high drug withdrawal rates as a result of adverse events, and difficulties with medication management. This has created a heavy burden for caregivers and AD patients, physically and financially. According to statistics, there are around 9.83 million AD patients in China, and the number is still growing.

Rivastigmine is currently a first-line treatment for mild to moderate AD. Rivastigmine Twice Weekly Transdermal Patch adopts an innovative drug delivery system and simplifies the dosage regimen, improving on the disadvantages of the oral formulation of Rivastigmine while relieving difficulties in administration for patients and their caregivers. Compared with the oral formulation, patch medication is administered transdermally, reducing adverse gastrointestinal reactions such as nausea and vomiting. Plasma concentration achieved through use of patches is more stable than that of oral formulation, allowing patients to receive stable treatment at the sufficient dosage. Patches are also more convenient than oral formulation for patients who have difficulty swallowing. In addition to these benefits, compared with the once-daily Rivastigmine transdermal patch, the twice weekly patch is administered less frequently, simplifies the dosage regimen, improves patient compliance, and provides a new option to patients for long-term disease management.

The Rivastigmine Twice Weekly Transdermal Patch, being the world's first patch formulation of Rivastigmine to be administered twice weekly, has been approved for marketing in several European countries. The product and its formulation methods are protected globally under a number of patents. Rivastigmine Twice Weekly Transdermal Patch was developed by the research and development platform for transdermal patch of Luye Pharma AG, a subsidiary of the Company in Germany, which is one of the largest independent transdermal drug delivery system manufacturers in Europe. Luye Pharma AG possesses transdermal drug delivery system manufacturing facilities with highly complex production processes and technologies with high technical barrier, and such facilities have passed GMP inspections, and Japanese GMP inspections.

The Group believes that Rivastigmine Twice Weekly Transdermal Patch has promising market prospects. In order to promote the product for the benefit of more patients in China, the Group and GENSCI entered into an agreement in December 2021 to grant GENSCI the commercialization rights of Rivastigmine Twice Weekly Transdermal Patch and other products in mainland China.

The CNS therapeutic area, which includes AD, has long been a strategic focus of the Group. With breakthroughs in new drug development, the Group's product portfolio in the field of CNS is becoming more diverse.

The Group has built a diversified CNS portfolio. In January 2023, Rykindo<sup>®</sup> (Risperidone for Extended-release Injectable Suspension) was approved for marketing in the U.S., making it the first new CNS drug developed by a Chinese pharmaceutical company to receive approval for use in the U.S., as far as the Company is aware. In November 2022, Ruoxinlin (Toludesvenlafaxine Hydrochloride Sustained-release Tablets) was approved for marketing in China as the first "Class 1 Chemical Drug" for the treatment of Major Depression Disorder developed by a Chinese company, as far as the Company is aware. Other products in the portfolio, such as Seroquel<sup>®</sup> (quetiapine fumarate) and its extended-release tablets, and once-daily Rivastigmine Transdermal Patches, are sold in China and abroad, in addition to Rivastigmine Twice Weekly Transdermal Patches, which are available in major European markets.

In the Group's pipeline, LY03010 (Paliperidone Palmitate Extended-release Injectable Suspension) is at the Marketing Approval Application stage in China and the U.S.. LY03003 (Rotigotine Extended-release Microspheres for Injection), currently being developed in China and abroad, has been granted priority review for its New Drug Application in China. Several other new products, such as LY03015, a VMAT2 inhibitor, are undergoing clinical trials in China and abroad. The Company has built competitive capabilities in conducting research and development, regulatory, clinical, supply chain, and commercial activities internationally, laying a solid foundation for commercializing new products around the world in the future.

By Order of the Board LUYE PHARMA GROUP LTD. Liu Dian Bo Chairman

Hong Kong, 31 October 2023

As at the date of this announcement, the executive directors of the Company are Mr. LIU Dian Bo, Mr. YANG Rong Bing, Mr. YUAN Hui Xian and Ms. ZHU Yuan Yuan; the non-executive directors of the Company are Mr. SONG Rui Lin and Mr. SUN Xin; and the independent non-executive directors of the Company are Mr. ZHANG Hua Qiao, Professor LO Yuk Lam, Mr. LEUNG Man Kit, Mr. CHOY Sze Chung Jojo and Ms. XIA Lian.