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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

NDA FILED FOR RIVASTIGMINE TWICE WEEKLY TRANSDERMAL PATCH IN JAPAN

The board of directors (the “**Board**”) of Luye Pharma Group Ltd. (the “**Company**”, together with its subsidiaries, the “**Group**”) announces that its partner Towa Pharmaceutical Co., Ltd. (“**Towa**”) has filed a New Drug Application (“**NDA**”) to the Ministry of Health, Labour and Welfare in Japan for the Rivastigmine Twice Weekly Transdermal Patch for treating mild to moderate dementia associated with Alzheimer’s disease.

The Rivastigmine Twice Weekly Transdermal Patch was developed by the Group on its proprietary transdermal patch platform, utilizing an innovative drug delivery system to administer rivastigmine transdermally twice a week. In December 2020, the Group entered into an agreement with Towa, granting the latter an exclusive license to develop and commercialize this drug in Japan.

The NDA was filed by Towa based on the interim analysis results of a Phase 3 clinical trial in Japan involving patients with dementia associated with Alzheimer’s disease which met the primary efficacy endpoint.

Alzheimer’s disease is a neurodegenerative disease that causes a progressive decline in memory and other aspects of cognition. It is the most common type of dementia, accounting for 50%-75% of all cases. According to data from Japan’s Ministry of Internal Affairs and Communications, out of the country’s total population of 125 million people, 29.1% of the total population were 65 years old or older in 2023. Additionally, a study shows the lifetime risk of dementia in the Japanese elderly population exceeds 50%, and over 50% of all dementia cases are Alzheimer’s disease.

For people with Alzheimer's disease, a decline in the ability to manage medication is said to be one of the early symptoms, and orally disintegrating tablets and patches have been suggested to be capable of improving medication adherence. The Rivastigmine Twice Weekly Transdermal Patch is administered less frequently versus the once-per-day rivastigmine patches generally available in the market, which helps to maintain better medication adherence.

The Group is developing and commercializing the Rivastigmine Twice Weekly Transdermal Patch for the global market. The product has been approved for marketing in multiple European countries and China. In addition to Japan, the product is also being registered or developed with partners in several Southeast Asian and Latin American countries for commercialization.

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

Hong Kong, 6 June 2024

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 Dr. LYU Dong; 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.