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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

APPROVAL OBTAINED FOR THE GROUP'S NEW DRUG LY03020 FOR CLINICAL TRIALS IN THE U.S.

The board of directors (the "**Board**") of Luye Pharma Group Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") announces that the U.S. Food and Drug Administration ("**FDA**") has approved its Investigational New Drug ("**IND**") application for LY03020, a dual TAAR1/5-HT_{2C}R agonist intended to treat schizophrenia. Developed on the Group's New Chemical Entity/New Therapeutic Entity ("**NCE/NTE**") platform, LY03020 is a next-generation antipsychotic and the world's first agonist against both the trace amine-associated receptor 1 ("**TAAR1**") and the 5-HT_{2C} receptor ("**5-HT_{2C}R**"). It is also undergoing clinical trials in China.

Schizophrenia is a severe mental disorder affecting approximately 24 million people worldwide, of which 3.7 million are in the U.S. About 30% of patients with treatment-resistant schizophrenia do not respond well to the first- and second-generation antipsychotics. The next-generation antipsychotics are highly anticipated to address these unmet needs, as they can primarily activate the presynaptic membrane. This mechanism of action ("**MoA**") is a key difference from existing antipsychotics that typically antagonize D_2 and 5-HT_{2A} receptors on the postsynaptic membrane. As a result, the next-generation antipsychotics are expected to reduce adverse reactions such as extrapyramidal symptoms ("**EPS**") and metabolic syndrome associated with existing antipsychotics, while significantly improving positive symptoms, negative symptoms and cognitive impairments common in schizophrenia.

LY03020 targets both TAAR1 and 5-HT_{2C}R. TAAR1 is primarily expressed on the presynaptic membrane, and its activation reduces the release of monoamine neurotransmitters such as dopamine ("**DA**") and serotonin ("**5-HT**") into the synaptic cleft. 5-HT_{2C}R is expressed on both pre- and post-synaptic membranes. The activation of presynaptic 5-HT_{2C}R further lowers the release of neurotransmitters like 5-HT, thereby enhancing the inhibition of negative symptoms. The activation of postsynaptic 5-HT_{2C}R thus helps to control adverse effects of metabolic syndrome such as weight gain and abnormal glucose/lipid levels.

Preclinical studies have demonstrated that LY03020 can significantly improve the positive and negative symptoms, as well as cognitive impairments associated with schizophrenia, without noticeable risks for EPS or metabolic syndrome like weight gain and abnormal glucose/lipid levels.

There are significant unmet treatment needs in the Central Nervous System ("**CNS**") therapeutic area which includes schizophrenia, but the development of new drug aiming to address these needs has been relatively slow. The Group has built a differentiated CNS portfolio that is globally competitive. The Group's CNS portfolio includes Erzofri® (paliperidone palmitate) extended-release injectable suspension and Rykindo® (risperidone) extended-release injectable suspension, both of which have been approved for marketing in the U.S.; and Ruoxinlin® (Toludesvenlafaxine Hydrochloride Extended-Release Tablets) and Jinyouping® (Rotigotine Microspheres for Injection), both of which have been launched in China. In addition, the company is conducting clinical trials for several other investigational drugs, such as LY03021, which targets NET, DAT and $GABA_AR$, and LY03015, which targets VMAT2 and Sigma1.

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

Hong Kong, 14 January 2025

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.