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

MRNA VACCINE LY01620 FOR THE TREATMENT OF CERVICAL PRECANCEROUS LESIONS AND HPV-RELATED TUMORS TO ENTER INTO PHASE II CLINICAL TRIAL IN CHINA

The board of directors (the "**Board**") of Luye Pharma Group Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") announces that LY01620, a messenger RNA ("**mRNA**") vaccine developed by the Group, is about to enter into a Phase II clinical trial in China. The study plans to enroll patients with histologically confirmed human papillomavirus 16 ("**HPV16**")-positive cervical high-grade squamous intraepithelial lesion ("**HSIL**") to further evaluate the efficacy and safety of LY01620.

LY01620 is a therapeutic mRNA vaccine, registered as a Class 1 therapeutic biological product, targeting the E6 and E7 protein antigens of the HPV16 subtype. LY01620 utilizes mRNA to express HPV-specific antigens E6/E7, inducing the body to generate specific T-cell immune responses to eliminate HPV-infected cervical epithelial cells, thereby blocking the carcinogenesis process and restoring cervical epithelial cells to a normal state.

The Phase I clinical study of LY01620 in China has yielded positive results, supporting the initiation of the Phase II study. The Phase I study was designed to evaluate the safety, tolerability, immune response, immunogenicity, and preliminary efficacy of LY01620 in patients with HPV16-positive, histologically confirmed HSIL. The results demonstrated that LY01620 significantly activates both cellular and humoral immunity, achieving an HPV clearance rate of nearly 90%. The proportion of histopathological improvement nearly reaches that of the standard surgical treatment. Furthermore, the product is non-invasive and does not affect reproductive function. The overall safety and tolerability profile was favorable, with the adverse reactions observed were common vaccine-related adverse reactions.

Compared with conventional surgical treatment, therapeutic vaccines can be applied at different stages of disease progression following HPV infection, blocking progression to cervical cancer. The Group's management believes that, as a highly effective non-surgical immunotherapy approach, the development of a therapeutic HPV vaccine has become an urgent clinical need. LY01620 is expected to fill the gap in therapeutic HPV vaccines, providing a new treatment option for HPV-related diseases. Furthermore, the Group is actively exploring the clinical application potential of LY01620 in HPV-related solid tumors, further unlocking the therapeutic value and potential of the product.

The Group's proprietary mRNA technology platform integrates end-to-end capabilities spanning antigen screening, mRNA sequence optimization, proprietary delivery system development and GMP-compliant manufacturing at scale. The Group has the capability to develop individualized and off-the-shelf mRNA vaccine products based on tumor neoantigens by leveraging this platform.

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

Hong Kong, 20 August 2026

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. HUANG Liming; 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.