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# LUYE PHARMA GROUP LTD. 绿叶制药集团有限公司 (Incorporated in the Bermuda with limited liability) (Stock Code: 02186)

### **VOLUNTARY ANNOUNCEMENT**

## APPROVAL FOR CLINICAL TRIAL FOR CLASS I NEW CHEMICAL DRUG — ANTI-TUMOR INNOVATIVE DRUG (LY01013) IN CHINA

Reference is made to the announcement of Luye Pharma Group Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") dated 26 February 2018 (the "**Announcement**") in relation to the development of the Group's product candidate, Class I New Chemical Drug — Anti-tumor Innovative Drug LY01013 ("**LY01013**"). Unless otherwise defined, capitalised terms used in this announcement shall have the same meanings as those defined in the Announcement.

The board of directors of the Company (the "**Board**") is pleased to announce that LY01013 has obtained the approval from China Food and Drug Administration to initiate clinical trials. LY01013 is an oral strong small-molecule indoleamine 2,3-dioxygenase ("**IDO**")/tryptophan 2,3-dioxygenase ("**TDO**") inhibitor, which can overcome IDO/TDO enzymemediated immune tolerance, activate effector T-cells and modulate tumor immune microenvironment. The product can be used in conjunction with, and even enhance the tumor-killing inhibitory effect of, other drugs, such as immune check-points and chemotherapy drugs. LY01013 is unique and we are closely monitoring the development of global oncology drugs, considering the Group's product characteristics, to develop appropriate clinical development strategies.

In connection with LY01013, the Group has applied for a compound patent, a polymorph patent and a preparation technology patent. The intended indications include the treatment of lung cancer, kidney cancer, bladder cancer, head and neck cancer and melanoma.

The Company expects that LY01013 will vigorously facilitate the development of the Group in the field of tumor immunity and continue to consolidate the Group's dominant position in the field of oncology drug treatment. Apart from China, the Group is also committed to registering and launching LY01013 in the United States, Europe, Japan and other countries.

#### **ABOUT IDO**

The IDO family consists of IDO and isozyme TDO. They are highly expressive in a variety of tumor microenvironment, and act as a rate-limiting enzyme that catalyzes tryptophan catabolism along the kynurenine pathway. Through tryptophan depletion, it can suppress T-cell proliferation, as the kynurenine produced can facilitate T-cell apoptosis and induce regulatory T-cell proliferation and other mechanisms to mediate tumor immune escape. IDO/TDO is an important regulatory target in tumor immunotherapy.

### **ABOUT TUMOR IMMUNOTHERAPY**

Under normal circumstances, tumor mutations occur under the surveillance of the immune system and are eliminated during immunosurveillance and immunoediting. Nevertheless, tumor cells can produce molecules, such as PD-L1, IDO, IL-10 and TGF $\beta$ , to suppress the immune response against the body's immunosurveillance. Meanwhile, some inhibitory molecules, such as PD1, TIM3, LAG3, are expressed on the surface of T-cells, resulting in the phenomenon of T-cell depletion in the body's immune system. By activating the body's immune system, tumor immunotherapy can enhance anti-tumor immunity of the tumor microenvironment, thus controlling and killing tumor cells.

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

Hong Kong, 31 July 2018

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 director of the Company is Mr. SONG Rui Lin; and the independent non-executive directors of the Company are Mr. ZHANG Hua Qiao, Professor LO Yuk Lam, Mr. LEUNG Man Kit and Mr. CHOY Sze Chung Jojo.