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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

LY03009 COMMENCED PHASE I CLINICAL TRIAL IN AUSTRALIA

The board of directors of Luye Pharma Group Ltd. (“the Company”, together with its subsidiaries, the “Group”) announced that the Group’s product candidate, monthly microspheres injection LY03009, commenced phase I clinical trial in Australia.

LY03009 is one of the Group’s key central nervous system product candidates developed on a long acting and extended-release formulation platform, indicated for Parkinson’s Disease (PD) and moderate to severe restless legs syndrome (RLS). LY03009 is a microspheres injection for monthly dosing, helping to maintain the stable drug levels in plasma during aimed dosing intervals. It possesses the benefits of continuous dopaminergic stimulation, which will reduce the risk of motor complications and delay introduction of levodopa in the treatment of Parkinson’s Disease. The continuity of effective drug level overnight is expected to improve nocturnal symptom control and function on awakening. The targeted dosing interval of every month can reduce administration frequency, simplify the regimen, provide convenience, and ultimately contribute to the improvement of treatment compliance and clinical outcomes.

According to the Journal of Neurology, Parkinson’s disease is the most common movement disorder and is the second most common neurodegenerative disease. Approximately 1–2% of the population over 65 years of age suffers from Parkinson’s disease. This figure increases to 3–5% for the population over 85 years of age.

According to the Journal of the National Institutes of Health, the prevalence estimates of restless legs syndrome in Europe and North America are 1.9–4.6% of general adult populations.

With ageing population worldwide, the Board believes that LY03009 has promising market prospects and will enrich the Group’s future product portfolio.

Apart from LY03009, the Group has a number of other pipeline projects relating to the central nervous system which are under concurrent development in China and overseas markets, with projects such as LY03004 for schizophrenia and bipolar I disorder, LY03003 for Parkinson's disease and moderate to severe restless legs syndrome, LY03005 for major depressive disorder, LY03010 for schizophrenia and schizoaffective disorder and LY30410/LY03013 for mild to moderate Alzheimer's disease and LY03012 for chronic pain. The registration processes of the above pipeline products are progressing well in strategic markets such as China, the U.S., Europe and Japan, and the products are expected to be launched in these countries and further expanded into the global market.

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

Hong Kong, 4 January 2021

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.