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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

MARKETING REGISTRATION OF RISPERIDONE MICROSPHERES FOR INJECTION (II) (瑞欣妥®) APPROVED BY NMPA

The board of directors (the "**Board**") of Luye Pharma Group Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") is pleased to announce that the marketing registration of Risperidone Microspheres for Injection (II) (LY03004, 瑞欣妥®) has been approved by the National Medical Products Administration ("**NMPA**") of the People's Republic of China ("**China**"). It is the first innovative formulation developed under the Group's long acting and extended technology platform that received marketing approval. 瑞欣妥® is an extended-release microspheres for injection administered bi-weekly for the treatment of schizophrenia.

瑞欣妥® is a long-acting drug administered bi-weekly by intramuscular injection. Compared to orally administered antipsychotics, long-acting formulations do not require daily administration, and are thus better received by patients and could lower the sense of self-stigmatization associated with their diseases. Patients are also less unlikely to skip drug administration, and face a lower risk of drug overdose with long-acting drugs. Patients using long-acting injectables have steady plasma drug levels and will not suffer an immediate relapse when drugs are not administered in a timely manner due to a slower drop of plasma drug level. 瑞欣妥® can significantly improve the medication compliance issues which are common among patients with schizophrenia in relation to oral antipsychotic drugs, and simplify the treatment regimen.

瑞欣妥® also has several advantages over another marketed long-acting injectable drug. For example, unlike the reference drug, there is no need for administration of the oral formulation following the first injection of 瑞欣妥®. Furthermore, steady plasma drug levels can be reached much faster with 瑞欣妥® than with the reference product. Thus, patients at acute phase who are less compliant and cooperative can benefit from the fast symptom control afforded by 瑞欣妥®. After the discontinuation of use, the concentration of 瑞欣妥® in human body drops markedly faster than that of the reference drug, making it convenient for doctors to adjust dosage according to patients' conditions. Patients using 瑞欣妥® also have stable clinically effective plasma drug level and can benefit from more convenient clinical treatment as a result.

Due to its sufficient clinical advantages, 瑞欣妥® was granted priority review by the Center for Drug Evaluation under National Medical Products Administration (NMPA) in December 2019, making early access possible for Chinese patients suffering from schizophrenia.

In addition to the China market, 瑞欣妥® is also under development in overseas markets. It is under marketing authorization application stage in the U.S. and completed phase I clinical trial in Europe. Further development and launch in emerging markets are also planned. Its patents have been granted in China (including mainland and Hong Kong), the U.S., Europe, Japan, South Korea, Russia, Canada and Australia, which will be expired until 2032.

Schizophrenia is a severe mental disorder, characterized by profound disruptions in thinking, affecting language, perception and the sense of self. According to the World Health Organization (WHO), schizophrenia affects more than 21 million people worldwide, and one in every two persons suffering from schizophrenia does not receive care for the condition. Schizophrenia is a major mental disease in China. It is estimated that there are at least 10 million schizophrenia patients in China[(1)]. The low treatment rate, poor compliance, high recurrence rate, high hospitalization rate and high disability rate of schizophrenia have brought heavy burden to the families of patients and society.

The Group has launched several products for the central nervous system therapeutic area, including Seroquel, Seroquel XR, Rivastigmine patches, Fentanyl patches and Buprenorphine patches, covering over 80 countries and regions around the world, including large pharmaceutical markets in China, the U.S., Europe and Japan, as well as fast growing emerging markets.

The Group's central nervous system division has set up a marketing and sales team of 110 members in relation to five major sales regions in China, covering all regions of the country.

(1) Huang YQ, Wang Y, Wang H, et al. Lancet Psychiatry. Published Online 18 February 2019.

In addition to 瑞欣妥®, the Group has a number of other pipeline projects focusing on the central nervous system under concurrent development in China and overseas markets, including projects such as LY03003 for Parkinson's disease and moderate to severe restless legs syndrome, LY03005 for major depressive disorder, LY03010 for schizophrenia and schizoaffective disorder, a Class 1 new drug product LY03012 for chronic pain and LY30410 for mild to moderate Alzheimer's disease. The registration work in relation to the above pipeline products has been 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 markets.

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

Hong Kong, 14 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.