

Luye Pharma submits its Parkinson's drug for clinical trial approval

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Luye Pharma announced that its new investigational drug, Rotigotine Extended Release Microspheres for Injection (LY03003) for the treatment of Parkinson's disease has been submitted to the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan for clinical trial approval. Meanwhile Phase III clinical trials for LY03003 in the U.S. and China are progressing smoothly.

LY03003 is one of Luye Pharma's key products in the central nervous system (CNS) therapeutic area and can produce Continuous Dopamine Stimulation (CDS) on a long-term basis. Luye Pharma has been developing the drug simultaneously in key strategic markets, such as the U.S., China, Europe and Japan, preparing to launch first in the U.S. and China, then later to other markets worldwide.

LY03003 is an injection to be administered intramuscularly once a week. It was developed independently by Luye Pharma on its long-acting and extended-release R&D platform. The stable release of the drug in the human body can reduce the "on-off" phenomenon commonly seen in drug treatment for patients with Parkinson's disease and can significantly improve the motor complications which are common for patients with late-stage Parkinson's disease. It is expected that the long-term application of the drug can delay the development of motor complications. Besides this once-weekly dosage, the company is further developing the once-monthly injection of Rotigotine Extended Release Microspheres so as to provide better options for the clinical treatment of Parkinson's disease.

"As global aging worsens, we believe LY03003 will have very good market prospects in the future, further enriching and strengthening the company's current central nervous system portfolio. We are increasing our investment in China, the United States, Europe, and Japan to accelerate the launch speed for self-developed products in several of our most important strategic markets. We hope to accelerate the global launch of these drugs so that they can be accessible to more patients all over the world", said a senior manager at the company.

