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ASIA EDITION

Luye Pharma's Rykindo might be the first Chinese Innovative Drug to receive U.S. FDA approval

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Luye Pharma Group has announced submission of a new drug application (NDA) to the U.S. Food and Drug Administration for Rykindo, completed on March 28. Rykindo (LY03004) Risperidone Extended-release Microsphere for Injection is expected to become the first Chinese innovative drug to receive U.S. FDA approval for marketing in the United States.

The NDA submission for Rykindo is regarded as a milestone step for the company, expecting a big pay-off from the potential industrialization of its long-invested long-acting and extended-release technology R&D platform. This is not only a key step in Luye Pharma's globalization initiative, but also a major step for China in bringing innovative formulations to the world, receiving wide attention from all walks of life. After going through R&D, CMC and process optimization testing, the scaling-up of production, registration review and commercial preparations, Luye Pharma is now fully prepared for the global launch of Rykindo and other innovative formulations.

Rykindo is an extended-release microsphere independently developed by Luye Pharma. It is administered once every two weeks by intramuscular injection to treat schizophrenia and bi-polar disorder. The NDA submission this time includes the results from one pivotal and two supportive clinical studies, involving a total of 172 patients in the U.S. The results of the pivotal study demonstrated no lag period with the first injection and an equivalent pharmacokinetic profile of Rykindo® at steady state when compared to the marketed reference product of risperidone long-acting injection. Similar safety profiles were observed between Rykindo® and the reference product in all three studies. Rykindo® as an injectable drug can improve medication compliance in patients with schizophrenia, which is a common issue with oral antipsychotic drugs, simplifying the treatment regimen due to the need for an injection only once every two weeks. Furthermore, Rykindo has several advantages over the reference drug, for example, there is no need to administer an oral formulation for three weeks after the first injection

of Rykindo when compared to the reference drug. Steady plasma drug level can also be achieved much faster with Rykindo® when compared to the reference product.

According to Luye Pharma, Rykindo is expected to be launched in the U.S. and China first, during the 2019 - 2020 period. Meanwhile, Rykindo®'s registration process in Europe and other emerging countries is progressing smoothly.

In the central nervous system (CNS) therapeutic area where Rykindo® is applied, the global patient population is extremely large and constantly growing. Luye Pharma's strategic approach in this treatment area will set the tone for the company's next stage of business growth. Currently, the company's CNS drugs available in the market include: Seroquel and Seroquel XR, Rivastigmine single-day patches, Fentanyl patches, Buprenorphine patches, etc., covering over 80 countries and regions around the world, including large pharmaceutical markets - China, the U.S., Europe and Japan, as well as fast growing emerging markets. Furthermore, the company has a number of other pipeline projects covering the CNS area for the concurrent development of Chinese and overseas markets, with projects such as Rotigotine extended-release microspheres (LY03003), Anshufacine Hydrochloride extended-release tablets (LY03005), Paliperidone Palmitate injectable suspension (LY03010), and Rivastigmine multi-day patch (LY30410). The company expects to bring more quality and innovative drugs to patients around the world.

Liu Dianbo, Chairman of Luye Pharma Group commented, "We will work tirelessly to accelerate the launch of Rykindo in the U.S. and China, and to speed up the registration process for new drugs in the NDA preparation phase, phase III and critical clinical stages. We look forward to bringing more high-quality and innovative drugs to global patients in need!"