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Luye Pharma's Rykindo® gets US FDA approval

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Rykindo® is an extended-release microsphere independently developed by Luye Pharma

Luye Pharma Group has announced submission of a new drug application (NDA) to the U.S. Food and Drug Administration ("FDA") 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.