

Luye files FDA NDA for China-developed Rykindo

By Elise Mak, Staff Writer

Chinese drugmaker Luye Pharma Group Ltd. said it filed an NDA submission to the U.S. FDA for Rykindo, its novel risperidone extended-release microsphere for injection, to treat schizophrenia and bipolar disorder. It could become the first innovative drug developed by China to get marketing clearance in the U.S.

“This is the first NDA submission of a new formulation drug to the U.S. FDA by a Chinese pharmaceutical company,” Sammy Jiang, vice-president of strategy and business development at Luye, told *BioWorld*. “To date, only a few Korea-made innovative drugs and a Taiwan-developed HIV therapy drug have scored the FDA approval, but none from mainland China,” she added.

The announcement sent Luye’s share price (HKG:2186) from HK\$6 (US\$0.764) on Thursday to HK\$6.86 (US\$0.874) on Friday in Hong Kong. And on Monday, the stock rose 3.9 percent to HK\$7.13.

“We expect the FDA approval to come in March next year, and we plan to submit an NDA to the Chinese drug regulators in the second half of this year,” said Youxin Li, president of global R&D at Luye Pharma, at the annual results presentation in Hong Kong.

The firm is ready to launch Rykindo worldwide and is now seeking more approvals in Europe and other emerging markets.

Developed solely by Luye, Rykindo is derived from the company’s in-house long-acting and extended-release technology R&D platform. Luye calls the NDA submission for Rykindo “a milestone step” and expects a payoff from the potential industrialization of that R&D platform.

Rykindo is believed to be superior to the current antipsychotic drugs that are taken orally. It is an injection given only once every two weeks, which could improve compliance in patients and simplify the treatment regimen.

Patients also do not need to take an oral formulation in three weeks after the first injection of Rykindo. Compared to the reference product, the steady plasma drug level can also be reached much faster with Rykindo.

The dosages of Rykindo to be marketed would be 12.5 mg, 25 mg, 37.5 mg and 50 mg of risperidone per vial.

To expedite the NDA process, Luye submitted its application via the 505(b)(2) pathway. And in February 2018, the FDA agreed to waive pediatric clinical trials, after Luye filed a request for a full waiver based on the prevalence of pediatric schizophrenia in the relevant international databases.

To support the recent NDA submission, Luye combined results from one pivotal study and two supportive clinical studies, with

a sample size of 172 subjects.

The pivotal study demonstrated no lag period after the first injection and an equivalent pharmacokinetic profile of Rykindo at steady state compared to Johnson & Johnson’s long-acting injectable risperidone, Risperdal Consta. All three studies also showed similar safety profiles between Rykindo and Risperdal Consta.

The target group for Rykindo is huge, Luye noted. The World Health Organization estimates that schizophrenia affects more than 21 million people worldwide, with one in every two patients lacking access to treatment.

After the patent of Risperdal Consta expires in December 2020, Luye said it expects that biosimilars to the drug will come onto the market and that Rykindo will be a competitive player in the space given its advantages over the originator drug.

Jiang revealed that Luye is considering two ways to commercialize Rykindo in the U.S.

“Either we seek potential local partners to bring the drug to the market, or we reach out to a contract sales organization to market it for us,” she explained.

Luye expects Rykindo to generate sales revenue of \$280 million in 2024 in the U.S. and five European markets. In China, the drug could bring ¥1 billion (US\$149 million) in 2015 and ¥1.6 billion in 2030.

The central nervous system (CNS) is one of Luye’s focus areas.

Besides Rykindo to treat schizophrenia and bipolar disorder, Luye also has in its pipeline rotigotine extended-release microspheres (LY-03003) for Parkinson’s disease; anshufacine hydrochloride extended-release tablets (LY-03005) for depression; and paliperidone palmitate injectable suspension (LY-03010) and rivastigmine multiday patch (LY-30410) for schizophrenia and schizoaffective disorders.

Last year, the drugmaker acquired the rights to Astrazeneca plc’s antipsychotics Seroquel (quetiapine fumarate) and Seroquel XR for \$546 million to enrich its CNS product portfolio. The deal comes with technologies and established sales networks in 51 countries and regions. (See *BioWorld*, May 9, 2018.)

Currently, Luye has marketed its CNS drugs in more than 80 countries and regions. They include Seroquel and Seroquel XR, rivastigmine single-day patches, fentanyl patches and buprenorphine patches. As for its pipeline, the firm also has two more drug candidates in phase III trials in the U.S. and five in phase III studies in China. It also has obtained IND approvals for five assets. ♦