

Luye Pharma's innovative drug enters final stage of NDA Process

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Luye Pharma Group, an international pharmaceutical company dedicated to the R&D, manufacturing and sale of innovative medications, today announced that it has entered the final stage of New Drug Application (NDA) submissions for the innovative drug, Risperidone Extended Release Microspheres for Injection (LY03004), after previous positive pre-NDA meeting with the U.S. Food and Drug Administration (FDA) and subsequent related procedures.

Luye Pharma had previously requested an NDA number for LY03004 and received a Pre-Assigned NDA application number (212849) from the FDA in 2018. The submission dossier for LY03004 is completed and being published in the eCTD format according to FDA requirements.

Luye Pharma successfully reached an agreement with the FDA to waive all pediatric clinical studies of LY03004 and obtained FDA's approval of using Rykindo® as LY03004's brand name for the treatment of Schizophrenia or Schizoaffective Disorder.

A senior managing representative at Luye Pharma Group commented: "We have been working diligently on the submission packages, assembling the regulatory, clinical, nonclinical, and most recently, CMC components of LY03004, and plan to submit the formal NDA soon. We expect LY03004 will be launched in the U.S. and China markets by the end of 2019."

In addition to LY03004, Luye Pharma has numerous pipeline projects targeting the central nervous system therapeutic area, for development both in the U.S and European markets, with projects such as Rotigotine extended-release microspheres for injection (LY03003) for Parkinson's disease, Ansifaxine Hydrochloride extended-release tablets (LY03005) for anti-depression, Rivastigmine multi-day transdermal patch (30410) for mild to moderate Alzheimer's disease, and Paliperidone Palmitate injectable suspension for intramuscular use (LY03010). Moreover, registration of Rivastigmine single-day transdermal patch has already been accepted by National Medicine Products Administration in China.

The registrations of the above products are progressing well in strategic markets such as China, the U.S., Europe and Japan, expecting to launch in these countries and further expand into the global market.

