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ASIA EDITION

Luye Pharma receives China approval for CNS drug

July 23, 2018 | News

Luye Pharma acquired the rights for Seroquel (Quetiapine Fumarate) and Seroquel XR from AstraZeneca in 51 countries and regions, including China, with the acquisition finalized in June 2018.



Luye Pharma Group has announced that its Central Nervous System (CNS) drug, Seroquel XR (Quetiapine Fumarate XR), has received approval from the official Chinese medical authorities for a new indication in the treatment of depression arising from bipolar disorder. The approval of this new indication will not only help to benefit a great number of people living with mental illness, but will also boost sales of the drug.

Seroquel XR is an atypical antipsychotic (APP) drug with anti-depressant properties. It is mainly used for the treatment of schizophrenia and bipolar disorder, and is approved in some markets for the treatment of depression and generalized anxiety disorder. The drug has been marketed in more than 80 countries and regions around the world and is widely recognized by doctors and patients. In the first half of this year, Luye Pharma acquired the rights for Seroquel (Quetiapine Fumarate) and Seroquel XR from AstraZeneca in 51 countries and regions, including China, with the acquisition finalized in June 2018.

CNS is one of Luye Pharma's four core therapeutic areas. Apart from marketed products, several other CNS products are being concurrently developed in China and overseas markets. Risperidone Extended Release Microspheres (LY03004) for the treatment of schizophrenia and bipolar disorder has reached the NDA (new drug application) stage in the United States and China. Rotigotine Extended Release Microspheres (LY03003) indicated for Parkinson's disease and Ansofaxine Hydrochloride Extended Release Tablet (LY03005) indicated for depression have begun Phase III clinical trials. Multi-day Rivastigmine Transdermal Patches for the treatment of mild to moderate Alzheimer's disease has also entered into a key stage of clinical trials. Other new drug development projects such as LY03012, an investigational drug for analgesia, are also in progress.