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Luye Pharma seeks USFDA approval for antidepressant drug

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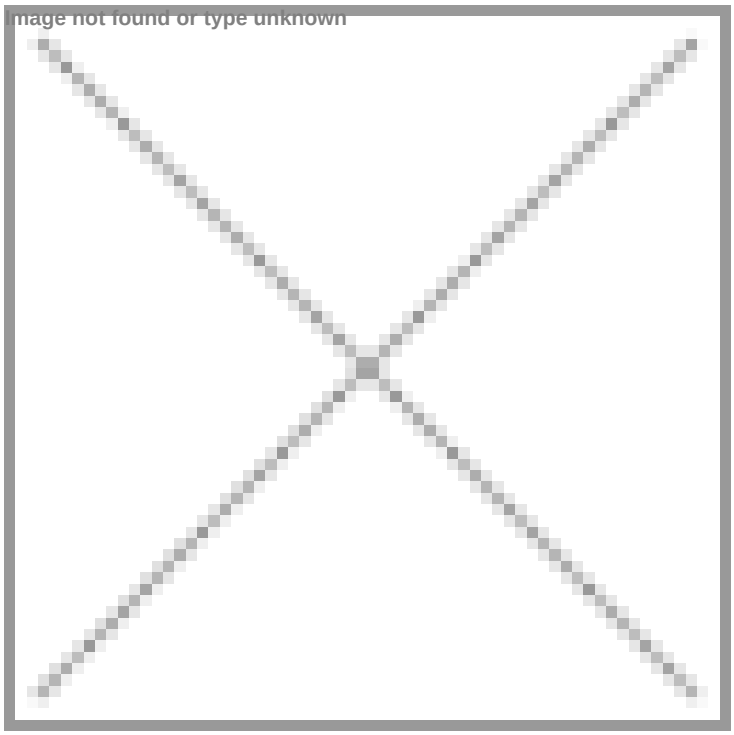
Luye Pharma Submits New Drug Application in the U.S. for Its Antidepressant Drug LY03005



China based Luye Pharma Group has announced submission of a new drug application (NDA) to the U.S. Food and Drug Administration (FDA) for LY03005, a new chemical drug for the treatment of major depressive disorder. It is also the second U.S. FDA NDA submission in the central nervous system (CNS) filed by the company.

The application was based on the consensus reached with the FDA under End-Of-Phase 2-CMC (EOP2-CMC) meeting and Pre-NDA (PNDA) meeting. LY03005 is an exclusive CNS product developed under Luye Pharma's new chemical/therapeutic entities (NCE/NTE) R&D platform. It is a serotonin-norepinephrine-dopamine triple reuptake inhibitor (SNDRI), and one of the active metabolites is a serotonin-norepinephrine reuptake inhibitor (SNRI).

Depression is one of the most common CNS diseases, with more than 300 million patients around the world. It is the leading cause of disability worldwide and a major contributor to the overall global burden of disease. Today, fewer than 50% of patients are receiving effective treatment, with rates of effective treatment in many countries lower than 10%.

Patients using traditional anti-depressants such as selective serotonin reuptake inhibitors (SSRIs) and serotonin-norepinephrine reuptake inhibitors (SNRIs) typically have certain drawbacks such as anhedonia, sexual dysfunction and inability to improve cognitive impairment, etc. Compared to traditional anti-depressants, SNDRI is expected to help preserve patients' sexual function and produce a more rapid onset with higher efficacy.

Luye Pharma has obtained patents covering the chemical compound, crystal form and formulation of LY03005. The patents in relation to the chemical compound and crystal form have been granted in target markets such as China, United States, Europe, Japan and Korea.

"The global patient population affected by CNS diseases is large and growing, with serious distress caused by these diseases greatly affecting both patients and their families. We look forward to bringing more high-quality and innovative drugs to global patients in need, addressing their unmet medical needs", said a senior management representative from Luye Pharma Group.

Luye Phama is currently increasing investment to accelerate the development of new drugs in this therapeutic area. Several investigational drugs are in the NDA or late clinical trial stage, and are expected to be launched in major global markets staring from 2020. In addition to LY03005, the NDA submission for LY03004 for the treatment of schizophrenia and bipolar disorder was filed in the U.S. this March, with its manufacturing facility already having passed the FDA's Pre-Approval Inspection (PAI). Other R&D projects include LY03003 for Parkinson's disease, LY03010 for schizophrenia and schizoaffective disorder, LY30410 for mild to moderate Alzheimer's disease and LY03012 for chronic pain, among others.

These investigational drugs will leverage Luye Pharma's global supply chain and market channels in more than 80 countries and regions, forming a competitive product portfolio along with existing products, together achieving synergy and accelerating the execution of the company's global strategic plans for the CNS therapeutic field.