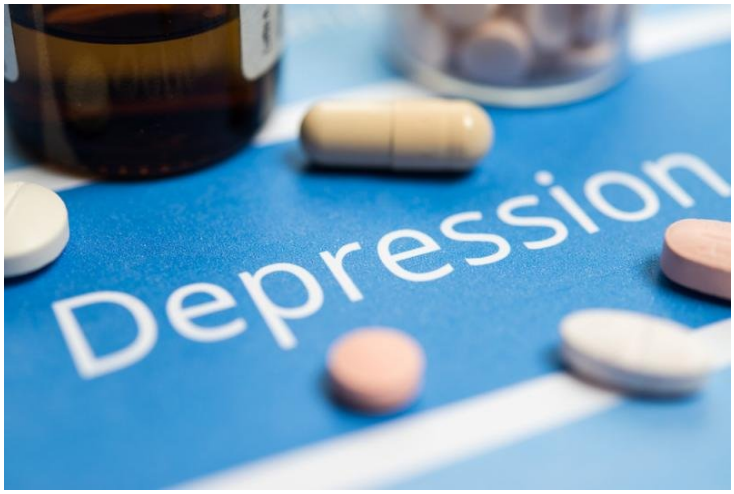
BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Luye Pharma's anti-depression drug to start clinical trials in Japan

22 August 2019 | News

Submits a clinical trial application for Ansofaxine Hydrochloride Extended-Release Tablets (LY03005) for the treatment of depression



Luye Pharma Group has announced its submission of the clinical trials application for a new chemical drug, Ansofaxine Hydrochloride Extended-Release Tablets (LY03005) for the treatment of depression in Japan, with the trials expected to begin soon. Meanwhile, phase III clinical trials for LY03005 in China and a pivotal study conducted in the U.S. are both progressing smoothly.

LY03005 is one of Luye Pharma's key products in the central nervous system (CNS) therapeutic area, developed by the company's New Compounds R&D platform. It is a serotonin-norepinephrine-dopamine triple reuptake inhibitor (SNDRI) in extended-release tablet form. Luye Pharma plans to register and launch LY03005 in the U.S., Japan, China, Europe and other markets.

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. In Japan, the number of patients with mental illness has been growing in recent years, among which the growth of those with depression is particularly obvious. Driven by demand for medication, sales of anti-depressants by Japan's National Health Insurance (NHI) increased by a compound annual growth rate of 4.9% between 2015 and 2017, totalling approximately JPY 158.6 billion (approximately USD 1.44 billion) in 2017.

Traditional anti-depressants such as selective serotonin reuptake inhibitors (SSRIs) and serotoninnorepinephrine reuptake inhibitors (SNRIs) typically have certain drawbacks such as anhedonia, sexual dysfunction and inability to improve cognitive impairment, etc. Compared to traditional anti-depressants, LY03005 is expected to help preserve patients' sexual function, have a better safety profile and produce a more rapid onset with higher efficacy, thus providing improved options for the clinical treatment for patients.

Luye Pharma has obtained patents covering the chemical compound, crystal form and formulation of extended-release tablets. The patents for the chemical compound and crystal form have been obtained in the target countries such as China, the U.S., Europe, Japan, South Korea, and others.

The central nervous system therapeutic area which LY03005 was developed for is considered one of Luye Pharma's four core therapeutic areas for long-term development. Luye Pharma's strategic approach in this treatment area will set the tone for the company's next stage of business growth. The company has a number of pipeline products in the CNS therapeutic area being concurrently developed for the Chinese and overseas markets. In addition to LY03005, Rotigotine Extended Release Microspheres for injection (LY03003) for Parkinson's disease has entered phase I clinical trials in Japan, as well as phase III clinical trials in China and the U.S. The NDA for Risperidone Extended Release Microspheres for injection (LY03004) for schizophrenia and bipolar disorder has been filed in the U.S., while other new drug development projects such as Paliperidone Palmitate injectable suspension (LY03010) for schizophrenia and schizoaffective disorder and Rivastigmine Multi-day Transdermal Patch (LY30410) for mild to moderate Alzheimer's disease are also in progress.

A representative from senior management at Luye Pharma Group said, "We are very optimistic about the prospects of these drugs. In the future, we will continue to increase investment to accelerate the launch of these products in the major strategic markets including China, the U.S, Japan, Europe and other markets, helping even more patients globally. We are highly confident in the development prospects of our CNS product pipeline."

Luye Pharma Group has announced its submission of the clinical trials application for a new chemical drug, Ansofaxine Hydrochloride Extended-Release Tablets (LY03005) for the treatment of depression in Japan, with the trials expected to begin soon. Meanwhile, phase III clinical trials for LY03005 in China and a pivotal study conducted in the U.S. are both progressing smoothly.

LY03005 is one of Luye Pharma's key products in the central nervous system (CNS) therapeutic area, developed by the company's New Compounds R&D platform. It is a serotonin-norepinephrine-dopamine triple reuptake inhibitor (SNDRI) in extended-release tablet form. Luye Pharma plans to register and launch LY03005 in the U.S., Japan, China, Europe and other markets.

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. In Japan, the number of patients with mental illness has been growing in recent years, among which the growth of those with depression is particularly obvious. Driven by demand for medication, sales of anti-depressants by Japan's National Health Insurance (NHI) increased by a compound annual growth rate of 4.9% between 2015 and 2017, totalling approximately JPY 158.6 billion (approximately USD 1.44 billion) in 2017.

Traditional anti-depressants such as selective serotonin reuptake inhibitors (SSRIs) and serotoninnorepinephrine reuptake inhibitors (SNRIs) typically have certain drawbacks such as anhedonia, sexual dysfunction and inability to improve cognitive impairment, etc. Compared to traditional anti-depressants, LY03005 is expected to help preserve patients' sexual function, have a better safety profile and produce a more rapid onset with higher efficacy, thus providing improved options for the clinical treatment for patients.

Luye Pharma has obtained patents covering the chemical compound, crystal form and formulation of extended-release tablets. The patents for the chemical compound and crystal form have been obtained in the target countries such as China, the U.S., Europe, Japan, South Korea, and others.

The central nervous system therapeutic area which LY03005 was developed for is considered one of Luye Pharma's four core therapeutic areas for long-term development. Luye Pharma's strategic approach in this treatment area will set the tone for the company's next stage of business growth. The company has a number of pipeline products in the CNS therapeutic area being concurrently developed for the Chinese and overseas markets. In addition to LY03005, Rotigotine Extended Release Microspheres for injection (LY03003) for Parkinson's disease has entered phase I clinical trials in Japan, as well as phase III clinical trials in China and the U.S. The NDA for Risperidone Extended Release Microspheres for injection (LY03004) for schizophrenia and bipolar disorder has been filed in the U.S., while other new drug development projects such as Paliperidone Palmitate injectable suspension (LY03010) for schizophrenia and schizoaffective disorder and Rivastigmine Multi-day Transdermal Patch (LY30410) for mild to moderate Alzheimer's disease are also in progress.

A representative from senior management at Luye Pharma Group said, "We are very optimistic about the prospects of these drugs. In the future, we will continue to increase investment to accelerate the launch of these products in the major strategic markets including China, the U.S, Japan, Europe and other markets, helping even more patients globally. We are highly confident in the development prospects of our CNS product pipeline."