

Kyowa Kirin Announces FDA Acceptance of Istradefylline (KW-6002) New Drug Application Resubmission in the US

Tokyo, Japan, April 4, 2019 --- Kyowa Hakko Kirin Co., Ltd. (Tokyo: 4151, President and CEO: Masashi Miyamoto, "Kyowa Kirin") announced that the U.S. Food and Drug Administration (FDA) has accepted for review the resubmitted New Drug Application (NDA) for istradefylline (KW-6002), an investigational selective adenosine A_{2A} receptor antagonist, for use as adjunctive treatment to levodopa/carbidopa in adult patients with Parkinson's disease (PD) experiencing "OFF" episodes.

The target Prescription Drug User Fee Act (PDUFA) action date for a decision by the FDA is in August 27, 2019. The submission is based on findings from randomized, multi-center, double-blind, placebo-controlled trials in patients with PD taking a stable dose of levodopa/carbidopa with or without other PD medications.

"People living with Parkinson's Disease have difficulty moving that often worsens during 'off' periods, and there is a significant need for new treatments", said Jeffrey S. Humphrey, M.D., President and Chief Medical Officer of Kyowa Kirin Pharmaceutical Development. "We are excited by the possibility of bringing a new medicine to people living with Parkinson's Disease and look forward to working closely with FDA during the review process."

"Istradefylline, is an A_{2A} receptor antagonist, and if approved by FDA, may provide a novel non-dopaminergic pharmacologic approach to treating OFF episodes for people living with PD." said Dr. Stuart Isaacson, MD, Parkinson's Disease and Movement Disorders Center of Boca Raton, Florida.

The Kyowa Hakko Kirin Group companies strive to contribute to the health and well-being of people around the world by creating new value through the pursuit of advances in life sciences and technologies.

About Kyowa Kirin

Kyowa Hakko Kirin Co., Ltd. is a research-based life sciences company, with special strengths in biotechnologies. In the core therapeutic areas of oncology, nephrology and immunology/allergy, Kyowa Hakko Kirin leverages leading-edge biotechnologies centered on antibody technologies, to continually discover innovative new drugs and to develop and market those drugs world-wide. In this way, the company is working to realize its vision of becoming a Japan-based global specialty pharmaceutical company that contributes to the health and wellbeing of people around the world.

You can learn more about the business at: www.kyowa-kirin.com.

About Istradefylline

Istradefylline is an orally administered, selective adenosine A_{2A} receptor antagonist indicated in Japan for the improvement of the "wearing-off" phenomenon in patients with Parkinson's disease on levodopa-containing preparations and has been marketed in Japan under the brand name NOURIAST® since May 30, 2013. Istradefylline has no approved indication in the US.

About Parkinson's disease

Parkinson's disease is a progressive, neurodegenerative disease characterized by motor symptoms such as tremors, rigidity, slow movement and postural instability. It is thought to be caused by progressive degeneration associated with decreased levels of dopamine in certain parts of the brain,

i.e., the substantia nigra and striatum.

About adenosine A_{2A} receptor

Adenosine is a neuromodulator that is widely distributed in the human body and adenosine A_{2A} receptors are G protein-coupled receptors. In the brain, adenosine A_{2A} receptors are found in the basal ganglia, where degeneration or abnormality is noted in Parkinson's disease. The basal ganglia are known to play an important role in motor control.