

News release

Kyowa Kirin Announces Positive Phase 2b Results for KW-6356 in Patients with Parkinson's Disease

TOKYO, Japan, October 21, 2020 -Kyowa Kirin Co., Ltd. (TSE: 4151, President and CEO: Masashi Miyamoto, "Kyowa Kirin") announces today that the phase 2b study of KW-6356 in patients with Parkinson's disease on treatment with levodopa-containing preparations has met the primary endpoint.

The study was a multicenter, randomized, double-blind and placebo-controlled clinical trial in Japan to investigate the efficacy of KW-6356 in 502 patients with Parkinson's disease on treatment with levodopa-containing preparations.

The primary endpoint was the change from baseline in movement disorder society-unified Parkinson's disease rating scale (MDS-UPDRS) part III (motor symptoms) score between KW-6356 and placebo over 26 weeks of administration. The study result met its primary endpoint as the change in the KW-6356 group was greater than in the placebo group with a statistically significant difference. No major safety issues were observed in any of the groups.

"The positive results mark another great milestone for the development of KW-6356," said Yoshifumi Torii, Ph.D., Executive Officer, Vice President, Head of R&D Division of Kyowa Kirin. "We will keep working to prove KW-6356's potential and to provide a more valuable solution for patients with Parkinson's disease."

The results of the study are planned to be presented in detail through future academic conferences or publications.

The Kyowa 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 KW-6356

KW-6356 is a selective antagonist of adenosine A_{2A} receptors developed by Kyowa Kirin. Adenosine A_{2A} receptors are a type of receptor for adenosine, a substance found in the body. They are distributed across the basal ganglia, where the functional focus of PD is located, and are thought to be involved in the

regulation of motor functions. KW-6356 has a high affinity and selectivity for adenosine A_{2A} receptors, and is therefore expected to obtain approval for wider indications as the next generation of Istradefylline, which was launched in the United States (brand name: NOURIANZ[®]) and Japan (brand name: NOURIAST[®]) by Kyowa Kirin.

About Parkinson's disease

Parkinson's disease is a progressive, neurodegenerative disease characterized by motor symptoms such as tremors, rigidity, slow movement, and abnormal postural reflexes. 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.

MDS-UPDRS

The MDS-UPDRS (Movement Disorder Society-Unified Parkinson's Disease Rating Scale) consists of four evaluation categories. Part I describes non-motor symptoms experienced during daily life (13 items); part II describes motor symptoms experienced during daily life (13 items); part 3 pertains to the examination of motor symptoms (18 items); and part IV pertains to motor-symptom complications (6 items). Each question is answered based on a five-level score from 0 to 4, where 0 represents "normal", 1 represents "slight", 2 represents "mild", 3 represents "moderate", and 4 represents "severe".