News release

Kyowa Kirin Announces Marketing Authorisation Application for Istradefylline Validated by European Medicines Agency

Tokyo, Japan, January 6th , 2020 -- Kyowa Kirin Co., Ltd. (TSE: 4151 President and CEO: Masashi Miyamoto, "Kyowa Kirin") today announces that its marketing authorisation application (MAA) for istradefylline (KW-6002) as an adjunctive treatment to levodopa-based regimens in adult patients with Parkinson's disease (PD) experiencing "OFF" time, has been validated by the European Medicines Agency (EMA) and is now under review.

This MAA is based on findings from randomised, multi-national, including EU, US and Japan double-blind, placebo-controlled trials in patients with PD taking a stable dose of levodopa-based regimens with or without other PD medications.

"Parkinson's disease is the fastest growing neurological disorder in the world in terms of prevalence, disability and deaths[1]," said Abdul Mullick, President, Kyowa Kirin International (Europe, Middle East and Africa (EMEA)). "There is significant need for new treatments for this debilitating condition. We are very excited about the possibility of bringing a new medicine to patients that works in a different way from current therapies. We look forward to working with the EMA during the review process."

"I welcome the news of this validation, enabling the EMA to begin the review process," said Tomohiro Sudo, Head of Global Product Management Office, Kyowa Kirin, "We are committed to providing this innovative medicine as a new treatment option for Parkinson's disease patients who need more treatments to improve their situation. We will keep making our best efforts to improve the lives of patients in the European Union."

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 Kyowa Kirin

Kyowa Kirin commits to innovative drug discovery driven by state-of-the-art technologies. Kyowa Kirin focuses on creating new values in the four therapeutic areas: nephrology, oncology, immunology/allergy and neurology. Under the Kyowa Kirin brand, the employees from 36 group companies across North America, Europe and Asia/Oceania unite to champion the interests of patients and their caregivers in discovering solutions wherever there are unmet medical needs.

You can learn more about the business of Kyowa Kirin at https://www.kyowakirin.com

About istradefylline

Istradefylline is an orally administered, selective adenosine A_{2A} receptor antagonist. Istradefylline was approved in Japan (product name: NOURIAST®) in March 2013 for improving the "wearing-off" phenomenon in patients with Parkinson's disease on levodopa-containing preparations. Istradefylline was also approved in the US (product name: NOURIANZ™) in August 2019 for use as adjunctive treatment to levodopa/carbidopa in adult patients with Parkinson's disease experiencing "off" episodes.

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.

[1] [GBD 2016 Parkinson's Disease Collaborator Group. Lancet Neurol 2018; 17: 939 - 953]

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