News release

Kyowa Kirin Provides Update on Application for Marketing Authorisation of Istradefylline in Europe for the Treatment of 'OFF' Episodes in People Living with Parkinson's

TOKYO, Japan, 26 July, 2021 – Kyowa Kirin Co., Ltd. (TSE:4151, President and CEO: Masashi Miyamoto, "Kyowa Kirin") today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) issued a negative opinion for istradefylline as an add-on treatment to levodopa (L-Dopa) based regimens in adults living with Parkinson's, experiencing end-of-dose motor fluctuations. Kyowa Kirin International remain committed to istradefylline and people living with Parkinson's and are currently reviewing the options available, which may include re-examination.

"We are disappointed by the CHMP opinion. However, we remain confident in the benefit-risk profile of istradefylline and are committed to making a difference to the lives of people living with Parkinson's, an area which has had few innovative therapies for decades," said Abdul Mullick, President of Kyowa Kirin International. "There are currently few new treatment options available to manage end-of-dose motor fluctuations in Parkinson's, and we believe that istradefylline offers people living with the condition a chance to regain some control over the management of their 'OFF' time. We remain committed to pursuing the registration of istradefylline in the EU."

"Parkinson's is a complex condition that affects every person living with it differently and is characterised by a broad range of symptoms that can significantly impact their quality of life," said Professor Heinz Reichmann, Professor and Chair of the Neurology Department at the University of Dresden. "There is currently an urgent need for innovative treatments such as istradefylline for people living with Parkinson's, to support them and their families in reducing their 'OFF' time. I hope that the CHMP will reconsider their position on istradefylline."

"First of all, I would like to appreciate those who have contributed to the development of istradefylline." Said Tomohiro Sudo, Executive Officer, Head of Global Product Strategy Department at Kyowa Kirin. "Although unfortunately it is a negative opinion from the CHMP this time, we will continue to think of how we can contribute to people living with Parkinson's and their families as we do in the US and Japan."

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 istradefylline

Istradefylline is a novel, first-in-class non-dopaminergic, adenosine A_{2A} receptor antagonist that reduces 'OFF' time in people living with Parkinson's through selective targeting of adenosine A_{2A} receptors in the basal ganglia. Whilst dopaminergic treatment targets the dopamine receptors in the direct and indirect pathways to facilitate movement, istradefylline, as an add-on to L-Dopa, reduces the activity of the indirect pathway which suppresses movement. Therefore, it helps restore the balance within the basal ganglia.[1,2]

Istradefylline has been approved for use in Japan by the Ministry of Health, Labour and Welfare since 2013, under the brand name of NOURIAST®. In August 2019 It also received approval from the U.S. Food and Drug Administration (FDA) as adjunctive treatment to levodopa / carbidopa in adult patients with Parkinson's experiencing "OFF" episodes and is marketed under the name of NOURIANZ®.[3,4]

About Parkinson's and 'OFF' episodes

Parkinson's is a chronic, progressive neurodegenerative condition that affects small regions in the brain that control movement, balance and posture.[5] It is the fastest growing neurodegenerative disorder in the world,[6] with an estimated 10 million people in the world currently living with the condition.[7] Although it is classically characterised by motor symptoms (symptoms involving movement), people living with Parkinson's also experience a large range of non-motor symptoms, which add to the complexity of living with the condition.[5] Although Parkinson's is not life threatening there is currently no cure. Over time symptoms progress and can be unpredictable, imposing a significant impact on daily life.[5] This impact can extend to caregivers, friends and family, whose own wellbeing and quality of life can deteriorate as a result.[8]

'OFF' episodes is used to describe the return of Parkinson's symptoms, also known as 'OFF' symptoms, and can be triggered by a variety of phenomena, including:[9]

- Delayed onset of response to medication
- Reduced duration of benefit from a medication
- Reduced or no efficacy of a dose of medication

About Kyowa Kirin International in neurology

Kyowa Kirin International is committed to building meaningful partnerships with the wider Parkinson's community and is working with healthcare professionals, government agencies, policymakers and patient advocacy groups to improve care and support for people living with Parkinson's.

About Kyowa Kirin

Kyowa Kirin strives to create and deliver novel medicines with life-changing value. As a Japan-based Global

Specialty Pharmaceutical Company with a more than 70-year heritage, we apply cutting-edge science including an expertise in antibody research and engineering, to address the needs of patients and society across multiple therapeutic areas including Nephrology, Oncology, Immunology/Allergy and Neurology. Across our four regions – Japan, Asia Pacific, North America and EMEA/International – we focus on our purpose, to make people smile, and are united by our shared values of commitment to life, teamwork/Wa, innovation, and integrity. You can learn more about the business of Kyowa Kirin at: https://www.kyowakirin.com/.

Kyowa Kirin International is a subsidiary of Kyowa Kirin Co., Ltd.

References

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