

June 27, 2023

UCB Japan Submitted Additional Application of Fintepla® (fenfluramine) in Japan for the Treatment of Seizures Associated with Lennox-Gastaut Syndrome

Kyoto, Japan, June 27, 2023 - Nippon Shinyaku Co., Ltd. (Nippon Shinyaku; Headquarters, Kyoto; President, Toru Nakai) announced today that UCB Japan Co. Ltd. (UCB Japan; Headquarters: Tokyo; President, Kanako Kikuchi) submitted additional application of Fintepla® Oral Solution 2.2mg/mL (generic name; fenfluramine hydrochloride) for the treatment of seizures in patients with Lennox-Gastaut syndrome (LGS) to the Ministry of Health, Labour and Welfare (MHLW) in Japan.

Nippon Shinyaku entered into an exclusive distribution agreement in Japan for Fintepla® with Zogenix Inc. (acquired by UCB in 2022) as of March 18, 2019. Nippon Shinyaku will be marketing Fintepla® based on this agreement after UCB Japan obtains approval from MHLW. In addition, Nippon Shinyaku has been marketing Fintepla® as a treatment for epileptic seizures associated with Dravet syndrome (DS) since November 2022 in Japan.

LGS is a severe form of intractable epilepsy that develops in infancy and childhood. It is also a serious disease presenting with a variety of treatment-resistant seizures, mental developmental disorders, and movement disorders. The main types of seizures of LGS are tonic seizure, atypical absence seizure, and atonic seizure. Among them, atonic seizure is a dangerous seizure in which muscle tone is momentarily lost, leading to head or other injuries due to a fall. LGS has been designated as an intractable disease by MHLW, and there are estimated to be about 4,300 patients living with LGS in Japan.

Fintepla® possesses dual activities to inhibit seizures: acting as 5-HT (serotonin) releaser with agonist activity at several 5-HT receptors, and as a positive modulator of Sigma-1 receptor. Fintepla® was designated as an orphan drug by MHLW for the indication of DS and LGS. Fintepla® is approved in the U.S. and Europe for the treatment of seizures associated with DS and LGS in patients two years of age and older.

Nippon Shinyaku is focusing on the field of intractable, rare disorders. We hope that Fintepla® will become a new treatment option for LGS in Japan.

About Nippon Shinyaku

Based on Nippon Shinyaku's business philosophy, "Helping people lead healthier, happier lives," we aim to be an organization trusted by the community through creating unique medicines that will bring hope to patients and families suffering from illness. Please visit our website (<https://www.nippon-shinyaku.co.jp/english/>) for products or detailed information.

About UCB Japan

UCB Japan (<https://www.ucbjapan.com/>) was established in 1988 as the Japanese subsidiary of UCB, a global biopharmaceutical company headquartered in Brussels, Belgium. The company is developing its pharmaceutical business with a focus on anti-epileptic drugs, rheumatoid arthritis and psoriasis drugs. As a biopharmaceutical leader in creating value for patients, the company aims to provide new treatment options for patients who have not achieved satisfactory improvement with conventional therapies.

Contact

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