NEWS RELEASE

NIPPON SHINYAKU CO., LTD.

September 26, 2022

Fintepla® (fenfluramine) Approved in Japan for the Treatment of Seizures Associated with Dravet syndrome

Kyoto, Japan, September 26, 2022 - 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) has obtained marketing approval from the Ministry of Health, Labour and Welfare (MHLW), for Fintepla® Oral Solution 2.2 mg/mL (ZX008; fenfluramine hydrochloride) for the treatment of seizures in patients with Dravet syndrome (DS) in Japan.

Fintepla® will be marketed by Nippon Shinyaku based on the exclusive distribution agreement signed in 2019 between Zogenix, Inc. (acquired by UCB S.A. in 2022) and Nippon Shinyaku, with UCB Japan taking responsibility as the manufacturer and distributor.

DS is a rare, devastating and life-long form of epilepsy that generally begins in infancy or early childhood and is marked by frequent treatment-resistant seizures, frequent resulting hospitalizations and medical emergencies, significant developmental and motor and behavioral impairments. In Japan, DS has been designated as an intractable disease by MHLW, and there are estimated to be about 3,000 patients living with DS in Japan, based on MHLW Patient Survey.

Fintepla® possesses dual activities to inhibit seizures: acting as a potent 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 Dravet syndrome in August, 2021.
Fintepla® is approved in the U.S. and Europe for the treatment of seizures associated with DS in patients two years of age and older. In the U.S., an additional indication of Fintepla® for the treatment of seizures associated with Lennox-Gastaut syndrome in patients two years of age and older was approved in March, 2022.

Nippon Shinyaku is focusing on the field of intractable, rare disorders. We hope that Fintepla® will contribute to the treatment for patients suffering from DS in Japan.

【Indications】

The treatment of seizures associated with Dravet syndrome as an add-on therapy to anti-epileptic medicines for the patients whose seizures are not controlled by other anti-epileptic medicines.

【Usage and Dosage】

1. Concomitant use with stiripentol

   The usual oral dosage of fenfluramine for adults and children 2 years of age and older is 0.2 mg/kg daily in two divided doses. The dosage may be increased or decreased according to symptoms to a daily dose not exceeding 0.4 mg/kg, but the dosage should be increased after an interval of at least one week. The daily dose should not exceed 17 mg.

2. Without concomitant use of stiripentol:

   The usual oral dosage of fenfluramine for adults and children 2 years of age and older is 0.2 mg/kg daily in two divided doses. The dosage may be increased or decreased according to symptoms to a daily dose not exceeding 0.7 mg/kg, but the dosage should be increased after an interval of at least one week. The daily dose should not exceed 26 mg.

About Nippon Shinyaku

Our mission is to help people lead healthier and happier lives. Through creating unique medicines that will bring hope to patients and families struggling with illness, we aim to be an organization trusted by the community. Please visit our website (https://www.nippon-shinyaku.co.jp/english/index.php) for products or detailed information.

About UCB Japan

UCB Japan (https://www.ucbjapan.com/) was established in 1988 as the Japanese subsidiary of UCB S.A., 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

Corporate Communications Dept., Nippon Shinyaku
FAX: +81-75-321-9128