

NEWS RELEASE



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Zogenix Submission of New Drug Application for ZX008 (Fenfluramine Hydrochloride) in Japan

Kyoto, Japan, December 22, 2021 – Nippon Shinyaku Co., Ltd. (Nippon Shinyaku; Headquarters: Kyoto; President: Toru Nakai) announced that Zogenix, Inc. (Zogenix; Headquarters: CA, U.S.A.; President and CEO: Stephen J. Farr, Ph.D.) has submitted a New Drug Application (NDA) to The Ministry of Health, Labour & Welfare (MHLW) for the marketing approval of ZX008 (fenfluramine hydrochloride) for the treatment of epileptic seizures associated with Dravet syndrome (DS) in Japan.

Nippon Shinyaku entered into an exclusive distribution agreement in Japan for ZX008 for the treatment of DS and Lennox-Gastaut syndrome (LGS) with Zogenix as of March 18, 2019. Zogenix retains responsibility for completing its global clinical development programs for ZX008 in Japan for DS and LGS. If approved in Japan, Nippon Shinyaku will commercialize ZX008 in Japan through the exclusive distribution agreement.

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.

ZX008 is a prescription medication used to treat seizures associated with DS in patients. ZX008 possesses dual activities to inhibit seizures: acting as a potent 5-HT (serotonin) releaser with agonist activity at 5-HT receptors, and as a positive modulator of Sigma-1 receptor. ZX008 is approved in the U.S. and Europe for the treatment of seizures associated with DS.

Nippon Shinyaku is focusing on the field of intractable, rare disorders. We hope that ZX008 will contribute to the treatment for patients suffering from DS in Japan.

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/>) for products or detailed information.

About Zogenix

Zogenix is a global biopharmaceutical company committed to developing and commercializing therapies with the potential to transform the lives of patients and their families living with rare diseases. The company's first rare disease therapy, ZX008, has been approved by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency and is in development in Japan for the treatment of seizures associated with Dravet syndrome, a rare, severe lifelong epilepsy. The U.S. FDA recently accepted for filing Zogenix's supplemental New Drug Application (sNDA) and granted Priority Review for the use of ZX008 for the treatment of seizures associated with an additional rare epilepsy, Lennox-Gastaut syndrome (LGS). For more information, visit www.zogenix.com.