Zogenix Launches Global Access Program for FINTEPLA® (Fenfluramine) Oral Solution

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- *FINTEPLA is approved in the U.S. and European Union as an add-on therapy for the treatment of seizures associated with Dravet syndrome in patients aged two years and older.*
- *The new program supports physician access to FINTEPLA in other parts of the world, where local regulations allow, including European countries where reimbursement has not yet been established.*

EMERYVILLE, Calif., April 27, 2021 (GLOBE NEWSWIRE) -- Zogenix (NASDAQ: ZGNX), a global biopharmaceutical company developing rare disease therapies, today announced the launch of its new global access program for FINTEPLA (fenfluramine) oral solution. FINTEPLA was approved in the U.S. and European Union in 2020 as an add-on therapy for the treatment of seizures associated with a debilitating rare epilepsy called Dravet syndrome in patients aged two years and older. The Zogenix Access Program expands access for physicians in other parts of the world, where local regulations allow, including European countries where reimbursement has not yet been established.

“Three randomized clinical studies have demonstrated FINTEPLA's ability to provide transformational and durable seizure reduction for many Dravet syndrome patients whose seizures were not adequately controlled despite treatment with one or more other anti-epileptic medicines,” said Bradley S. Galer, M.D., Executive Vice President and Chief Medical Officer at Zogenix. “With these results and more than one thousand treated Dravet syndrome patients, physicians in many countries have expressed interest in FINTEPLA for their patients. We are pleased to be able to take this step to support their requests and help more patients in need.”

Zogenix has partnered with Durbin, a part of Uniphar Group’s Product Access Division and a leading specialist in the international distribution of specialized pharmaceuticals, to manage the Zogenix Access Program for FINTEPLA. Durbin has extensive global experience providing, high-quality support while adhering to complex local requirements.

“We are delighted to be working in partnership with Zogenix on this important access program,” said Dan Piggott, Managing Director of Uniphar Group’s Product Access Division. “We look forward to helping facilitate broader access to FINTEPLA for patients with critical unmet medical needs.”

About the Zogenix Access Program
The Zogenix Access Program is for physicians who are interested in treating their patients with FINTEPLA in countries where it is not yet available commercially or through local access schemes. The program does not provide free-of-charge access to FINTEPLA and does not affect patients already taking FINTEPLA as part of a clinical study. Specifics of the program may vary by country based on local regulations.

In the U.S. and Europe, treatment with FINTEPLA is initiated and supervised by physicians with experience in the treatment of epilepsy under a Risk Evaluation Mitigation Strategy (REMS) program (U.S.) or Controlled Access Program (EU). Similarly, access through this program must be requested by the patient’s treating physician. Where local regulations allow, an initial registration process enables the program team to begin working with physicians on treatment and important safeguard planning.

Physicians can learn more about the Zogenix Access Program for FINTEPLA by sending an email inquiry to zogenixaccessprogram@zogenix.com.

About FINTEPLA®
Fintepla is a new treatment option that in clinical studies provided significant, well-tolerated, and lasting seizure reduction to many Dravet syndrome study patients. In 2020, FINTEPLA (fenfluramine) oral solution was approved by the U.S. Food & Drug Administration (FDA) and by the European Commission as an add on therapy to other anti-epileptic medicines for the treatment of seizures associated with Dravet syndrome in patients aged two years and older. In addition, Zogenix recently reported positive results of a third Phase 3 study of FINTEPLA in Dravet syndrome to support planned registration in Japan, a study that corroborated the statistically significant and clinically meaningful convulsive seizure reductions seen in earlier multi-national Phase 3 studies. FINTEPLA is also being studied for the potential treatment of seizures associated with other rare epilepsies.

In the United States, please see important prescribing and safety information at www.Fintepla.com. In Europe, please see important prescribing and safety information at www.Fintepla.eu.

About Dravet Syndrome
Dravet syndrome is a rare, devastating and life-long form of epilepsy that generally begins in infancy and is marked by frequent, treatment-resistant seizures, significant developmental, motor, and behavioral impairments, and an increased risk of sudden unexpected death in epilepsy (SUDEP). Affecting one in 15,700 live births in the U.S. and approximately one in 20,000 to 40,000

live births in Europe, most patients follow a course of developmental delay with cognitive, motor, and behavioral deficits that persist into adulthood. Dravet syndrome severely impacts quality of life for patients, families, and caregivers due to the high physical, emotional, caregiving, and financial burden associated with the disease.

About Durbin
Durbin is a specialist pharmaceutical services provider, distributing critical medications to over 160 different countries. A part of Uniphar Group's Product Access Division, Durbin works in partnership with global pharmaceutical and biotech companies to provide Early Access Programs (EAPs), including Named Patient Supply and Cohort Programs. The company has over 25 years' experience designing and implementing EAPs from concept and specializes in developing robust and compliant voluntary data collection initiatives that run seamlessly alongside the programs they manage.

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, FINTEPLA ® (fenfluramine) oral solution, has been approved by the U.S. 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 company has two additional late-stage development programs, one in a rare epilepsy called Lennox-Gastaut syndrome and one in a mitochondrial disease called TK2 deficiency. Zogenix plans to initiate a study of FINTEPLA in a genetic epilepsy called CDKL5 Deficiency Disorder (CDD) and is also collaborating with Tevard Biosciences to identify and develop potential next-generation gene therapies for Dravet syndrome and other genetic epilepsies.

Forward Looking Statements
Zogenix cautions you that statements included in this press release that are not a description of historical facts are forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "indicates," "will," "intends," "potential," "suggests," "assuming," "designed," and similar expressions are intended to identify forward-looking statements. These statements include the timing of the availability of FINTEPLA through the Zogenix Access Program; and Zogenix's expectations on the submission of a J-NDA by Nippon Shinyaku in Japan. These statements are based on Zogenix's current beliefs and expectations. The inclusion of forward-looking statements should not be regarded as a representation by Zogenix that any of its plans will be achieved. Actual results may differ from those set forth in this release due to the risks and uncertainties inherent in Zogenix's business, including, without limitation: Zogenix's ability to successfully launch the Zogenix Access Program for FINTEPLA globally; Zogenix may not be successful in executing its sales and marketing strategy for the commercialization of FINTEPLA in the U.S. and Europe, including due to the costs and procedures related to the REMS certification process, the controlled access program or the Zogenix Access Program; the COVID-19 pandemic may disrupt Zogenix's business operations, impairing the ability to commercialize FINTEPLA, including through the Zogenix Access Program; and other risks described in Zogenix's prior press releases as well as in public periodic filings with the U.S. Securities & Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Zogenix undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

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