Zogenix Product FINTEPLA® (Fenfluramine) Recognized for Setting a New Standard for Dravet Syndrome Treatment Outcomes

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- *In* Epilepsy & Behavior *editorial, authors write that FINTEPLA data demonstrate "unprecedented level of seizure control" for treated patients living with Dravet syndrome, a severe, debilitating childhood-onset epilepsy.*
- *Authors also recognize FINTEPLA for achieving clinically important results in caregiver-reported outcomes such as patient and family quality of life.*

EMERYVILLE, Calif., July 21, 2021 (GLOBE NEWSWIRE) -- Zogenix (NASDAQ: ZGNX), a global biopharmaceutical company developing and commercializing rare disease therapies, announced that its product FINTEPLA® (fenfluramine) oral solution has been recognized by two distinguished clinicians in an *Epilepsy & Behavior* editorial titled "*Raising the Bar: Fenfluramine Sets New Treatment Standards for Dravet Syndrome*."

In the editorial, the authors, Joseph Sullivan, M.D., of the UCSF Benioff Children's Hospitals, and Helen Cross, M.B.,Ch.B. Ph.D., of the UK's UCL Institute of Child Health, note that the treatment and diagnosis of severe, rare epilepsies such as Dravet syndrome have improved in the U.S. and Europe with earlier accurate diagnosis (genetic testing), better access to a network of specialized medical care, and availability of new medications. In particular, they note that FINTEPLA has achieved responder rates for seizure reduction at the >/=75% level that were previously only observed at the >/= 50% level. In their assessment, the authors write that future Dravet syndrome treatments "should be evaluated against the demonstrated efficacy of fenfluramine."

"Our primary goal in treating Dravet syndrome patients is to safely reduce the number and severity of seizures that contribute to poor long-term neurodevelopmental outcome and higher risk of death," said Dr. Sullivan. "With the availability of more approved treatment choices and the significant levels of seizure reduction seen with fenfluramine, we now have additional tools to achieve profound seizure reduction, better neurodevelopmental outcomes, and improved quality of life for a large percentage of our patients."

FINTEPLA was approved in the U.S. and European Union in 2020 for the treatment of seizures associated with Dravet syndrome patients aged two years and older. The authors write that the novel outcomes reported with FINTEPLA treatment, such as effects on executive functions, have effectively raised the bar for assessment of future therapies. Their opinion is based on the body of previously released data from the clinical trials that supported the U.S. and EU regulatory reviews, as well as data from patients treated up to three years in an ongoing open-label study and in early access programs. Across studies, the data demonstrate that FINTEPLA provides safe, effective, and durable seizure reduction for a majority of treated Dravet syndrome patients, including those who, prior to treatment with FINTEPLA, had continued to experience a high seizure burden despite treatment with one or more other antiepileptic medicines.

Across studies, FINTEPLA has been generally well-tolerated, with no observed cases of pulmonary arterial hypertension (PAH) or valvular heart disease (VHD). The most common adverse events were reported as decreased appetite, fatigue, diarrhea, and pyrexia.

Please see important FINTEPLA prescribing and safety information at www.fintepla.com.

"From our years of partnership with the physician and caregiver communities, we have come to know the dramatic unmet needs that Dravet syndrome patients and their families face every day," said Bradley S. Galer, M.D., Chief Medical Officer of Zogenix. "We are thrilled that these experts have perceived strong benefits for fenfluramine as a new treatment option for physicians, patients and families, and see it as a standard against which new treatments should be evaluated. Zogenix remains committed to continuing to investigate fenfluramine's potential to help more patients and families living with rare epilepsy conditions."

** The editorial will be published in the August 2021 issue of Epilepsy & Behavior and is available online now to registered users. [Joseph Sullivan, J. Helen Cross, Raising the bar: Fenfluramine sets new treatment standards for Dravet syndrome, Epilepsy & Behavior, Volume 121, Part A, 2021,108061,ISSN 1525-5050 (https://doi.org/10.1016/j.yebeh.2021.108061 or https://www.sciencedirect.com/science/article/pii/S152550502100295X)]*

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 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 also plans to initiate a study of FINTEPLA in a genetic epilepsy called CDKL5 Deficiency Disorder (CDD) and is collaborating with Tevard Biosciences to identify and develop potential next-generation gene therapies for Dravet syndrome and other genetic epilepsies.

Forward-Looking Statement

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 potential that fenfluramine oral solution could be an important new treatment option for Dravet syndrome patients; Zogenix's plans to commercialize fenfluramine in Europe and Zogenix's plans with respect to its development programs. 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: FINTEPLA may not achieve broad market acceptance as a treatment option of Dravet syndrome which would limit the company's ability to general revenues; Zogenix's ability to successfully launch FINTEPLA, including launching a controlled access program implemented due to risks related to valvular heart disease and pulmonary arterial hypertension; the COVID-19 pandemic may disrupt Zogenix's business operations, impairing the ability to commercialize FINTEPLA in Europe and Zogenix's ability to generate product revenue in Europe; Zogenix may not be successful in executing its sales and marketing strategy for the commercialization of FINTEPLA in Europe; unexpected adverse side effects or inadequate therapeutic efficacy of fenfluramine that could limit commercialization, or that could result in recalls or product liability claims; 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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