Zogenix To Present New Long-term Data on FINTEPLA® (fenfluramine) in Lennox-Gastaut Syndrome (LGS) at AAN 2022

March 4, 2022

- *Two podium and one poster presentation share important new findings on FINTEPLA's safety profile and its impact on non-seizure related benefits for LGS patients*

- *LGS is a debilitating childhood-onset developmental and epileptic encephalopathy estimated to affect approximately 30,000-50,000 patients in the U.S.*[1]

EMERYVILLE, Calif., March 04, 2022 (GLOBE NEWSWIRE) -- Zogenix (Nasdaq: ZGNX), a global biopharmaceutical company developing and commercializing rare disease therapies, announced that new data from the company's research and development program for FINTEPLA® (fenfluramine) in Lennox Gastaut syndrome (LGS) will be presented at the hybrid American Academy of Neurology (AAN) Annual Meeting 2022, in-person in Seattle (April 2-7) and held virtually (April 24-26).

"At AAN, we look forward to sharing our latest research for FINTEPLA in LGS that highlights long-term evidence of its cardiovascular safety profile as well as sustained reduction in drop seizure frequency," said Bradley S. Galer, M.D., Executive Vice President and Chief Medical Officer, Zogenix. "Additionally, we are encouraged by compelling findings in the improvement of everyday executive functioning, which is a critical measure for physicians, patients and caregivers managing this challenging condition. Collectively, this research underscores our enduring commitment to addressing the unmet treatment needs in LGS."

The analyses include the FINTEPLA open-label study data (NCT03355209) in LGS at two podium presentations, and authors will be available to discuss the data during a discussion:

- **Interim Analysis of Long-Term Safety and Efficacy of FINTEPLA (fenfluramine) in Patients with Lennox-Gastaut Syndrome**
  Knupp, Scheffer, Ceulemans, et al.
  Session S13: Epilepsy/Clinical Neurophysiology (EEG): Antiseizure Medications
  Authors available: Monday, April 4, 2022, at 2:48 PM PT

- **Long-Term Cardiovascular Safety of Fenfluramine for Lennox-Gastaut Syndrome: Interim Analysis of Open-Label Safety Study**
  Agarwal, Farfel, Gammiatoni, et al.
  Session S24: Epilepsy/Clinical Neurophysiology (EEG): Clinical Epilepsy
  Authors available: Tuesday, April 5, 2022, at 4:18 PM PT

A poster will also be presented about the impact of FINTEPLA on everyday executive function in patients, as captured using the Behavior Rating Inventory of Executive Function (BRIEF®).

- **Fenfluramine Improves Everyday Executive Functioning in Patients With Lennox-Gastaut Syndrome: Analysis of Phase 3 Data**
  Bishop, Isquith, Gioia, et al.

The abstracts being presented are available on the AAN website and will be available following the meeting on the Zogenix Newsroom site.

About Lennox-Gastaut Syndrome
Lennox-Gastaut Syndrome is a rare and devastating lifelong childhood-onset epilepsy that can arise from multiple different causes. LGS is characterized by many different seizure types, including many that result in frequent falls and injuries. The intellectual and behavioral problems associated with LGS, as well as around-the-clock care requirements, add to the complexity of life with this disease.[2]

About FINTEPLA® (fenfluramine) oral solution
FINTEPLA is approved by the FDA and European Commission for the treatment of seizures associated with Dravet syndrome and is in development in Japan for the treatment of seizures associated with Dravet syndrome. FINTEPLA is also being investigated as a potential treatment for Lennox-Gastaut syndrome (LGS) and other rare and severe childhood-onset epilepsy disorders.

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. Food and Drug Administration (FDA) and the European Medicines Agency and is under regulatory review 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 FINTEPLA for the treatment of seizures associated with an additional rare epilepsy, Lennox-Gastaut syndrome (LGS). Zogenix is also initiating 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. The company has an additional late-stage development program, MT-1621, in a mitochondrial disease called TK2 deficiency.

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 potential for FINTEPLA to lead to improvement of functioning in patients with LGS; Zogenix’s commercialization plans in the U.S. and 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: the timing and completion of the announced merger between Zogenix and UCB S.A., and any effects of the announcement, pendency or completion of the announced merger, including the anticipated benefits therefrom; FINTEPLA may not achieve broad market acceptance as a treatment option of seizures associated with LGS or Dravet syndrome which would limit Zogenix’s ability to general revenues; 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 or controlled access program; the COVID-19 pandemic may continue to disrupt Zogenix’s business operations, impairing the ability to commercialize FINTEPLA in the U.S. and Europe and Zogenix's ability to generate product revenue in the U.S. and Europe and conduct its development programs; unexpected adverse side effects or inadequate therapeutic efficacy of fenfluramine that could limit regulatory approval or commercialization, or that could result in recalls or product liability claims; later developments with FDA that may be inconsistent with the already completed meetings; additional data from Zogenix's ongoing studies may contradict or undermine the data previously reported; the potential for the FDA to delay timing of review of the sNDA due to the FDA's internal resource constraints or other reasons; 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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[1] Zogenix estimates.

[2] National Institute of Neurological Disorders and Stroke. Lennox-Gastaut Syndrome Information Page. Last Accessed Jan 2022.

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