# Zogenix Presents Positive Findings on the Impact of Treatment with FINTEPLA® (ZX008) on Everyday Executive Function in Patients with Dravet Syndrome

December 2, 2018

*Data Presented During Late-Breaker Session at 72nd American Epilepsy Society Annual Meeting*

*Additional New Analyses Underscore Psychosocial Burden on Family*

EMERYVILLE, Calif., Dec. 02, 2018 (GLOBE NEWSWIRE) -- Zogenix, Inc. (NASDAQ:ZGNX), a pharmaceutical company developing therapies for the treatment of rare diseases, today announced results from a post-hoc analysis of its investigational drug, FINTEPLA® (ZX008), on caregiver-reported everyday executive function in children and young adults with Dravet syndrome, who participated in the Company's first pivotal Phase 3 clinical trial, Study 1. These data, as well as results from two analyses assessing the impact of Dravet syndrome on patients' siblings and caregivers, will be presented during the 72 ndAmerican Epilepsy Society (AES) Annual Meeting taking place in New Orleans. Full posters can be found on www.zogenix.comhere.

In Study 1 (poster 2.406), of the 119 total patients in the trial, 77 patients, aged 5-18 years, were assessed using the Behavior Rating Inventory of Executive Function (BRIEF®) scale. The BRIEF scale was developed to assess everyday executive function in the home and school environments for children and young adults from 5-18 years of age. The data from Study 1 were mapped to the BRIEF®2 scale, which is a more current, validated version with more stable and sensitive scales for assessing changes related to everyday executive function. Patients were randomized to one of three treatment groups: FINTEPLA 0.8 mg/kg/day (30 mg maximum daily dose; n=28), FINTEPLA 0.2 mg/kg/day (n=24) or placebo (n=25). Using the BRIEF2 scale, Reliable Change Index scores (RCIs) were calculated to evaluate whether changes from baseline to end of study in individual scores were clinically meaningful or were changes greater than expected due to measurement error, practice effects, and other factors, such as age.

Following 14 weeks of treatment, patients treated with FINTEPLA experienced clinically meaningful improvement on the Behavior Regulation and Emotion Regulation Indexes compared with those in the placebo group (p=0.02). A significantly greater proportion of patients in the pooled FINTEPLA treatment group also showed benefit on the Plan/Organize scale of the Cognitive Regulation Index compared with the placebo group (p<0.04). No significant, clinically meaningful differences were observed among the treatment groups for worsening of everyday executive function.

"The clinically meaningful impact of FINTEPLA on behavioral and emotional regulation is encouraging, as these are considered the 'building blocks' necessary for higher-level cognitive function," said Gerard A. Gioia, Ph.D., Division Chief, Neuropsychology, Children's National Health System, Rockville, MD, co-author of the BRIEF and BRIEF2 scales. "Ongoing studies will be important for fully evaluating the longer-term impacts of FINTEPLA treatment on executive function."

Two other presentations at AES (posters 2.423 and 2.424) include new analyses of data from the Sibling Voices Survey, which was developed by Zogenix to assess the emotional impact of growing up with a sibling with severe childhood epileptic encephalopathies (EE), such as Dravet syndrome and Lennox-Gastaut syndrome. Both analyses involved anonymous sibling and parent respondents representing 107 families of patients with EE, and these new findings again underscore the need to address disease burden on the family in addition to the patient.

- The first analysis evaluated the psychosocial concerns of siblings growing up with a brother or sister with a severe EE. Young siblings (aged 13-17) reported feelings of guilt, resentment, and jealousy toward their sibling. Most adult siblings expressed concern over the psychological/emotional toll of caring for their affected sibling should care transition from their parents to themselves.
- A second analysis compared parental perception to that of siblings on quality of life and mood symptoms. There was a more than two-fold difference between parental perception and siblings' responses on items regarding "sadness about the sibling's diagnosis," "not getting enough attention from mom and dad," and "how stressed are you over your sibling's diagnosis."

**About Study 1**
The randomized, double blind, placebo controlled, Phase 3 study enrolled 119 patients across sites in the U.S., Canada, Europe and Australia. The median age of patients was 8 years (range, aged 2-18 years). Following a six-week baseline observation period, patients were randomized to one of three treatment groups: FINTEPLA 0.8 mg/kg/day (30 mg maximum daily dose; n=40), FINTEPLA 0.2 mg/kg/day (n=39), and placebo (n=40) in which FINTEPLA or placebo was added to current regimens of antiepileptic drugs. Patients were titrated to their target dose over two weeks and then remained at that fixed dose for 12 weeks. The mean baseline convulsive seizure frequency across the study groups was approximately 40 seizures per month.

As previously reported, Study 1 met its primary objective demonstrating that FINTEPLA, at a dose of 0.8 mg/kg/day, was superior

to placebo as adjunctive therapy in the treatment of Dravet syndrome in children and young adults based on change in the frequency of convulsive seizures between the 6-week baseline observation period and the 14-week treatment period ($p<0.001$). The most common treatment emergent adverse events (>10% in any treatment group) in Study 1 included diarrhea, vomiting, fatigue, pyrexia, nasopharyngitis, upper respiratory tract infection, fall, weight decreased, decreased appetite, lethargy, seizure and somnolence. Prospective cardiac safety monitoring throughout the study did not identify clinical or echocardiographic evidence of valvular heart disease or pulmonary hypertension in any patient.

**About Zogenix**
Zogenix is committed to developing and commercializing transformative therapies to improve the lives of patients and their families living with rare diseases. For more information, visit www.zogenix.com.

**Forward Looking Statements**
Zogenix cautions you that statements included in this press release or in the poster presentations 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 Zogenix's plans to present data and other posters at AES and the potential efficacy of FINTEPLA (ZX008) and the potential for FINTEPLA to relieve the psychosocial burden of patients with Dravet syndrome or their families. 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 or in any poster presentation due to the risks and uncertainties inherent in Zogenix's business, including, without limitation: the uncertainties associated with the clinical development and regulatory approval of product candidates such as FINTEPLA; unexpected adverse side effects or inadequate therapeutic efficacy of FINTEPLA that could limit approval and/or 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 Securities and 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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