Zogenix Announces New Data on Psychological and Socioeconomic Impact of Dravet Syndrome and Other Epileptic Encephalopathies at 13th European Congress on Epileptology

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EMERYVILLE, Calif., Aug. 30, 2018 (GLOBE NEWSWIRE) -- Zogenix, Inc. (NASDAQ: ZGNX), a pharmaceutical company developing therapies for the treatment of rare central nervous system (CNS) disorders, today announced new findings from multiple studies assessing the psychological and socioeconomic impact of epileptic encephalopathies, such as Dravet syndrome, in the United States and Europe. These studies, as well as new results from an ongoing open-label prospective study of ZX008 in Dravet syndrome, were presented at the 13thEuropean Congress on Epileptology (ECE), taking place this week in Vienna, Austria and can be accessed here.

Psychological Impact of Epileptic Encephalopathies on Siblings
Two presentations analyzed data from the Sibling Voices Survey, which was developed to assess the emotional impact of growing up with a sibling with Dravet syndrome, Lennox-Gastaut Syndrome (LGS), or other severe childhood epileptic encephalopathies.

- The first analysis found that siblings of children with epileptic encephalopathies may be at risk for anxiety or depression, with a significant proportion of both younger siblings and adult siblings reporting symptoms of anxiety and depressed mood. These findings were presented in a podium session and nominated for an ECE Best Poster Award.
- A separate analysis of data from the Sibling Voices Survey focused on the specific concerns of younger children (< 18 years old) who experience growing up with a sibling with an epileptic encephalopathy. A substantial percentage of siblings reported being worried or scared, having less attention from their parents, activities being disrupted, and more responsibilities. The most frequent emotions reported by the younger cohort (9 – 12 years old) included being easily startled, unhappiness and grumpiness, while the older cohort (13 – 17 years old) reported irritability, unhappiness and bad dreams. Siblings in the younger cohort were more likely to report feeling uncomfortable talking about their siblings diagnosis and less likely to report having someone to confide in or talk to about their siblings' diagnosis compared to the older cohort.

A third and separate poster presented results from a Caregiver Benefit Scale for caregivers of children with epileptic encephalopathies and other chronic diseases. The results indicate caregivers of children with epileptic encephalopathies report lower benefits than caregivers from a community sample, but the benefit was similar to caregivers of children with Down syndrome and Muscular Dystrophy.

"These data suggest that the frequency and unpredictability of seizures in Dravet syndrome and other epileptic encephalopathies create a heavy burden that significantly impact the quality of life of the entire family unit," said Lauren Schwartz, Ph.D., Department of Rehabilitation Medicine, University of Washington in Seattle. "Alleviating or reducing this seizure burden has the potential to not only affect the lives of patients, but also improve the quality of lives of their caregivers and siblings."

Socioeconomic Impact of Dravet Syndrome in Germany
A study of the socioeconomic burden of illness associated with Dravet syndrome within the German healthcare system found patient seizure burden was the major contributor to direct costs and incurred substantial other costs, such as specialist care or therapy for additional symptoms.

- 77% of patients experienced at least one seizure in the past month and 30% experienced status epilepticus in the previous 12 months.
- 89% of patients/caregivers have a severely disabled pass and 76% require significant to extreme categories of nursing care.

Durability and Safety of ZX008 in Belgian Dravet syndrome Cohort
Updated results from the Belgian, open-label prospective study of fenfluramine in patients with Dravet syndrome continue to demonstrate the long-term durability of effect with patients experiencing a median 87% reduction in convulsive seizures over the entire observation period (N=15, median 36 months; range 9 to 80 months) compared to the 3-month baseline period. Additionally, 67% of subjects experienced a ≥ 75% reduction in convulsive seizure frequency per month compared to baseline.

Fenfluramine was generally well-tolerated and demonstrated a safety profile consistent with the prior reports from the Belgian cohort. No patients exhibited cardiac valvulopathy or pulmonary hypertension at any time in the study. The most common adverse events were anorexia (n=11), sleepiness (n=9), fatigue (n=8), and mood changes (n=8).

"Combined with the data from our recently completed Phase 3 pivotal trials for ZX008 in Dravet syndrome, we are pleased with the durability of treatment effect that has been observed with fenfluramine in this cohort of patients who continue to experience clinically meaningful reductions in seizure frequency," said Bradley S. Galer, M.D., executive vice president and chief medical officer at Zogenix.

Dravet syndrome is a rare, severe and intractable form of epilepsy that begins in infancy with frequent and/or prolonged seizures.[1] Studies have reported an incidence rate for Dravet syndrome of approximately 1 per 16,000 live births with onset occurring within the first year of life. Patients and caregivers managing these epilepsies – especially those who have been unable to control seizures with other treatments – experience daily, frequent and/or prolonged seizures that significantly impact their daily quality of life.[2] Many caregivers must quit their jobs to care for their affected child, a commitment that results in substantial financial, physical, psychosocial and emotional burden.[3]

ZX008 is designated as an orphan drug as it pertains to Dravet syndrome and LGS in both the U.S. and Europe, and has received Breakthrough Therapy designation in the U.S. for the treatment of Dravet syndrome. ZX008, fenfluramine HCl oral solution, is an investigational compound that is being developed as a potential treatment for seizures in patients with Dravet syndrome and Lennox-Gastaut syndrome. It is currently not approved by any regulatory authorities to treat any condition.

About Zogenix
Zogenix, Inc. (Nasdaq: ZGNX) is a pharmaceutical company dedicated to developing therapies for people living with severe central nervous system (CNS) disorders who have limited or no treatment options. Led by a team of experts in rare disease development and CNS conditions, Zogenix is rapidly advancing the clinical investigation and development of ZX008 (fenfluramine hydrochloride) for patients with severe, rare epilepsies, including Dravet and Lennox-Gastaut syndromes.

For more information, visit www.zogenix.com.

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 are based on the Zogenix's current beliefs and expectations. These forward-looking statements include statements regarding the socioeconomic impact and caregiver burdens of Dravet syndrome and other epilepsies, and ZX008's potential to be an important new treatment for Dravet syndrome. 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 uncertainties associated with the clinical development and regulatory approval of product candidates such as ZX008, including potential delays in the timing of regulatory submissions; the results from the open-label study could undermine the safety and efficacy results observed in other studies conducted by Zogenix to date; the socioeconomic impact and caregiver burden may change over time due to improved treatment options or other economic or social changes; the top-line data Zogenix has reported is based on preliminary analysis of key efficacy and safety data, and such data may change following a more comprehensive review of the data related to the clinical trial and such top-line data may not accurately reflect the complete results of the trial, and the FDA may not agree with Zogenix's interpretation of such results; unexpected adverse side effects or inadequate therapeutic efficacy of ZX008 may limit regulatory approval and/or commercialization, or may 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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Source: Zogenix, Inc.