Zogenix Announces Initiation of Phase 3 Program for ZX008 in Dravet Syndrome

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SAN DIEGO, Jan. 11, 2016 (GLOBE NEWSWIRE) -- Zogenix, Inc. (Nasdaq:ZGNX), a pharmaceutical company developing therapies for the treatment of central nervous system (CNS) disorders, today announced the initiation of the first Phase 3 clinical trial for the Company's lead product candidate, ZX008, as an adjunctive treatment of seizures in children with Dravet syndrome.

"We are extremely pleased to have advanced the ZX008 program to the start of the Phase 3 trial. It is an important step toward making this potentially breakthrough treatment available to Dravet patients and their families," said Gail M. Farfel, Ph.D., Chief Development Officer of Zogenix.

The Phase 3 program for ZX008 includes two randomized, double-blind placebo-controlled studies that will include two dose levels of ZX008 (0.2 mg/kg/day and 0.8 mg/kg/day, up to a maximum daily dose of 30 mg), as well as placebo. Zogenix intends to enroll 105 subjects in each of the two studies, with 35 patients in each treatment arm. In addition to the U.S. Phase 3 study, a second multi-national study, which will be conducted primarily in Europe, is expected to initiate in the first quarter of 2016. The primary endpoint of both studies is the change in frequency of convulsive seizures as compared to placebo. The key secondary endpoints include 40% and 50% responder analyses and convulsive seizure-free interval.

"We are eager to begin this clinical trial as a potential new treatment option for children with Dravet syndrome," said Dr. Joseph Sullivan, Associate Professor of Neurology & Pediatrics at University of California, San Francisco (UCSF), Director of the UCSF Pediatric Epilepsy Center and Principal Investigator of the North American ZX008 trial. "Effective treatment options for this catastrophic epilepsy syndrome are quite limited. The data generated so far for ZX008 have been encouraging. We look forward to seeing results from the Phase 3 clinical trial."

About Zogenix

Zogenix, Inc. (Nasdaq:ZGNX) is a pharmaceutical company committed to developing and commercializing CNS therapies that address specific clinical needs for people living with orphan and other CNS disorders who need innovative treatment alternatives to improve their daily functioning.

For more information, visit www.zogenix.com.

About Dravet Syndrome

Dravet syndrome (also known as Severe Myoclonic Epilepsy of Infancy) is a rare, severe and therapy-resistant form of epilepsy most often caused by an identifiable gene defect that results in abnormal functioning of a sodium channel in the brain. Children with Dravet syndrome experience severe, long-lasting, fever-related seizures in the first year of life. Other seizures typically arise later, including myoclonus (involuntary muscle spasms) and status epilepticus (prolonged seizures), which often result in severe cognitive and developmental impairment. Episodes of status epilepticus require immediate emergency care and can be fatal.

Individuals with Dravet syndrome face a higher incidence of SUDEP (sudden unexplained death in epilepsy) and have associated conditions, which also require proper treatment and management. Children with Dravet syndrome do not outgrow this condition and it affects every aspect of their daily lives.

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 company's current beliefs and expectations. These forward-looking statements include statements regarding the timing of the commencement of the second Phase 3 clinical study for ZX008 and ZX008's potential as a breakthrough adjunct treatment for seizures associated with 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 commencement, enrollment and completion of clinical trials; the potential that earlier clinical trials and studies may not be predictive of future results; Zogenix's reliance on third parties to conduct its clinical trials, enroll patients, manufacture its preclinical and clinical drug supplies and manufacture commercial supplies of its drug products, if approved; unexpected adverse side effects or inadequate therapeutic efficacy of ZX008 that could limit approval and/or commercialization, or that could result in recalls or product liability claims; Zogenix's ability to fully comply with numerous federal, state and local laws and regulatory requirements, as well as rules and regulations outside the United States, that apply to its product development activities; 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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