Zogenix Receives Fast Track Designation From FDA for Development of ZX008 in Dravet Syndrome

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EMERYVILLE, Calif., Jan. 19, 2016 (GLOBE NEWSWIRE) -- Zogenix, Inc. (Nasdaq:ZGNX), a pharmaceutical company developing therapies for the treatment of central nervous system (CNS) disorders, today announced receipt of Fast Track designation from the U.S. Food and Drug Administration (FDA) for the development program for the Company's investigational product, ZX008, as a treatment of seizures associated with Dravet syndrome, a rare and catastrophic form of childhood epilepsy.

“The FDA granting Fast Track designation provides important support as we advance the development program for ZX008 in Dravet syndrome towards a potential approval as quickly as possible,” said Stephen Farr, Ph.D., Chief Executive Officer of Zogenix. “We recently initiated our first Phase 3 clinical trial in the U.S., and the second trial, primarily to be conducted in Europe, is expected to begin this quarter.”

The FDA's Fast Track program was established to facilitate the development and expedite the review of drugs with the potential to treat serious conditions and address unmet medical needs. Companies that receive Fast Track designation are provided the opportunity for more frequent interactions with the FDA during clinical development and are eligible for accelerated approval and/or priority review, if relevant criteria are met. Additionally, companies that receive Fast Track designation are allowed to submit completed sections of their New Drug Application (NDA) for the drug on a rolling basis, resulting in the potential for an expedited FDA review process.

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 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; Fast Track designation may not result in an expedited regulatory review process; 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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