Zogenix Receives Orphan Drug Designation in the European Union for ZX008 in Lennox Gastaut Syndrome

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EMERYVILLE, Calif., March 01, 2017 (GLOBE NEWSWIRE) -- Zogenix, Inc. (NASDAQ:ZGNX), a pharmaceutical company developing therapies for the treatment of orphan and central nervous system (CNS) disorders, today announced that the European Commission (EC) has designated ZX008 (fenfluramine) as an orphan medicinal product for the treatment of Lennox Gastaut Syndrome (LGS), a refractory, debilitating childhood-onset epilepsy. The EC's approval follows a positive opinion in January from the European Medicine Agency's (EMA) Committee for Orphan Medicinal Products (COMP).

“This Orphan Drug Designation is an important component in our strategy to evaluate potential expanded uses of ZX008 in other rare and severe epilepsy conditions,” said Stephen J. Farr, Ph.D., President and Chief Executive Officer of Zogenix. “Compelling preliminary efficacy data from an on-going, open-label Phase 2 study for ZX008 in LGS were presented in December 2016 at the American Epilepsy Society Annual Meeting. Based on these promising results, we intend to move forward with a Phase 3 clinical study for ZX008 in LGS in the second half of 2017.”

Orphan Drug Designation is granted by the EC to drugs that are intended for the treatment of life-threatening or chronically debilitating, rare diseases where no satisfactory treatment of the condition concerned is authorized. If such a treatment exists, then the medicine must be of significant benefit to those affected by the condition. Rare diseases are those defined as having a prevalence of not more than five per 10,000 population in Europe. The Orphan Drug Designation provides potential incentives for the sponsor from the European Union to develop a medicine for a rare disease, such as protocol assistance, reduced fees, funding from the EC for clinical trials and protection from competition once the medicine is placed on the market, including ten years of market exclusivity.

Zogenix is currently enrolling patients in the U.S. and internationally for a ZX008 Phase 3 program in Dravet syndrome, another intractable, severe epilepsy that begins in infancy. ZX008 is designated as an orphan drug in both the U.S. and Europe, and it also received Fast Track designation in the U.S. for the treatment of Dravet syndrome.

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.

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 potential commercialization of ZX008; ZX008's potential as a treatment for seizures associated with LGS; the enrollment of patients in the on-going Phase 3 clinical trials of ZX008 for patients with Dravet syndrome; the continued evaluation of patients in the open-label Phase 2 clinical trial of ZX008 for patients with LGS and the timing of the launch of a Phase 3 program for LGS. 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: risks that the benefits associated with orphan drug designation may not be realized, including that orphan drug exclusivity may not effectively protect a product from competition and that such exclusivity may not be maintained; 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; the potential for distraction of management related to the transition of management responsibilities; 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.

CONTACT: Investors: Andrew McDonald
Founding Partner, LifeSci Advisors LLC
646-597-6987 | Andrew@lifesciadvisors.com

Primary Logo

Zogenix, Inc.