Zogenix Announces Presentation of ZX008 Mechanism of Action Data at Annual Meeting of Society of Biological Psychiatry

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New Research Expands Understanding of ZX008 Mechanism in Treating Seizures

EMERYVILLE, Calif., May 22, 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 new data on the mechanism of action of ZX008 was presented in a poster at the 72nd Annual Meeting of the Society of Biological Psychiatry, held May 18 – 20, 2017, in San Diego, CA (see study data here). ZX008 (low-dose fenfluramine) is being developed as an adjunctive treatment for Dravet syndrome (DS), a rare epileptic encephalopathy.

The assumption to date has been that the anti-seizure activity of fenfluramine is mediated through known, primarily serotonergic mechanisms. However, the meaningful and prolonged reductions in seizure frequency observed following the use of fenfluramine in patients with DS has not been replicated in studies with other serotonergic agents, such as fluoxetine and lorcaserin. These new results exploring mechanism of action demonstrate that fenfluramine, in addition to its serotonergic effects, also exhibits activity at the sigma-1 receptor. Fenfluramine acts as a positive allosteric modulator of the receptor. Recent literature has suggested that activation of the sigma-1 receptor alleviates seizures in validated animal seizure models[1,2]. In contrast, lorcaserin displayed no activity at the sigma-1 receptor.

“Collectively, these data support the hypothesis that the unique activity of fenfluramine in Dravet syndrome may be due to both its activity on serotonin receptors and also from its activity as a positive allosteric modulator of the sigma-1 receptor,” said Gail Farfel, Ph.D., Executive Vice President and Chief Development Officer of Zogenix, and one of the authors of the poster. “The use of low-dose fenfluramine has generated a significant reduction in seizure frequency in an ongoing open-label study of patients with Dravet syndrome. Zogenix’s Phase 3 program for ZX008 is further evaluating the potential of low-dose fenfluramine as an adjunctive treatment for seizures in Dravet syndrome. Data from the Company’s first Phase 3 clinical trial is expected in the third quarter of 2017.”

The title of the poster presentation (Abstract #663) was, "*An Examination of the Mechanism of Action of Fenfluramine in Dravet Syndrome: A Look beyond Serotonin*".

[1] Vavers et al., Behavioral Brain Research, 2017

[2] Guo et al., British Journal of Pharmacology, 2015

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 ZX008’s potential as a treatment for seizures associated with Dravet syndrome; the mechanism of action of ZX008 as well as the mechanism of action other serotonergic agents; and the timing of top line results for the on-going Phase 3 clinical trials. 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: new data on the mechanism of action of ZX008 and other serotonergic agents; 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; top-line data from Study 1 may not support our NDA for ZX008 in Dravet syndrome; negative top-line data from Study 1 may delay or prevent commencement of the Phase 3 clinical trial in LGS; 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.

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

Primary Logo

Zogenix, Inc.