Zogenix Provides Regulatory Update for ZX008

October 19, 2015

Company Continues to Expect Phase 3 Clinical Program to Begin in Fourth Quarter of 2015

SAN DIEGO, Oct. 19, 2015 (GLOBE NEWSWIRE) -- Zogenix, Inc. (Nasdaq:ZGNX), a pharmaceutical company developing therapies for the treatment of central nervous system (CNS) disorders, today announced the recent receipt of a request from the U.S. Food and Drug Administration (FDA) for additional information related to the Company's proposed Phase 3 program for ZX008 prior to the FDA declaring Zogenix's Investigational New Drug Application (IND) effective. Zogenix has responded with the requested information required to initiate the clinical program. ZX008 previously received orphan drug designation from the FDA, and is expected to enter Phase 3 clinical studies during the fourth quarter of 2015 for the treatment of Dravet syndrome, a rare and debilitating form of epilepsy that begins in infancy.

The FDA's specific information requests are related to normative ranges for echocardiograms being conducted during the course of the pediatric Phase 3 program, and an amended Phase 3 study protocol to reflect a required follow-up echocardiogram 3 to 6 months after patients discontinue treatment with ZX008.

"We are confident that we have adequately addressed the FDA's information requests and look forward to receiving their response shortly," said Stephen Farr, Ph.D., President and CEO of Zogenix. "Importantly, our expected ZX008 clinical development timeline remains unchanged, including the expectation that the Phase 3 program will begin in the fourth quarter of 2015. We will provide further regulatory updates as appropriate."

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 help them return to normal 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" 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 Phase 3 clinical studies for ZX008. 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 risk 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 commencement of clinical trials and the receipt of regulatory approvals; the potential that earlier clinical trials may not be predictive of future results; unexpected adverse side effects or inadequate therapeutic efficacy of ZX008 that could limit approval and/or commercialization; Zogenix's ability to fully comply with numerous federal, state and local laws and regulatory requirements that apply to its product development activities; and other risks described in the company's prior press releases and 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 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

Zogenix, Inc.