Zogenix Completes Enrollment in Phase 3 Trial of FINTEPLA® in Lennox-Gastaut Syndrome

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EMERYVILLE, Calif., July 08, 2019 (GLOBE NEWSWIRE) -- Zogenix, Inc. (NASDAQ: ZGNX), a global pharmaceutical company developing rare disease therapies, today announced that it has completed enrollment for, and randomized the last patient into the treatment period of, Study 1601, the Company's Phase 3 clinical trial of its lead investigational therapy, FINTEPLA® (ZX008, fenfluramine), for the treatment of seizures associated with Lennox-Gastaut Syndrome (LGS), a severe and often treatment-resistant childhood-onset epilepsy.

"We have been extremely pleased with the rate of enrollment in this trial and look forward to the availability of top-line safety and efficacy data in the first quarter of 2020," said Gail M. Farfel, Ph.D., Executive Vice President and Chief Development Officer of Zogenix. "Based on the compelling data generated in the previously completed Phase 2 study, we believe this promising drug candidate has the potential to become an important new treatment option for the control of seizures in patients suffering from LGS."

Study 1601 is a multi-national, randomized, double-blind, placebo-controlled trial of two fixed doses of FINTEPLA as adjunctive therapy for seizures in children and adults with LGS. After establishing a baseline seizure frequency for four weeks, patients are randomized into one of three treatment groups (0.2 or 0.8 mg/kg/day FINTEPLA, maximum of 30 mg/day, or placebo) for a two-week period of dose titration before being held at a fixed dose for 12 weeks of maintenance treatment. The study randomized a total of 263 patients, with approximately 87 subjects per group. The primary endpoint of the clinical trial is the change in the number of seizures that result in drops between baseline and the combined titration and maintenance periods at the 0.8 mg/kg/day dose compared to placebo. The key secondary endpoints include change in the number of drop seizures between baseline and the combined titration and maintenance periods at the 0.2 mg/kg/day dose compared to placebo, and the proportion of patients achieving a 50% reduction in drop seizures. Patients who complete the maintenance treatment period may be eligible to enter a 12-month open-label extension to evaluate the long-term safety, tolerability and effectiveness of FINTEPLA in LGS.

FINTEPLA for the treatment of LGS has previously been designated as an orphan drug by both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency.

About Zogenix
Zogenix is a global pharmaceutical company committed to developing and commercializing transformative therapies to improve the lives of patients and their families living with rare diseases. In addition to development for Lennox-Gastaut Syndrome, the Company's lead candidate, FINTEPLA® (ZX008, fenfluramine), has been accepted for review by the European Medicines Agency and is in development in Japan for the treatment of seizures associated with Dravet syndrome. Zogenix is preparing to resubmit its New Drug Application for Dravet syndrome to the U.S. Food and Drug Administration.

Forward-Looking Statement
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 include the potential timing of top-line data for Study 1601; FINTEPLA's potential as a promising drug candidate and important new treatment option for the control of seizures in patients suffering from LGS; and Zogenix's plans related to the resubmission of the new drug application (NDA) for FINTEPLA in patients with Dravet syndrome. These statements are based on Zogenix's current beliefs and expectations. 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 timing of the data from Study 1601 could be delayed; the results of Zogenix's Phase 2 clinical trial of FINTEPLA in patients suffering from LGS may differ from the results of the Phase 3 clinical trial; the FDA may refuse to accept the NDA following Zogenix's planned resubmission of the NDA of FINTEPLA for the treatment of Dravet syndrome; the FDA may not agree with Zogenix's interpretation of the results of the clinical trials of FINTEPLA; later developments with the FDA that may be inconsistent with feedback received at prior meetings with the FDA; additional data from Zogenix's ongoing studies may contradict or undermine the data submitted in the NDA for FINTEPLA; the uncertainties associated with the clinical development and regulatory approval of product candidates such as FINTEPLA; unexpected adverse side effects or inadequate therapeutic efficacy of FINTEPLA that could limit approval and/or commercialization, or that could result in recalls or product liability claims; and other risks described in Zogenix's prior press releases as well as in public periodic filings with the U.S. Securities & 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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