Zogenix Enters Exclusive Distribution Agreement with Nippon Shinyaku for FINTEPLA® in Japan

March 19, 2019

EMERYVILLE, Calif., March 19, 2019 (GLOBE NEWSWIRE) -- Zogenix, Inc. (Nasdaq: ZGNX), a global pharmaceutical company developing rare disease therapies, today announced that it has entered into an exclusive distribution agreement with Nippon Shinyaku, Co., Ltd., a leading Japanese pharmaceutical product developer and distributor, for the commercialization of its lead product candidate, FINTEPLA® (ZX008, fenfluramine), in Japan. Zogenix is developing FINTEPLA internationally for the treatment of Dravet syndrome and Lennox-Gastaut syndrome (LGS), two rare and often catastrophic childhood-onset epileptic encephalopathies.

Under the terms of the agreement, Nippon Shinyaku will receive exclusive commercial rights to FINTEPLA in Japan. In exchange, Zogenix will receive payments totaling $20 million, a major portion of which was paid at signing and the remainder of which will be paid over the next two years. Zogenix will also be eligible to receive future regulatory and sales-based milestone payments. In addition, Zogenix will supply product to Nippon Shinyaku and receive a tiered transfer price based on Zogenix's manufacturing costs, as well as the annual net sales of FINTEPLA in Japan.

Zogenix will retain responsibility for completing its global clinical development programs for FINTEPLA, including those already underway to support Zogenix's planned submissions of new drug applications in Japan for Dravet syndrome and LGS.

"Nippon Shinyaku's expertise and commitment to rare diseases make the company an attractive strategic distribution partner for FINTEPLA," said Stephen J. Farr, Ph.D., President and CEO of Zogenix. "Given the current limited available treatments for Dravet syndrome and LGS in Japan, we look forward to working with Nippon Shinyaku to advance FINTEPLA as a potential new treatment option for patients and their families."

At the execution of this agreement, Shigenobu Maekawa, President of Nippon Shinyaku, said, "Intractable and rare diseases is one of our most important areas of focus. We look forward to further contributing to the well-being of patients and their families, and addressing unmet medical needs in Dravet syndrome and LGS by working with Zogenix to bring FINTEPLA to market in Japan."

Zogenix recently completed its rolling submission of a New Drug Application (NDA) to the U.S. Food & Drug Administration (FDA) and the submission of a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for FINTEPLA for the treatment of seizures associated with Dravet syndrome. The EMA has accepted the Company's MAA for review, and Zogenix anticipates an approvability decision could be reached by the EMA in the first quarter of 2020. The Company expects to hear from the FDA regarding the filing status of its NDA submission shortly.

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. The company's lead candidate, FINTEPLA® (ZX008, fenfluramine) has been accepted for review by the European Medicines Agency; is awaiting an acceptance decision by the U.S. Food & Drug Administration; and is in development in Japan. For more information, visit www.zogenix.com.

Forward Looking Statements
Zogenix cautions you that statements included in this report 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 timing and amount of the $20 million payment that was not received upon signing the exclusive distribution agreement with Nippon Shinyaku, the achievement of regulatory or sales-based milestones by Nippon Shinyaku, Zogenix's plans regarding the development of FINTEPLA in Dravet syndrome and LGS, the timing and results of the ongoing clinical trials in Japan, and the timing or outcome of any pending decisions by the FDA, EMA, or other regulatory agencies. 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 press release due to the risks and uncertainties inherent in Zogenix's business, including, without limitation: the ongoing clinical trials of FINTEPLA in Japan may fail to reach their primary endpoints; even if the clinical trials are successfully, the Japanese regulatory agency may require additional clinical trials or analyses prior to a regulatory submission for the approval of FINTEPLA in Japan; the credit risk that Nippon Shinyaku fails to pay the remainder of the $20 million initial payment; the FDA may disagree that the existing safety and efficacy data is sufficient to allow an NDA approval; the FDA and/or the EMA may not agree with Zogenix's interpretation of the results of the clinical trials of FINTEPLA; additional data from Zogenix's ongoing studies may contradict or undermine the data submitted in the NDA and MAA 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 and filings with the U.S. 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 the Company 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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Source: Zogenix, Inc.