Zogenix Announces Acquisition of Modis Therapeutics, Inc.

- ***Advances Zogenix's strategy to provide transformative therapies to patients and families living with serious rare diseases***
- ***Adds MT1621, a proprietary, late-stage investigational medicine targeting Thymidine Kinase 2 deficiency (TK2d) that has received FDA Breakthrough Therapy and EMA PRIME designations***
- ***Investor conference call and webcast today at 8:30 AM ET***

EMERYVILLE, California, August 26, 2019 – Zogenix, Inc. (NASDAQ: ZGNX), a global pharmaceutical company developing rare disease therapies, today announced that it has entered into a definitive agreement to acquire Modis Therapeutics, Inc., a privately held biopharmaceutical company focused on developing novel therapies for rare genetic diseases with high unmet medical need. Modis's lead product candidate, MT1621, an investigational deoxynucleoside substrate enhancement therapy, is in late-stage development for the treatment of Thymidine Kinase 2 deficiency (TK2d), an inherited mitochondrial DNA depletion disorder that predominantly affects children and is often fatal.

"This transaction advances Zogenix's mission to become a leading rare disease pharmaceutical company by adding MT1621 to our pipeline of late-stage FINTEPLA® programs," said Stephen J. Farr, Ph.D., President and CEO of Zogenix. "Based on the compelling clinical data generated to date, we believe that MT1621 has the potential to significantly alter the course of the disease and improve outcomes in patients with TK2d. With Breakthrough Therapy and PRIME designations, MT1621 may be eligible for an accelerated regulatory path in both the U.S. and Europe, and we look forward to meeting and working with regulatory authorities to discuss next steps for the program."

A pivotal Phase 2 retrospective treatment study (called RETRO) of MT1621 substrate enhancement therapy in patients with TK2d was recently completed, with results demonstrating a substantial treatment benefit for patients. Thirty-eight patients from eight clinical sites in three countries (U.S., Spain and Israel) were enrolled in RETRO and received MT1621 treatment for up to seven years. Outcomes from patients enrolled in RETRO were compared to outcomes from a comprehensive, global TK2d natural history dataset of 68 patients. The difference in survival probability between MT1621-treated RETRO patients and untreated natural history control patients was statistically significant ($p<0.004$); all patients treated with MT1621 remain alive. In addition, patients treated with MT1621 demonstrated marked improvements in functional abilities, in some cases re-acquiring previously lost motor milestones. Safety data from RETRO indicated that MT1621 was generally safe and well-tolerated, with mild or moderate diarrhea being the most common treatment-related adverse event, occurring in 63% of patients. Treatment-related serious adverse events (SAEs) were reported in four patients. Two adult-onset patients stopped treatment due to asymptomatic increases in aminotransferases, without increases in bilirubin, which resolved upon discontinuation of treatment.

Under the terms of the transaction, Modis will receive an upfront payment of $250 million, comprised of $175 million in cash and $75 million in Zogenix common stock. Modis is also eligible to receive additional milestone payments consisting of $100 million upon receipt of U.S. Food and Drug Administration approval of MT1621in the

U.S. and $50 million upon European Medicines Agency approval in Europe. Zogenix will also pay a 5% royalty on any future net sales of MT1621.

“Zogenix shares our deep commitment to improving treatment options for patients with rare diseases,” said Joshua Grass, CEO of Modis Therapeutics. “This transaction reflects the strategic value of Modis and the results we have achieved with MT1621 to date, and we are confident that Zogenix is ideally positioned to complete development and bring MT1621 to patients in need as expeditiously as possible.”

Zogenix’s acquisition of Modis is subject to the satisfaction of customary closing conditions, including expiration or termination of the applicable waiting period under the Hart-Scott Rodino Antitrust Improvements Act of 1976 and approval of Modis’s stockholders. Pending satisfaction of the conditions to closing, the transaction is expected to close in September 2019.

SVB Leerink acted as financial advisor to Zogenix. Latham & Watkins is acting as legal advisor to Zogenix, and Fenwick & West is acting as legal advisor to Modis.

Conference Call

Zogenix will host a corporate update conference call and webcast to discuss the acquisition today, August 26, 2019, at 8:30 AM Eastern Time. Details to participate in the call are below.

Conference Call Details	
8:30 AM Eastern Time / 5:30 AM Pacific Time	
Toll Free:	1-877-407-9716
International:	1-201-493-6779
Conference ID:	13694139
Webcast (with slides):	http://public.viavid.com/index.php?id=135987

About TK2 Deficiency

Thymidine kinase 2 deficiency (TK2d) is a genetic disorder that results in mitochondrial dysfunction, leading in turn to inadequate energy production in cells. The disease presents as progressive and severe muscle weakness that profoundly impairs movement, breathing, eating, and other normal functions, and is often fatal. Believed to be significantly underdiagnosed, TK2d affects up to 2,500 patients in the U.S., primarily infants and young children. There are currently no approved therapies for this disease. To learn more, please visit www.tk2d.com.

About MT1621

MT1621 is an investigational deoxynucleoside combination therapy that targets the underlying pathophysiology of TK2 deficiency. Deoxynucleoside combination therapy has been shown to improve cell function and prolong life in preclinical models of TK2d. Data from initial clinical studies suggest that this therapy may meaningfully alter the course of disease in patients with TK2d. Modis is planning to conduct additional clinical studies with the goal of obtaining regulatory approval to make MT1621 available to patients globally.

About Modis Therapeutics

Modis Therapeutics, Inc. is a biopharmaceutical company focused on developing disease-modifying therapies for rare genetic diseases with high unmet medical need. It was formed in 2016 through a collaboration with academic experts in mitochondrial biology. The company's lead program (MT1621) is in clinical development for TK2d, an inherited mitochondrial disease. Modis Therapeutics is headquartered in Oakland, CA, with offices in New York City. For more information please visit www.modistx.com.

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 is preparing to resubmit its New Drug Application for FINTEPLA® (ZX008, fenfluramine) to the U.S. Food & Drug Administration for the treatment of seizures associated with Dravet syndrome, a rare and often-catastrophic infant-onset epilepsy that can include frequent and prolonged seizures and significant intellectual, behavioral, and motor disabilities. FINTEPLA® is under review by the European Medicines Agency and is in development in Japan, also for the treatment of Dravet syndrome, and is also in development globally for the treatment of Lennox-Gastaut syndrome, another severe childhood onset epilepsy.

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 expected timing, completion and effects of the acquisition of Modis and the other related transactions; the size of the patient population of TK2d; Zogenix's expectations that the RETRO study will serve as a pivotal study for FDA review of MT1621 for treatment of TK2d; the potential for MT1621 to significantly improve outcomes in patients with TK2d; the potential of MT1621 to receive for accelerated regulatory review in the U.S. or Europe ; and Zogenix's expectations that it discuss next steps with regulatory authorities for MT1621 program and that it will re-submit the NDA for FINTEPLA in patients with Dravet syndrome and the potential acceptance by the FDA thereof. 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 closing conditions for the transaction may not be satisfied or waived; risks associated with the acquisition of Modis and integration of Modis' operations into Zogenix's business, including an increase in near and long-term expenditures, exposure to unknown liabilities and diversion of Zogenix's management's time and attention; the inherent risks of clinical development of MT1621; the data Modis has reported is based on preliminary analysis of key efficacy and safety data, and such data may change following a more comprehensive review of the data related to the trial and such data may not accurately reflect the complete results of the trial; risks associated with relying on a retrospective analysis for pivotal efficacy and safety data for MT1621; Breakthrough Therapy and PRIME designations do not guarantee that the FDA or EMA will approve MT1621 or expedite its review of MT1621; the FDA may refuse to accept the re-submitted NDA for FINTEPLA the FDA may not agree with Zogenix's interpretation of the results of the clinical trials of MT1621 or FINTEPLA; 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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CONTACTS:

Zogenix
Melinda Baker
Senior Director, Corporate Communications
+1 (510) 788-8732 | corpcomms@zogenix.com

Investors
Andrew McDonald
Founding Partner, LifeSci Advisors LLC
+1 (646) 597-6987 | Andrew@lifesciadvisors.com