

## **Zogenix Completes Acquisition of Modis Therapeutics, Inc.**

September 9, 2019

### **Acquisition strengthens Zogenix's late-stage, rare disease pipeline with the addition of MT1621, a proprietary investigational therapy for Thymidine Kinase 2 deficiency (TK2d)**

EMERYVILLE, Calif., Sept. 09, 2019 (GLOBE NEWSWIRE) -- Zogenix, Inc. (NASDAQ: ZGNX), a global pharmaceutical company developing rare disease therapies, today announced that it has successfully completed its acquisition of Modis Therapeutics, Inc., a privately-held biopharmaceutical company, and added MT1621 to its late-stage development pipeline. MT1621 is a novel investigational deoxynucleoside substrate enhancement therapy for the treatment of Thymidine Kinase 2 deficiency (TK2d), an inherited mitochondrial DNA depletion disorder that predominantly affects children and is often fatal.

"We welcome Modis to our growing Zogenix team," said Stephen J. Farr, Ph.D., President and CEO of Zogenix. "With our strengthened portfolio, we are very excited to now be advancing two very promising potential new therapies to patients and families in need - FINTEPLA for Dravet and Lennox-Gastaut syndromes and MT1621 for TK2 deficiency."

At closing, Zogenix paid Modis approximately \$175 million in cash, funded in full via the Company's existing balance sheet, and approximately \$75 million in Zogenix common stock based on a 25-day volume weighted average price of \$46.68 per share. Modis is also eligible to receive milestone payments consisting of \$100 million upon U.S. Food and Drug Administration approval of MT1621 and \$50 million upon European Medicines Agency approval of MT1621. Zogenix will also pay a 5% royalty on any future net sales of MT1621.

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

#### **About MT1621 and TK2 Deficiency**

MT1621 is an investigational deoxynucleoside substrate enhancement therapy in late-stage development for the treatment of TK2 deficiency (TK2d), 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.

MT1621 is designed to restore mitochondrial function by targeting the underlying pathophysiology of TK2d. Deoxynucleoside substrate enhancement therapy has been shown to improve cell function and prolong life in preclinical models of TK2d. Data from a Phase 2 retrospective treatment clinical study called RETRO demonstrated increased survival probability and improved functional abilities for patients treated with MT1621 compared with untreated natural history control patients, and suggest that MT1621 may meaningfully alter the course of the disease. With Breakthrough Therapy and PRIME designations already received, MT1621 may be eligible for an accelerated regulatory path in both the U.S. and Europe. Zogenix will continue to work with regulatory authorities in the U.S. and Europe to discuss next steps for the MT1621 program.

#### **About Zogenix**

Zogenix is a global pharmaceutical company whose mission is to develop and commercialize therapies that transform the lives of patients and their families living with rare diseases. The company's lead compound is FINTEPLA® (ZX008, fenfluramine) for the treatment of seizures associated with Dravet and Lennox-Gastaut syndromes, two rare and often-catastrophic childhood-onset epilepsies often marked by frequent and prolonged seizures and significant intellectual, behavioral, and motor disabilities. Zogenix is preparing to resubmit its New Drug Application for FINTEPLA® for Dravet syndrome to the U.S. Food & Drug Administration; FINTEPLA® for Dravet syndrome is under review by the European Medicines Agency and is also in development in Japan. The Company expects top-line data from its ongoing Phase 3 trial for FINTEPLA® in Lennox-Gastaut syndrome in the first quarter of 2020. With the recent acquisition of Modis Therapeutics, Zogenix added MT1621, a novel investigational deoxynucleoside substrate enhancement therapy for the treatment of TK2 deficiency (TK2d), to its late-stage development pipeline.

#### **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 size of the patient population 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: 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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