Sigilon Therapeutics Receives Orphan Drug Designation for SIG-007 for the Treatment of Fabry Disease

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CAMBRIDGE, Mass., March 05, 2021 (GLOBE NEWSWIRE) -- Sigilon Therapeutics, Inc. (NASDAQ:SGTX), a biotechnology company that seeks to develop functional cures for chronic diseases through its Shielded Living Therapeutics™ platform, today announced that the United States Food and Drug Administration (FDA) has granted orphan drug designation to SIG-007 for the treatment of Fabry disease, a progressive, life-threatening lysosomal disease.

SIG-007 is comprised of cells that are genetically modified with a non-viral vector to express human alpha-galactosidase A, or AGAL. Fabry disease is caused by AGAL deficiency and the accumulation of certain substrates within a patient's cells, which contribute to multi-organ complications including kidney failure, gastrointestinal symptoms, strokes, and heart disease at a young age.

"The current standard of care for Fabry disease requires intravenous administration, which may involve long infusion times and the potential for infusion-associated reactions. While these therapies have helped patients manage their disease, long-term exposure has led to severe complications, including impaired renal function," said Deya Corzo, M.D., Chief Medical Officer at Sigilon. "Based on preclinical results, we believe SIG-007 may provide continuous and prolonged release of functional enzyme at levels sufficient to produce clinical benefits, while alleviating the treatment burden for these patients."

Commented Rogerio Vivaldi, M.D., President and Chief Executive Officer of Sigilon: "This marks our third orphan drug designation, and further highlights our commitment to bringing potential functional cures to patients who suffer from chronic, rare diseases. We are pleased to have secured this important designation at such an early stage of SIG-007's development."

Sigilon has initiated several IND enabling studies with plans to file four INDs within the next 12-24 months, which includes SIG-007 in patients with Fabry disease.

Orphan drug designation is granted by the FDA Office of Orphan Products Development to advance the evaluation and development of safe and effective therapies for the treatment of rare diseases or conditions affecting fewer than 200,000 people in the United States. Having received the designation, Sigilon is eligible for various development incentives for SIG-007, including tax credits for qualified clinical trials and seven years of market exclusivity in the United States following commercial approval by the FDA. For more information about orphan designation, please visit the FDA website.

About Sigilon Therapeutics
Sigilon Therapeutics seeks to develop functional cures for chronic diseases through its Shielded Living Therapeutics™ platform. Sigilon's product candidates are non-viral engineered cell-based therapies designed to produce the crucial proteins, enzymes or factors needed by patients living with chronic diseases such as hemophilia, lysosomal disorders and diabetes. The engineered cells are protected by Sigilon's Afibromer™ biomaterials matrix, which shields them from immune rejection and fibrosis. Sigilon was founded by Flagship Pioneering in conjunction with Daniel Anderson, Ph.D., and Robert Langer, Sc.D., of the Massachusetts Institute of Technology.

Forward-Looking Statements
This press release contains forward-looking statements, including, without limitation, statements relating to the potential benefits of our product candidate SIG-007 and our plans to make regulatory submissions. Investors are cautioned not to place undue reliance on these forward-looking statements. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, those risks and uncertainties related to our preclinical research, product candidates, the initiation and enrollment for our clinical trials and the regulatory filings related thereto and other risks identified in our SEC filings, including our Prospectus filed with the SEC on December 7, 2020 and subsequent filings with the SEC. We caution you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. We disclaim any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent our views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.

SOURCE: Sigilon Therapeutics

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