Sigilon Therapeutics Announces Acceptance of Clinical Trial Application in the UK for SIG-005 for the Treatment of Mucopolysaccharidosis Type I

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CAMBRIDGE, Mass., Sept. 09, 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 Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom has accepted the Company's Clinical Trial Application (CTA) for SIG-005 in Mucopolysaccharidosis Type I (MPS-1), a chronic, progressive lysosomal disease.

SIG-005 contains a human cell line genetically modified with a non-viral vector designed to express human a-L-iduronidase (IDUA), an enzyme which is missing or defective in patients with MPS-1. The IDUA enzyme is essential for the breakdown of glycosaminoglycans (GAGs) in the lysosomes of patients with MPS-1, as the progressive accumulation of GAGs results in multi-organ involvement.

"With its impact on many systems throughout the body, MPS-1 presents unique treatment challenges and presently requires regular maintenance therapy that can place a significant burden on patients and their families," said Rogerio Vivaldi, M.D., President and Chief Executive Officer of Sigilon. "Our goal with SIG-005 is to develop a non-viral, durable, redosable, and controllable approach that can deliver sustained levels of IDUA to patients with MPS-1. With this approval, we remain on track to initiate our Phase 1/2 study in the UK in the second half of this year."

The Company has also filed a CTA in Brazil and plans to submit an Investigational New Drug Application with the U.S. Food and Drug Administration.

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 diseases 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 includes forward-looking statements. These forward-looking statements generally can be identified by the use of words such as "anticipate," "expect," "plan," "could," "may," "will," "believe," "estimate," "forecast," "goal," "project," and other words of similar meaning. These forward-looking statements address various matters, including the potential benefits of SIG-005, our ability to initiate the Phase 1/2 clinical trial of SIG-005 in MPS-1 by the end of 2021, if at all, and the status of our regulatory submissions related thereto. Each forward-looking statement contained in this press release is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statement. Applicable risks and uncertainties include, among others, that favorable preclinical results are not predictive of clinical trial results, our ability to resolve the clinical hold on SIG-001, the FDA or other regulators may request additional preclinical studies or clinical trials beyond those that we currently anticipate, and the risks identified under the heading "Risk Factors" in our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2021, and filed with the Securities and Exchange Commission (the "SEC"), as well as the other information we file with the SEC. We caution investors not to place considerable reliance on the forward-looking statements contained in this press release. You are encouraged to read our filings with the SEC, available at www.sec.gov, for a discussion of these and other risks and uncertainties. The forward-looking statements in this press release speak only as of the date of this document, and we undertake no obligation to update or revise any of these statements. Our business is subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties.

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