# Sigilon Therapeutics Announces Clinical Hold on SIG-001 Phase 1/2 Study in Hemophilia A

July 9, 2021

CAMBRIDGE, Mass., July 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 reported that the U.S. Food and Drug Administration (FDA) has notified the Company that its Phase 1/2 study of SIG-001 in patients with severe or moderately severe hemophilia A, has been placed on clinical hold. The clinical hold was initiated following the Company's submission of a serious adverse event (SAE) and temporary enrollment halt to the FDA and other regulatory agencies.

To date, three patients have been dosed with SIG-001. The third patient, who received the highest dose of study drug, developed inhibitors to Factor VIII (FVIII) — a well-known complication of FVIII therapy. The patient is responding well to medical treatment and his condition continues to improve. Among other things, the FDA has requested additional information or data on factors potentially contributing to the development of inhibitors in this patient, such as family history and immune stimulation from a recent vaccination. All three patients enrolled in this study will continue to be followed per study protocol, while the company investigates the SAE.

"Patient safety is our top priority, and we are encouraged that the patient is recovering," said Rogerio Vivaldi, M.D., President and CEO of Sigilon. "In collaboration with the regulatory agencies and our advisors, we are conducting a thorough investigation of this event to confirm whether there was a causal relationship between the development of inhibitors and SIG-001. We are committed to working with the FDA to resolve the clinical hold."

The status of the SAE investigation will continue to be reviewed by the Safety Review Committee for SIG-001 and Sigilon will provide additional data when available.

**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 our platform and product candidates and our ability to resolve the clinical hold of the Phase 1/2 clinical trial of SIG-001. 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 we have incurred significant losses since inception and our need for additional funding; the SLTx platform consists of novel technologies that are not yet clinically validated for human therapeutic use; that we have only any results from the testing of any of our product candidates in clinical trials and any favorable preclinical results are not predictive of results that may be observed in clinical trials; we may be unable to obtain and maintain patent protection and other intellectual property rights for SIG-001 or any other product candidates and for our SLTx platform, or the scope of the patent and other intellectual property protection obtained may not be sufficiently broad; and the risks identified under the heading "Risk Factors" in our Quarterly Report on Form 10-Q for the period ended March 31, 2021 and in any subsequent filings with the Securities and Exchange Commission. 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.

Source: Sigilon Therapeutics

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