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

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CAMBRIDGE, Mass., Nov. 29, 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 fibrosed spheres were observed during a retrieval procedure in a patient in its Phase 1/2 study of SIG-001 in severe or moderately severe hemophilia A.

The SIG-001 trial had been placed on clinical hold by the FDA in July 2021 following Sigilon's submission of a serious adverse event report relating to the development of inhibitors to Factor VIII in one of three patients treated. This patient underwent a laparoscopic procedure prescribed by the investigator to retrieve implanted spheres. Upon inspection, it was determined that the spheres placed in the patient had fibrosed and that cells within the spheres were no longer viable.

While the Company investigates the fibrosed spheres in this patient, all three patients enrolled in the SIG-001 trial will continue to be followed per study protocol. These findings may have an impact on the timing of initiating dosing of patients in its planned Phase 1/2 clinical trial of SIG-005 for mucopolysaccharidosis type I (MPS-1).

"Patients' safety and welfare are our highest priority. We are gathering information in order to understand these observations," said Rogerio Vivaldi, M.D., President and CEO of Sigilon. "We will be working closely with the FDA, other regulators, and advisors to determine the impact of these observations on our programs."

The status of Sigilon's clinical hold investigation, including these findings, will be reviewed by the Safety Review Committee for SIG-001 at its next meeting in December.

**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 encapsulated by Sigilon's Afibromer™ biomaterials matrix, which is designed to shield 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 impact of this observation on our programs, including our ability to resolve the clinical hold of the Phase 1/2 clinical trial of SIG-001 and our timeline for the Phase 1/2 clinical trial of SIG-005. 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, manufacturing changes may not have the desired effect, the SLTx platform consists of novel technologies that are not yet clinically validated for human therapeutic use, and the risks identified under the heading "Risk Factors" in our Quarterly Report on Form 10-Q for the period ended September 30, 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.

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