August 8, 2022

Sapience Therapeutics Announces Surgical Sub-Study of Ongoing Phase 1-2 Trial of ST101 in Recurrent and Newly Diagnosed GBM Patients

-Sub-study is designed to evaluate the safety and tolerability of ST101 as monotherapy in recurrent GBM patients and in combination with radiation ± temozolomide in newly diagnosed patients-

- ST101 demonstrated clinical proof-of-concept with a confirmed partial response in a patient with recurrent GBM in Phase 2 expansion cohort-

HARRISON, N.Y., Aug. 8, 2022 /PRNewswire/ -- Sapience Therapeutics, Inc., a clinical-stage biotechnology company focused on the discovery and development of novel peptide therapeutics to address difficult-to-treat cancers, announced today that the company will conduct a sub-study of its ongoing Phase 1-2 clinical trial of ST101 in recurrent and newly diagnosed GBM patients. The sub-study will be conducted by Sapience in collaboration with principal investigators at Columbia University and Northwestern University. Partial funding for the sub-study was awarded to Fabio Iwamoto, Principal Investigator at Columbia University, through a research grant from the Ben and Catherine Ivy Foundation.

The study is a multi-site, open-label surgical sub-study of the Phase 1-2 protocol ST101 to determine the safety, tolerability, PK, PD, and proof-of-concept efficacy of ST101 in 18 patients with recurrent (n=6) and newly diagnosed GBM (n=12). The primary objectives of the study will be to evaluate the safety and tolerability of ST101 as monotherapy in recurrent GBM patients post resection and in newly diagnosed GBM patients in combination with radiation ± temozolomide post resection. The secondary objectives of the study will be to determine the penetration of ST101 in the brain and its correlation with plasma levels. In both study arms, patients will be resected following two to four doses of ST101 and will continue on ST101 following surgery.

"We are thrilled to continue to evaluate the therapeutic potential of ST101, which has demonstrated very promising clinical data in the ongoing Phase 1-2 study with confirmed partial responses in multiple tumor types, including GBM. In the surgical sub-study, we aim to demonstrate further evidence of ST101's ability to penetrate the brain and inhibit transcription of C/EBPβ, which is a master regulator of GBM tumors," said Fabio Iwamoto, Principal Investigator at Columbia University. "Our team at Columbia remains very excited about our work with Sapience and we look forward to continuing to deliver clinical benefit to cancer patients with ST101."

ST101 is a first-in-class peptide antagonist of C/EBPβ with a dual mechanism of action. ST101 antagonism of C/EBPβ promotes (1) a more favorable immune tumor microenvironment by inhibiting formation of immunosuppressive myeloid-derived suppressor cells (MDSCs) and (2) cytotoxic activity in tumor cells by disrupting C/EBPβ-driven oncogenic activity. In its ongoing Phase 1-2 study, ST101 has demonstrated clinical proof-of-concept with a mRANO-confirmed partial response in a patient with recurrent GBM, a durable RECIST 1.1-confirmed partial response in a patient with cutaneous melanoma and long-lasting stable disease in several additional patients.

Alice Bexon, Sapience's Chief Medical Officer, commented, "We remain very pleased with ST101's clinical profile and we look forward to evaluating ST101 in the surgical sub-study announced today. The data generated from this study, if positive, will provide early safety and efficacy signs that would allow us to advance ST101 into a first-line therapeutic option for GBM, which would be transformative for this patient population."

About ST101 and the Phase 1-2 Study

ST101, a first-in-class antagonist of C/EBPβ, is currently being evaluated in the Phase 2 portion of an ongoing Phase 1-2 clinical study in patients with advanced unresectable and metastatic solid tumors (NCT04478279). ST101-101 is an open-label, two-part, Phase 1-2 dose-finding study designed to determine the safety, tolerability, PK, PD, and proof-of-concept efficacy of ST101 in patients with advanced solid tumors. The study consists of two phases: Phase 1 dose escalation/regimen exploration and Phase 2 dose expansion. In the ongoing Phase 2 dose expansion, Sapience is actively enrolling patients with GBM, metastatic cutaneous melanoma, castration-resistant prostate cancer and locally advanced or metastatic hormone-receptor positive breast cancer. In the ongoing dose escalation part of the study, ST101 has demonstrated clinical proof-of-concept with a durable RECIST 1.1-confirmed partial response (PR) in a patient with cutaneous melanoma and evidence of long-lasting stable disease in several additional patients. In the ongoing Phase 2 dose expansion part of the study, ST101 has demonstrated clinical proof-of-concept with a mRANO-confirmed partial response in a patient with recurrent GBM and evidence of long-lasting stable disease in several additional patients.

ST101 has been granted Fast Track designation for recurrent GBM and advanced cutaneous melanoma in patients who have disease progression on or after anti-PD-1/anti-PD-L1 therapy, as well as orphan designations from the FDA for advanced melanoma, glioma and AML, and from the European Commission for the treatment of glioma.

About Sapience Therapeutics

Sapience Therapeutics, Inc. is a privately held, clinical-stage biotechnology company focused on discovering and developing novel peptide therapeutics for major unmet medical needs, particularly high mortality cancers. Sapience's approach holds potential to target intracellular interactions that are traditionally considered "undruggable targets". Its lead program, ST101, is a peptide antagonist of C/EBPβ that has demonstrated clinical proof-of-concept in multiple indications. For more information on Sapience Therapeutics, please visit www.sapiencetherapeutics.com and engage with us on LinkedIn.

Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements. Any statements herein other than statements of historical fact could be deemed to be forward-looking statements. These forward-looking statements may include, among other things, statements regarding future events that involve significant risks and uncertainties (including with respect to Sapience's preclinical and clinical development programs). These forward-looking statements are based on management's current expectations, and actual results and future events may differ materially as a result of certain factors, including, without limitation, our ability to obtain additional funds, and meet applicable regulatory standards and receive required regulatory approvals. Forward-looking statements speak only as of the date of this press release. Sapience does not undertake any obligation to update any forward-looking statements as a result of new information, future events, changed assumptions or otherwise, except as required by law.

Contacts
Sapience Therapeutics, Inc.
Barry Kappel, Ph.D., M.B.A.
President and Chief Executive Officer
info@sapiencetherapeutics.com

Media and Investor Contact:
Amy Conrad
Juniper Point
(858) 366-3243
amy@juniper-point.com

View original content to download multimedia: https://www.prnewswire.com/news-releases/sapience-therapeutics-announces-surgical-sub-study-of-ongoing-phase-1-2-trial-of-st101-in-recurrent-and-newly-diagnosed-gbm-patients-301601435.html

SOURCE Sapience Therapeutics, Inc.