June 2, 2022

Sapience Therapeutics Announces Expansion of Phase 2 Study Arm with ST101 in Patients with Recurrent Glioblastoma (GBM) Based on Confirmed Partial Response (PR)

- Response data supports monotherapy activity of ST101 in patients with recurrent GBM and provides further clinical proof-of-concept for therapeutic modulation of C/EBPß-

HARRISON, N.Y., June 2, 2022 /PRNewswire/ -- Sapience Therapeutics, Inc., a clinical-stage biotechnology company focused on the discovery and development of peptide therapeutics to address difficult-to-treat cancers, announced today interim clinical data, including a confirmed PR per mRANO (meaning >50% reduction in tumor measurements) in a glioblastoma (GBM) patient from its ongoing Phase 1-2 study in patients with advanced unresectable and metastatic solid tumors (NCT04478279).

In the Phase 2 expansion portion of the ongoing Phase 1-2 study of ST101, 14 GBM patients have been enrolled to date. Of these 14 patients, one patient has a confirmed PR after 18 weeks of therapy, seven patients have not reached the first on-study assessment, and six patients progressed. In both the Phase 1 and Phase 2 portions of the ongoing study, ST101 has demonstrated a favorable safety profile, with manageable mild-moderate infusion related reactions as the most common adverse event. Based on the confirmed PR announced today, Sapience intends to expand the recurrent GBM cohort to enroll additional patients.

"ST101 is showing promising results in GBM with a PR, which we have confirmed with repeat scans per mRANO and using an independent radiology reviewer. The tumor shrinkage we are seeing is especially encouraging given the significant unmet medical need in this disease and its poor prognosis," said Fabio Iwamoto, Principal Investigator at Columbia University. "Our team at Columbia is thrilled to be a part of this work and to deliver meaningful therapeutic benefit to cancer patients."

Dr. Alice Bexon, Sapience's Chief Medical Officer, added, "The confirmed response in GBM is very exciting news, which along with the continuing clinical benefit we are seeing from some of the Phase 1 patients, suggests that ST101 could make a major contribution to the treatment of cancer. Based on its novel mechanism of action, ST101 is the first in a new class of peptide therapeutics, and we look forward to advancing our Phase 2 study."

Data from the ST101 Phase 1 study will be presented at the American Society of Clinical

Oncology (ASCO) Annual Meeting on Sunday, June 5th, 2022, Abstract #3014.

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 expansion. In the ongoing dose escalation 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 confirmed partial response in a patient with recurrent GBM. Sapience is actively enrolling patients with GBM, metastatic cutaneous melanoma, locally advanced or metastatic hormone-receptor positive breast cancer and castration-resistant prostate cancer. 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 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, including confirmed partial responses in cutaneous melanoma in Phase 1 and GBM in Phase 2. ST101 is currently being evaluated in the Phase 2 portion of an ongoing Phase 1-2 clinical study with potential applications in various solid tumors and hematologic malignancies. 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-expansion-of-phase-2-study-arm-with-st101-in-patients-with-recurrent-glioblastoma-gbm-based-on-confirmed-partial-response-pr-301560073.html

SOURCE Sapience Therapeutics, Inc.