July 29, 2021

Sapience Therapeutics Commences Dosing in Final Dose-Escalation Cohort of Ongoing Phase 1-2 Study of ST101

-ST101 Demonstrated Clinical Proof-of-Concept with Confirmed PR in Phase 1 Study-

-Phase 2 Expected to Initiate in 2H 2021-

HARRISON, N.Y., July 29, 2021 /PRNewswire/ -- Sapience Therapeutics, Inc., a biotechnology company focused on the discovery and development of peptide therapeutics to address difficult-to-treat cancers, announced today that it has commenced dosing in the final dose-escalation cohort of an ongoing Phase 1-2 study of its lead program, ST101, for the treatment of patients with advanced and metastatic solid tumors.

In the ongoing study, ST101 has demonstrated clinical proof-of-concept with a RECIST 1.1-confirmed partial response (PR) in a patient with cutaneous melanoma and evidence of long-lasting stable disease in several additional patients. Following conclusion of the sixth dose cohort, Sapience plans to initiate four Phase 2 expansion cohorts in refractory, locally advanced and metastatic cutaneous melanoma, hormone-receptor-positive breast cancer, castrate-resistant prostate cancer, and glioblastoma starting in the second half of this year.

"ST101 is a very important program for Sapience and it has performed quite well in its initial Phase 1 clinical study," said Dr. Barry Kappel, Founder and Chief Executive Officer of Sapience Therapeutics. "ST101 has been well tolerated, non-immunogenic, and has a pharmacokinetic profile to support a once weekly dosing regimen. We are thrilled that ST101 has demonstrated early signs of clinical activity in several tumor types and we look forward to advancing ST101 into Phase 2 later this year."

Dr. Alice Bexon, Sapience's Chief Medical Officer, added, "The efficacy and safety of ST101 demonstrated in Phase 1 is very promising. We have not seen dose limiting toxicity to date, and we now have patients with nearly 1 year of exposure. ST101 is well positioned to be an exciting novel weapon against refractory cancers and to deliver a clinical benefit to patients."

In addition to the clinical update, Sapience also announces today that the European Commission (EC) granted orphan medicinal product designation to ST101 for the treatment of glioma. Orphan Drug Designation in the European Union ("EU") is granted by the EC based on a positive opinion issued by the EMA Committee for Orphan Medicinal Products. To qualify, an investigational medicine must be intended to diagnose, prevent or treat a chronically debilitating or life-threatening condition that affects fewer than five in 10,000

people in the EU, and there must be sufficient non-clinical or clinical data to suggest the investigational medicine may produce clinically relevant outcomes. EMA orphan drug designation provides companies with certain benefits and incentives, including protocol assistance, differentiated evaluation procedures for Health Technology Assessments in certain countries, access to a centralized marketing authorization procedure valid in all EU member states, reduced regulatory fees and 10 years of market exclusivity. Sapience previously announced receipt of orphan drug product designation from the U.S. Food and Drug Administration (FDA) in 2020.

About ST101

ST101 is a peptide antagonist of C/EBPβ, and in July 2020 it entered into a Phase 1-2 clinical study in patients with advanced unresectable and metastatic solid tumors (NCT04478279). C/EBPβ is a transcription factor overexpressed or activated in many cancers, but not active in normal cells (post-differentiation), providing a unique therapeutic opportunity. In tumors, C/EBPβ promotes survival and proliferation and regulates cellular differentiation. ST101 significantly decreases the expression of C/EBPβ target genes/proteins involved in oncogenesis including BCL-2, BIRC5/survivin, cyclins and ID family of proteins. As a result, ST101 induces selective cancer cell cytotoxicity across a variety of tumor types, including but not limited to breast cancer, melanoma, prostate cancer, GBM, lung cancer, and AML.

About Sapience Therapeutics

Sapience Therapeutics, Inc., is a privately held, clinical stage biotechnology company focused on discovering and developing peptide-based therapeutics for major unmet medical needs, particularly high mortality cancers. With platform-based discovery of peptide therapeutics that disrupt protein-protein interactions, Sapience's molecules hold potential to target intracellular interactions that are traditionally considered "undruggable targets". Its lead compound, ST101, is a first-in-class molecule 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, risks related to the application of the net proceeds from the offering to Sapience's product development objectives, 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-commences-dosing-in-final-dose-escalation-cohort-of-ongoing-phase-1-2-study-of-st101-301344217.html

SOURCE Sapience Therapeutics, Inc.