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Sapience Therapeutics Announces Publication Showcasing the Mechanism of Action and Anti-tumor Activity of ST101, a Novel and Selective Peptide Antagonist of C/EBP β , in Molecular Cancer Therapeutics

HARRISON, N.Y., Sept. 19, 2022 /PRNewswire/ -- Sapience Therapeutics, Inc., a clinical-stage biotechnology company focused on the discovery and development of peptide therapeutics to address oncogenic and immunogenic dysregulation that drive cancer, announced today that preclinical data on ST101, the company's first-in-class peptide antagonist of C/EBP β , were published online in *Molecular Cancer Therapeutics*, a journal of the American Association for Cancer Research. The published data describe preclinical evidence to support the advancement of ST101 as a novel therapy for treating advanced solid tumors. The full manuscript titled "*Anti-cancer activity of ST101, a novel antagonist of CCAAT/enhancer binding protein β* ", can be found online [here](#).

The data in the manuscript detail ST101-antagonism of CCAAT/Enhancer Binding Protein β (C/EBP β), a basic leucine zipper family transcription factor that is upregulated or overactivated in many cancers, resulting in gene transactivation that drives oncogenesis. ST101 binds C/EBP β , preventing its dimerization and enhancing ubiquitin-proteasome dependent C/EBP β degradation. ST101 exposure significantly decreases expression of C/EBP β target genes including genes responsible for survival, transcription factors and cell cycle-related proteins. The result of ST101 exposure is potent, tumor-specific in vitro cytotoxic activity in cancer cell lines including glioblastoma, breast, melanoma, prostate, and lung cancer, while normal human immune and epithelial cells are not impacted. In vivo xenograft models indicate that ST101 exposure results in potent tumor growth inhibition or regression, both as a single agent and in combination studies.

"The publication of ST101 in *Molecular Cancer Therapeutics* is an exciting achievement, highlighting the tremendous unmet need for novel therapies to treat solid tumor cancers and the role that ST101 can play to fill this need," said Jim Rotolo, Ph.D., Sapience's VP, Translational Pharmacology and Head of Research. "We are thrilled to publish the mechanism of action of ST101 and showcase the therapeutic promise of disrupting C/EBP β -driven oncogenic activity. We look forward to reporting and publishing additional data on ST101 and advancing the program through its ongoing Phase 1-2 study."

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.

About ST101 and the Phase 1-2 Study

ST101, a first-in-class antagonist of C/EBP β , 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](https://clinicaltrials.gov/ct2/show/study/NCT04478279)). ST101-101 is an open-label, 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 peptide therapeutics to address oncogenic and immunogenic dysregulation that drive cancer. Its pipeline of SPEARs™ (Stabilized Peptides Engineered Against Regulation) disrupt intracellular protein-protein interactions, enabling targeting of transcription factors which have traditionally been considered undruggable. Sapience's lead program, ST101, is a first-in-class antagonist of C/EBP β 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.

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