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Sapience Therapeutics Receives FDA Orphan Drug Designation for ST101 for the Treatment of Advanced Melanoma

HARRISON, N.Y., May 3, 2022 /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 the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) to its lead program, ST101, for the treatment of advanced melanoma for patients in stages IIB through IV. This is the third orphan drug designation received for the ST101 program, following orphan designations by the FDA for the treatment of AML in April 2018 and for glioma in June 2020.

ST101 is a first-in-class peptide antagonist of C/EBPβ 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 that are refractory to standard therapy (NCT04478279). This study includes expansion cohorts that are currently dosing and enrolling patients with GBM, cutaneous melanoma, locally advanced or metastatic hormone-receptor positive breast cancer and castration-resistant prostate cancer.

Dr. Barry Kappel, Sapience's CEO and President, commented, "Patients with advanced stage melanoma have very poor prognosis with a median survival of less than two years from diagnosis. The available treatments are limited, and many patients are refractory to targeted approaches or immunotherapy agents. With its unique mechanism of action targeting a key transcription factor C/EBPβ, we have a significant opportunity to deliver a novel therapeutic option with ST101. Our clinical plans remain on track, and we look forward to completing enrollment in all four expansion cohorts in Phase 2."

Dr. Gina Capiaux, Sapience's Vice President, Regulatory Affairs added, "Receiving our third Orphan Drug Designation is another important regulatory achievement that reinforces the FDA's recognition of the potential of ST101 to improve clinical outcomes in patients with advanced melanoma. We look forward to quickly advancing the development of ST101 for patients in need."

Orphan Drug Designation is granted to drugs or biological products for the treatment of rare diseases or conditions that impact fewer than 200,000 people in the United States. Incentives that come with the designation include eligibility for federal grants, research and development tax credits, waiver of filing fees, and the potential for a 7-year marketing exclusivity period. The designation does not alter the standard regulatory requirements and process for obtaining marketing approval. ST101 also previously received 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.

About ST101

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: a Phase 1 dose escalation/regimen exploration phase and a Phase 2 expansion phase. In the ongoing dose escalation 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. In the ongoing Phase 2 dose expansion part of the study, Sapience has initiated enrollment in 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 Phase 1 with a confirmed partial response (PR). 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.

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