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# Sapience Therapeutics Receives FDA Fast Track Designation for ST101 for Advanced Cutaneous Melanoma

HARRISON, N.Y., Dec. 15, 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 the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation (FTD) to its lead program, investigating ST101 for the treatment of advanced cutaneous melanoma in patients who have disease progression on or after anti-PD-1/anti-PD-L1 therapy. This is the second FTD designation received for the ST101 program, following FTD for recurrent glioblastoma (GBM), announced in early December 2021. ST101 is currently being evaluated in an ongoing Phase 1-2 clinical study in patients with advanced unresectable and metastatic solid tumors, which includes expansion cohorts in patients with cutaneous melanoma and refractory GBM.

Dr. Barry Kappel, Sapience's CEO and President, commented, "Melanoma is the fifth most diagnosed cancer in the U.S., with more than 100,000 new cases per year, and no well-established standard of care treatment regimen. We believe we have a significant opportunity to deliver a novel therapeutic option with ST101, which has a durable clinical efficacy and an excellent safety profile, for melanoma patients whose disease has progressed following treatment with anti-PD-1 therapy."

Dr. Gina Capiaux, PhD, Sapience's Head of Regulatory Affairs added, "This is the second Fast Track designation received for ST101, underscoring the advancement of our ST101 program and its potential therapeutic benefit for both melanoma and GBM patients. We are grateful for the opportunity to quickly advance the development of ST101 for patients in need."

Fast Track designation enables more frequent interactions with the FDA to expedite the development and review process for drugs intended to treat serious or life-threatening conditions that demonstrate the potential to address unmet medical needs. Sapience also previously received Orphan Drug Designation from the U.S. FDA and European Commission for ST101 for the treatment of glioma.

***About ST101***

ST101, a peptide antagonist of C/EBPβ, is currently being evaluated in an ongoing Phase 1-2 clinical study in patients with advanced unresectable and metastatic solid tumors (NCT04478279). 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 final dose-escalation 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 2021. 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 drug product designation from the U.S. Food and Drug Administration and orphan medicinal product designation by 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-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.

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