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Sapience Therapeutics Receives FDA Fast Track Designation for ST101 for the Treatment of Recurrent Glioblastoma Multiforme (GBM)

HARRISON, N.Y., Dec. 6, 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 to its lead program investigating ST101 for the treatment of recurrent glioblastoma (GBM). ST101 is currently being evaluated in an ongoing Phase 1-2 clinical study in patients with advanced unresectable and metastatic solid tumors, which includes a GBM expansion cohort.

In the ongoing Phase 1-2 study, ST101 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 with refractory solid tumors.

"Glioblastoma is the most aggressive, fatal form of brain cancer with limited-to-no therapeutic options. With the efficacy data from solid tumors and its ability to cross the blood-brain barrier, ST101 could meaningfully improve outcomes for patients battling this debilitating disease and we look forward to advancing it into Phase 2," said Dr. Barry Kappel, Sapience's CEO and President.

Dr. Gina Capiaux, PhD, Sapience's Head of Regulatory Affairs added, "This is an exciting regulatory milestone for our program. Fast Track designation for ST101 highlights this unmet need and allows us to work closely with the FDA to deliver this novel therapy to people with GBM as soon as possible."

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 previously received Orphan Drug Designation from the FDA and European Commission for ST101 for the treatment of glioma.

About Glioblastoma

Glioblastomas are a class of malignant glioma and represent the most common and serious type of primary brain tumors. GBMs account for approximately 14% of all primary brain and Central Nervous System (CNS) tumors and 50% of all malignant brain tumors. Despite standard treatments including surgery, chemotherapy, and radiation, GBM has a rapid

progression and high mortality with a median survival less than 8 months and a five-year survival rate of 6.6%.

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 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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