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Sapience Therapeutics Announces FDA Acceptance of IND Application for ST101 in Advanced Cancer Indications

ST101 Granted Orphan Drug Designation for the Treatment of Glioma

HARRISON, NY / ACCESSWIRE / June 2, 2020 /Sapience Therapeutics, Inc., a biotechnology company focused on the discovery and development of peptide therapeutics to address difficult-to-treat oncology indications, announced today that the U.S. Food and Drug Administration (FDA) has accepted the Investigational New Drug (IND) application for ST101, a peptide therapy being evaluated for the treatment of adults with unresectable and metastatic solid tumors. Sapience also announced that ST101 has been granted orphan drug designation by the FDA for the treatment of glioma.

"We are very excited to have achieved this regulatory milestone and delighted to be moving ST101 into the clinic," said Dr. Alice Bexon, Chief Medical Officer of Sapience Therapeutics. "This drug has the potential to attack the cancer in a completely new way, targeting characteristics of tumors that make them different from the rest of the body. We are particularly interested to explore ST101 in glioblastoma, where our preclinical data and ability to cross the blood-brain barrier have the potential to transform a disease that current treatments barely touch."

ST101 is a peptide antagonist of the transcription factor C/EBPβ, which is typically expressed and active in stem cells or early progenitor cells but not in most mature or differentiated cells. Certain cancers activate C/EBPβ, which results in the expression of genes with roles in cell proliferation, differentiation, and the cell cycle. Disruption of this transcription factor with ST101 results in targeted killing of cancer cells, as normal cells do not rely on C/EBPβ driven transcription for survival.

The Phase 1/2 trial will enroll patients at several leading clinical centers in the US and UK. The trial will start with a dose escalation phase to assess the safety and tolerability of ST101, followed by an expansion phase to evaluate preliminary efficacy in patients with glioblastoma, locally advanced/metastatic breast cancer, castration-resistant prostate cancer and melanoma. Site qualification activities are underway, and Sapience anticipates enrolling the first patient in July 2020.

About Orphan Drug Designation

Under the U.S. Orphan Drug Act, FDA's Office of Orphan Products Development grants

orphan drug designation to investigational drugs and biologics that are intended for the treatment, diagnosis or prevention of rare diseases that affect fewer than 200,000 people in the U.S. Orphan drug status is intended to facilitate drug development for rare diseases and may provide several benefits to drug developers, including protocol assistance , tax credits for qualified clinical trials costs, exemptions from certain FDA application fees, and seven years of market exclusivity upon regulatory product approval.

About Glioma

Gliomas are a form of cancer that represent the most common and serious types of primary brain tumors. Approximately 30% of all primary brain and Central Nervous System (CNS) tumors and 80% of all malignant brain tumors are gliomas. The term "glioma" constitutes a broad class of CNS tumors derived from glial origin, primarily including glioblastoma (GBM), astrocytoma, oligodendroglioma, and ependymoma. GBM accounts for nearly 70% of gliomas and is the most aggressive and deadliest of malignant brain tumors in adults. Despite standard treatments including surgery, chemotherapy, and radiation, the median survival for the majority of gliomas as a whole is 2-3 years and less than 15 months for GBM.

About Sapience Therapeutics

Sapience Therapeutics, Inc., is a privately held, preclinical 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. In 2016, Sapience Therapeutics closed its Series A financing, which was led by Eshelman Ventures and included investments from Celgene Corporation, TaiAn Technologies Corporation and Healthlink Capital. For more information on Sapience Therapeutics, please visit www.sapiencetherapeutics.com.

Forward-Looking Statements

This press release contains forward-looking statements, and any statements 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. These 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. These are forward-looking statements, which 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.

Contacts

Sapience Therapeutics, Inc.

Barry Kappel, Ph.D., M.B.A.
President and Chief Executive Officer
info@sapiencetherapeutics.com

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