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Sapience Therapeutics Receives Orphan Drug Designation from the U.S. FDA for ST-36 for the Treatment of Glioma

SCARSDALE, NY -- (Marketwired) -- 03/29/17 -- [Sapience Therapeutics, Inc.](#), a biotechnology company focused on developing novel therapeutics to address difficult to treat oncology indications, announced today that its lead candidate, ST-36, has received orphan drug designation by the U.S. Food and Drug Administration (FDA) for the treatment of glioma.

Gliomas are a form of malignant brain cancer that affect approximately 18,000 to 20,000 individuals annually in the U.S. Nearly 70% of gliomas are glioblastoma (GBM), which is the most severe and deadly form of brain cancer.

"We are very pleased to receive FDA Orphan Drug Designation for ST-36 for the treatment of glioma," stated Barry Kappel, president and chief executive officer of Sapience. "The FDA's decision is an important milestone in the development of our lead product candidate and highlights the high unmet medical need for new therapies that have the potential to transform the lives of glioma patients and their families."

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 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 assistance with clinical study design and drug development, 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 brain tumors and 80% of all malignant brain tumors are gliomas, which equates to approximately 18,000 to 20,000 new cases of glioma diagnosed annually in the U.S. The term "glioma" constitutes a broad class of central nervous system tumors derived from glial origin, primarily including 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. Although there are treatments available for GBM including surgical resection, chemotherapy, and radiation, the median survival of GBM patients is less than 15 months. Furthermore, the two- and five-year survival rates for GBM are only 15% and 5%, respectively, with a median progression free survival of 6.9 months.

About Sapience Therapeutics

Sapience Therapeutics, Inc., is a privately held, preclinical stage biotechnology company focused on developing novel therapeutics for major unmet medical needs, particularly high mortality cancers. Our drug development program involves translating science into novel therapies, and our initial goal is to develop a first-in-class treatment for glioblastoma (GBM), which is the most severe and deadly form of brain cancer. For more information on Sapience Therapeutics, please visit www.sapiencetherapeutics.com.

Cautionary Note on 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.

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Source: Sapience Therapeutics, Inc.