July 22, 2014

SAGE Therapeutics Receives Fast Track Designation for Lead Compound SAGE-547 to Treat Status Epilepticus

Designation Underscores Unmet Medical Need for Life-Threatening Seizure Condition

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- SAGE Therapeutics (NASDAQ: SAGE), a biopharmaceutical company developing novel medicines to treat life-threatening, rare central nervous system (CNS) disorders, announced today that the U.S. Food and Drug Administration (FDA) has granted fast track designation to the SAGE-547 development program. SAGE-547 is an allosteric modulator of $GABA_A$ receptors in development for the treatment of adult patients with refractory status epilepticus who have not responded to standard regimens (super-refractory status epilepticus, or SRSE). SAGE is currently evaluating SAGE-547 in a Phase 1/2 clinical trial for the treatment of SRSE. Preliminary data indicate that the first four patients enrolled in the clinical trial met the key efficacy endpoint, in that each was successfully weaned off his or her anesthetic agent while SAGE-547 was being administered. There have also been no reported drug-related serious adverse events in these four patients to date.

"The fast track designation for SAGE-547 recognizes the significant unmet need that exists in the treatment of super-refractory status epilepticus," said Jeff Jonas, MD, chief executive officer of SAGE Therapeutics. "The receipt of orphan drug designation earlier this year for status epilepticus and the fast track designation are both significant regulatory milestones for SAGE-547, and we will continue to work closely with the FDA to advance our lead compound and the additional programs in our pipeline for the treatment of life-threatening CNS disorders."

Fast track designation is granted by the FDA to facilitate the development and expedite the review of drug candidates that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs.

About SAGE-547

SAGE-547 is an allosteric modulator of both synaptic and extra-synaptic $GABA_A$ receptors. $GABA_A$ receptors are widely regarded as validated drug targets for a variety of CNS disorders, with decades of research and multiple approved drugs targeting these receptor systems. SAGE-547 is an intravenous agent in Phase 1/2 clinical development as an adjunctive therapy, a therapy combined with current therapeutic approaches, for the treatment of SRSE.

About Status Epilepticus (SE)

SE is a life-threatening seizure condition that occurs in approximately 150,000 people each year in the U.S., of which 30,000 SE patients die.[1] We estimate that there are 35,000 patients with SE in the U.S. that are hospitalized in the intensive care unit (ICU) each year. An SE patient is first treated with benzodiazepines, and if no response, is then treated with other, second-line, anti-seizure drugs. If the seizure persists after the second-line therapy, the patient is diagnosed as having refractory SE (RSE), admitted to the ICU and placed into a medically induced coma. Currently, there are no therapies that have been specifically approved for RSE; however, physicians typically use anesthetic agents to induce the coma and stop the seizure immediately. After a period of 24 hours, an attempt is made to wean the patient from the anesthetic agents to evaluate whether or not the seizure condition has resolved. Unfortunately, not all patients respond to weaning attempts, in which case the patient must be maintained in the medically induced coma. At this point, the patient is diagnosed as having SRSE. Currently, there are no therapies specifically approved for SRSE.

About SAGE Therapeutics

SAGE Therapeutics (NASDAQ: SAGE) is a biopharmaceutical company committed to developing and commercializing novel medicines to treat life-threatening, rare CNS disorders. SAGE's lead program, SAGE-547, is in clinical development for super-refractory status epilepticus and is the first of several compounds the company is developing in its portfolio of potential seizure medicines. SAGE's proprietary chemistry platform has generated multiple new compounds that target $GABA_A$ and NMDA receptors, which are broadly accepted as impacting many psychiatric and neurological disorders. SAGE Therapeutics is a public company launched in 2010 by an experienced team of R&D leaders, CNS experts and investors. For more information, please visit www.sagerx.com.

Forward-Looking Statements

Various statements in this release concerning SAGE's future expectations, plans and prospects, including without limitation, SAGE's expectations regarding SAGE-547 as a treatment for SRSE, the expected development pathway for its other drug candidates and its expectations with respect to the timing and success of its clinical trials, constitute forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by these forward-looking statements as a result of various important factors, including, without limitation, SAGE's ability to successfully demonstrate the efficacy and safety of its drug candidates, the pre-clinical and clinical results for its product candidates, which may not support further development of product candidates, actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials, obtaining, maintaining and protecting intellectual property, SAGE's ability to enforce its patents against infringers and defend its patent portfolio against challenges from third parties, competition from others developing products for similar uses, SAGE's ability to manage operating expenses, SAGE's ability to obtain additional funding to support its business activities and establish and maintain strategic business alliances and new business initiatives, SAGE's dependence on third parties for development, manufacture, marketing, sales and distribution of products, the outcome of litigation, and unexpected expenditures, as well as those risks more fully discussed in the section entitled "Risk Factors" in the final prospectus related to SAGE's initial public offering filed with the Securities and Exchange Commission pursuant to Rule 424(b) of the Securities Act, as well as discussions of potential risks, uncertainties, and other important factors in SAGE's subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent SAGE's views only as of today and should not be relied upon as representing its views as of any subsequent date. SAGE explicitly disclaims any obligation to update any forward-looking statements.

[1] DeLorenzo, Robert J., Pellock, John M., Towne, Alan R., Boggs, Jane G. Epidemiology of Status Epilepticus. *J Clin Neuro* 1995; 12(4): 316-325.

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Source: SAGE Therapeutics