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SAGE Therapeutics Announces First Patient Treated Under Phase 3 Expanded Access Protocol to Evaluate SAGE-547 in Patients With Super-Refractory Status Epilepticus

Phase 3 STATUS Trial - Randomized, Double-Blind, Placebo-Controlled Clinical Trial of SAGE-547 for the Treatment of Patients With SRSE - Expected to Initiate by Mid-2015

CAMBRIDGE, Mass., April 20, 2015 (GLOBE NEWSWIRE) -- SAGE Therapeutics (Nasdaq:SAGE), a clinical-stage biopharmaceutical company developing novel medicines to treat life-threatening, rare central nervous system (CNS) disorders, today announced completion of treatment for the first patient enrolled in its now initiated open-label expanded access protocol, designated Study 302. Study 302 is designed to offer SAGE-547 to patients affected by super-refractory status epilepticus (SRSE) and to evaluate the safety of SAGE-547 in patients with SRSE. The results from this clinical trial, along with results from SAGE's planned Phase 3 placebo-controlled clinical trial - called the STATUS Trial - and other clinical data obtained from the SAGE-547 development program are intended to form the basis of a New Drug Application (NDA) submission for SAGE-547.

Under expanded access, the U.S. Food and Drug Administration (FDA) works with companies to allow access to investigational therapies to patients with serious or life-threatening illnesses who do not otherwise qualify for participation in a clinical trial and for whom there are no comparable or satisfactory alternate therapies.

"We are pleased to commence our Phase 3 development program with the initiation of Study 302, our open-label expanded access protocol for SAGE-547 in SRSE, a life-threatening seizure disorder for which there are no approved therapies," said Jeff Jonas, M.D., chief executive officer of SAGE. "Study 302 will allow for the expedited treatment of patients who are located at hospitals that are not participating in our Phase 3 placebo-controlled clinical trial and who cannot be transferred to trial sites for medical or other reasons. In addition to Study 302, our team continues to rapidly execute on our development timelines, and we look forward to beginning enrollment of the Phase 3 STATUS Trial by mid-year."

Study 302, the Phase 3 open-label expanded access protocol, will make SAGE-547 available to patients in the United States, aged two years or older, who are affected with SRSE. Patients will receive SAGE-547 as an adjunctive therapy for a six-day treatment regimen and may be eligible for up to two treatments. Dose regimen, trial procedures and assessment of patient outcomes in the expanded access protocol will be consistent with the planned Phase 3 randomized, double-blind, placebo-controlled clinical trial of SAGE-547 for the treatment of patients with SRSE. Patients treated in the expanded access protocol will be monitored for two months following initiation of the last treatment.

"Study 302 will be an important feature of our SAGE-547 development program, as these data will contribute significantly to the SAGE-547 safety database for our planned NDA submission," said Steve Kanes, M.D., Ph.D., chief medical officer of SAGE. "We also plan to convert Study 302 sites into future Phase 3 STATUS Trial sites, potentially accelerating our Phase 3 trial enrollment."

SAGE plans to begin enrollment of the planned STATUS Trial by mid-year, following submission and review by the FDA of the final clinical trial protocol and updated chemistry, manufacturing and controls information.

In addition, the Phase 1/2 clinical trial of SAGE-547 in patients with SRSE has completed enrollment, and SAGE plans to report final clinical data at the Antiepileptic Drug and Device Trials XIII Conference, taking place May 13-15.

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 disorders, with decades of research and multiple approved drugs targeting these receptor systems. SAGE-547 is an intravenous agent entering Phase 3 clinical development as an adjunctive therapy, a therapy combined with current therapeutic approaches, for the treatment of super-refractory status epilepticus (SRSE), as well as in exploratory Phase 2a clinical trials for the treatment of essential tremor and as an adjunctive therapy for the treatment of severe postpartum depression. SAGE plans to begin enrollment of its planned Phase 3 clinical trial, called the STATUS Trial, in mid-2015. SAGE-547 has been granted both Fast Track and orphan drug designations by the U.S. Food and Drug Administration (FDA) for the treatment of SRSE. The active pharmaceutical ingredient, treatment IND and support for emergency-use patients have been contributed under agreement by the Regents of the University of California and the University of California Davis.

About Status Epilepticus

Status epilepticus (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.[i] 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 is a clinical-stage biopharmaceutical company committed to developing and commercializing novel medicines to treat life-threatening, rare central nervous system, or CNS, disorders. SAGE's lead program, SAGE-547, is entering Phase 3 clinical development for super-refractory status epilepticus, or SRSE, and is the first of several compounds the Company is developing in its portfolio of potential anti-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. 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, essential tremor and postpartum depression, statements concerning the potential safety and efficacy of SAGE-547 and durability of response, the final protocol design, statistical power and timing of a planned Phase 3 clinical trial and an open-label, expanded access protocol for SAGE-547, and whether the results from the planned Phase 3 clinical trial together with other available clinical data for SAGE-547 will be sufficient to support submission of an NDA for this product candidate, constitute forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995. In particular, it should be noted that FDA typically requires at least two well-controlled studies be completed prior to submission of an NDA. Whether a single Phase 3 trial of SAGE-547 will be sufficient to support submission of an NDA is typically a review issue to be discussed with FDA following completion of the trial. In addition, it should be noted that the data reported above for SAGE-547 are preliminary in nature. The Phase 1/2 clinical trial has not been completed and the emergency use cases are not part of that clinical trial. There is limited data concerning the safety and efficacy of SAGE-547. These data may not be repeated or observed in ongoing or future studies involving SAGE-547 or SAGE's other product candidates. 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 SAGE's annual report on Form 10-K for the fiscal year ended December 31, 2014, 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.

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

CONTACT: Investor Contact:

Paul Cox, SAGE Therapeutics

paul.cox@sagerx.com

617-299-8377

Media Contact:

Dan Budwick, Pure Communications

dan@purecommunicationsinc.com

973-271-6085

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