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Sage Therapeutics Receives Fast Track Designation for SAGE-217 for the Treatment of Major Depressive Disorder

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Sage Therapeutics (NASDAQ: SAGE), a clinical-stage biopharmaceutical company developing novel medicines to treat life-altering central nervous system (CNS) disorders, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation to SAGE-217 for development as a potential treatment for major depressive disorder (MDD). Fast Track is a process designed to facilitate the development and review of new treatments for serious conditions with unmet medical need such as MDD.

"The FDA Fast Track Designation is an important milestone in the development of SAGE-217, as it provides opportunities to potentially accelerate clinical development and future regulatory review of SAGE-217 for the treatment of MDD," said Amy Schacterle, Ph.D., Senior Vice President, Regulatory Affairs and Quality Assurance of Sage. "Our discussions with regulatory agencies continue to focus on determining the most appropriate and efficient pathways for bringing new therapies to patients."

About Fast Track Designation

Fast Track is a process designed to facilitate the development, and expedite the review, of drugs to treat serious conditions and fill an unmet medical need. Drugs that receive Fast Track designation may be eligible to be the subject of more frequent communications and meetings with FDA to review the drug's development plan including the design of the proposed clinical trials, use of biomarkers and the extent of data needed for approval. Drugs with Fast Track Designation may also qualify for priority review to expedite the FDA review process, if relevant criteria are met.

The purpose is to get important new drugs to the patient earlier. Fast Track addresses a broad range of serious conditions. For more information about Fast Track, please visit: https://www.fda.gov/ForPatients/Approvals/Fast/ucm405399.htm.

About SAGE-217

Sage's most advanced, oral product candidate is SAGE-217, a novel, orally-active neuroactive steroid that is a positive allosteric modulator of synaptic and extrasynaptic $GABA_A$ receptors. The GABA system is the major inhibitory signaling pathway of the brain and CNS, and contributes significantly to regulating CNS function. SAGE-217 is currently in Phase 2 development in both mood and movement disorders, with four Phase 2 clinical programs now underway.

About Major Depressive Disorder

Major depression disorder (MDD) is a common but serious mood disorder in which patients exhibit depressive symptoms, such as a depressed mood or a loss of interest or pleasure in daily activities consistently for at least a two-week period, and demonstrate impaired social, occupational, educational or other important functioning. Approximately 16 million people in the U.S. suffer from MDD each year.[1] While antidepressants are widely used for treatment, large scale studies have demonstrated the need for additional therapies.[2,3]

About Sage Therapeutics

Sage Therapeutics is a clinical-stage biopharmaceutical company committed to developing novel medicines to transform the lives of patients with life-altering central nervous system (CNS) disorders. Sage has a portfolio of novel product candidates targeting critical CNS receptor systems, GABA and NMDA. Sage's lead program, brexanolone (SAGE-547), is in Phase 3 clinical development for super-refractory status epilepticus, a rare and severe seizure disorder, and for postpartum depression. Sage is developing its next generation modulators, including SAGE-217 and SAGE-718, in various CNS disorders. For more information, please visit www.sagerx.com.

Forward-Looking Statements

Various statements in this release concern Sage's future expectations, plans and prospects, including without limitation: our statements as to the potential for expedited development and review for SAGE-217 in MDD as a result of Fast Track designation; our expectations regarding further development and the potential of SAGE-217 in the treatment of MDD; our view of the potential of the GABA mechanism and our product candidates in the treatment of CNS diseases and disorders; and our views as to the unmet need for additional treatment options in MDD and estimated number of patients with MDD. These forward-looking statements are neither promises nor guarantees of future performance, and are subject to a variety of risks and uncertainties, many of which are beyond our control, which could cause actual results to differ materially from those contemplated in these forward-looking statements, including the risks that: we may not achieve expedited development or review of SAGE-217 as a result of Fast Track designation; decisions or actions of the FDA or other regulatory agencies may affect the initiation, timing, design, size, progress and cost of clinical trials and our ability to proceed with further clinical trials of a product candidate; we may not be able to successfully demonstrate the efficacy and safety of SAGE-217 or any of our other product candidates at each stage of development; success in early stage clinical trials may not be repeated or observed in ongoing or future studies involving the same compound or other product candidates; and ongoing and future clinical results may not support further development of a product candidate or be sufficient to gain regulatory approval to market any product; we may decide that a development pathway for one of our product candidates in one or more indications is no longer feasible or advisable or that the unmet need no longer exists; the actual size of the MDD patient population may be significantly lower than our estimates and, even if SAGE-217 is successfully developed and approved for MDD, it may only be approved or used to treat a subset of the MDD population; and we may encounter technical and other unexpected hurdles in the development and manufacture of our product candidates; as well as those risks more fully discussed in the section entitled "Risk Factors" in our most recent Quarterly Report on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent our views only as of today, and should not be relied upon as representing our views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

[1] Nat. Inst. of Mental Health website, 2015; Available at https://www.nimh.nih.gov/health/statistics/prevalence/major-depression-among-adults.shtml.

[2] Trivedi MH et al. Evaluation of Outcomes with Citalopram for Depression using Measurement-Based Care in STAR*D: Implications for Clinical Practice*. Am J Psychiatry*, 2006,163:1, 28-40. doi: 10.1176/appi.ajp.163.1.28.

[3] Rush AJ et al. Acute and Longer-Term Outcomes in Depressed Outpatients Requiring One or Several Treatment Steps: A STAR*D Report. *Am J. Psychiatry*, 2006,163:11, 1905-1917. doi: 10.1176/ajp.2006.163.11.1905.

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