Sage Therapeutics Receives Fast Track Designation for SAGE-718 for the Treatment of Huntington's Disease

September 15, 2021

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Sep. 15, 2021-- Sage Therapeutics, Inc. (Nasdaq:SAGE), a biopharmaceutical company committed to developing novel therapies with the potential to transform the lives of people with debilitating disorders of the brain, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation to SAGE-718 for development as a potential treatment for Huntington's disease (HD). Fast Track is a process designed to facilitate the development and review of new treatments for serious conditions with unmet medical need such as HD.

"HD is an autosomal dominant genetic disorder that impacts the brain and by nature numerous generations of a family. Cognitive decline is often one of the earliest signs of the disease and this decline, in addition to other symptoms, results in a devastating impact on independence, general functioning, and quality of life. We believe that improving cognitive function is one of the core paths to maintaining quality of life in HD and remains an area of significant unmet medical need," said Jim Doherty, Ph.D., chief research officer at Sage Therapeutics. "In studies to date, treatment with SAGE-718 has been associated with improved cognitive performance, particularly in the domain of executive functioning. The FDA Fast Track Designation is an important milestone in the development of SAGE-718, as it provides opportunities to engage collaboratively with the FDA to further clinical development and future regulatory review of SAGE-718 for the treatment of HD."

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-718
SAGE-718, Sage's first-in-class NMDA receptor PAM and lead neuropsychiatric drug candidate, is in development as a potential oral therapy for cognitive disorders associated with NMDA receptor dysfunction, potentially including Huntington's disease (HD), Parkinson's disease (PD) and Alzheimer's disease (AD). Ongoing studies aim to evaluate whether SAGE-718 may have the potential to improve cognitive symptoms for these difficult-to-treat disorders. Sage expects to initiate a placebo-controlled Phase 2 trial with SAGE-718 in early to moderate HD in late 2021.

About Huntington's Disease
Huntington's disease (HD) is a rare, inherited neurodegenerative disease that progresses over time. Up to 30,000 adults are diagnosed with HD in the U.S. each year. Symptoms usually appear between ages 30–45, worsen over the following 15–20 years, and ultimately lead to death. Psychiatric and cognitive symptoms can severely affect people with HD.

About Sage Therapeutics
Sage Therapeutics is a biopharmaceutical company committed to developing novel therapies with the potential to transform the lives of people with debilitating disorders of the brain. We are pursuing new pathways with the goal of improving brain health, and our depression, neurology and neuropsychiatry franchise programs aim to change how brain disorders are thought about and treated. Our mission is to make medicines that matter so people can get better, sooner. 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 expectations regarding the potential benefit of Fast Track designation; our plans and expected timelines for development of SAGE-718; our view of the potential profile and benefit of SAGE-718 and potential indications; our expectations as to the unmet need in the treatment of Huntington's disease; and our other statements as to the potential opportunity for our programs and business. These statements constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. 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: Fast Track designation from the FDA may not lead to a faster or successful development of SAGE-718 and, even if development is successful, may not result in a faster or successful regulatory review process; the FDA may withdraw Fast Track designation at any time; we may not be successful in our development of SAGE-718 or any of our other product candidates in any indication we are currently pursuing or may in the future pursue; success in non-clinical studies or in earlier clinical trials or at interim time periods may not be repeated or observed in ongoing or future studies or in studies in other indications, and ongoing and future non-clinical and clinical results may not meet their primary or key secondary endpoints or be sufficient to file for or gain regulatory approval to market the product without further development work or may not support further development at all; we may encounter adverse events at any stage of development that negatively impact further development or that require additional nonclinical and clinical work which may not yield positive results; we may encounter delays in initiation, conduct or completion of our ongoing and planned clinical trials, including as a result of slower than expected site initiation or enrollment, the need or decision to expand the trials or other changes, that may impact our ability to meet our expected timelines; the FDA may not agree that the design or results of our nonclinical studies and clinical trials for SAGE-718 or any of our other product candidates, even if positive, are sufficient to file for or obtain regulatory approval in the indications that are the focus of our development plans even if we have had prior

discussions with the agency supporting our approach; other 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 development; the unmet need for additional treatment options for Huntington's disease or any other indications we are studying or may study in the future with SAGE-718 or any of our other product candidates may be significantly smaller than we expect; and we may encounter technical and other unexpected hurdles in the development and manufacture of SAGE-718 or any of our other product candidates which may delay our timing or change our plans, increase our costs or otherwise negatively impact our business; 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.

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