Sage Therapeutics Announces Topline Results from the Phase 2 DIMENSION Study of Dalzanemdor (SAGE-718) in the Treatment of Cognitive Impairment Associated with Huntington's Disease

November 20, 2024

The Phase 2 DIMENSION Study did not meet its primary endpoint

Dalzanemdor was generally well-tolerated; no new safety signals were observed

Based on these data, the Company does not plan further development of dalzanemdor

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 20, 2024-- Sage Therapeutics, Inc. (Nasdaq: SAGE) today announced topline results from the Phase 2 DIMENSION Study of dalzanemdor (SAGE-718) in participants with cognitive impairment (CI) associated with Huntington's Disease (HD). In the study, dalzanemdor did not demonstrate a statistically significant difference versus placebo on the primary endpoint, the change from baseline on the Symbol Digit Modalities Test (SDMT) at Day 84. Analyses of secondary endpoints did not demonstrate statistically significant or clinically meaningful differences in participants treated with dalzanemdor compared to placebo. Based on these results, the Company does not plan further development of dalzanemdor.

"We are disappointed by the results of the DIMENSION Study, especially for the individuals and families affected by Huntington's Disease who have long awaited new treatment options," said Barry Greene, Chief Executive Officer, Sage Therapeutics. "Innovation is desperately needed, and we are immensely grateful to the participants, investigators, and the entire Huntington's Disease community whose unwavering commitment to advancing research helped make this study possible."

DIMENSION Study Results

The DIMENSION Study was a 12-week, double-blind, placebo-controlled Phase 2 study to evaluate the effects of dalzanemdor in participants with CI associated with HD. A total of 189 participants were randomized.

- The DIMENSION Study did not demonstrate a statistically significant difference from baseline in participants treated with dalzanemdor versus placebo on the SDMT, a measure of cognitive function, at Day 84, the primary endpoint.
- Dalzanemdor was generally well-tolerated and no new safety signals were observed. The majority of treatment emergent adverse events were mild to moderate in severity.
- Analyses of secondary endpoints did not demonstrate statistically significant or clinically meaningful differences between the dalzanemdor and placebo treatment groups.

Given these findings, the Company also will close the ongoing PURVIEW Study, an open-label safety study of dalzanemdor in participants with HD.

About Sage Therapeutics
Sage Therapeutics (Nasdaq: SAGE) is a biopharmaceutical company committed to our mission of pioneering solutions to deliver life-changing brain health medicines, so every person can thrive. Sage developed the only two FDA-approved treatments indicated for postpartum depression and is advancing a pipeline to target unmet needs in brain health. Sage was founded in 2010 and is headquartered in Cambridge, Mass. Find out more at www.sagerx.com or engage with us on Facebook, LinkedIn, Instagram, and X.

Forward Looking Statements

Various statements in this release concern future expectations, plans and prospects, including without limitation statements regarding: our plan not to further develop dalzanemdor and to close the PURVIEW Study; our belief in the unmet need for new treatment options for brain health; and the mission, goals, opportunity and potential for our 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: the results of ongoing, planned or future clinical trials or nonclinical work with respect to any of our product candidates may be negative like the results we announced today from the DIMENSION Study; decisions or actions of the FDA or other regulatory agencies may affect the initiation, timing, design, size, or progress of ongoing or future clinical trials or the regulatory pathway for any of our product candidates or our ability to proceed with further development; we may encounter adverse results or 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 at any time encounter unexpected hurdles in the development and manufacture of our product candidates; and all of these factors and other developments related to our science or business could cause us not to achieve our mission or the goals for 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, and 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. Sage explicitly disclaims any obligation to update any forward-looking statements.

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