Sage Therapeutics to Provide Update on 2023 Key Initiatives at 41st Annual J.P. Morgan Healthcare Conference

January 8, 2023

Robust pipeline provides potential for long-term value creation, establishing Sage as a leader in brain health

Rolling New Drug Application (NDA) submission for zuranolone in MDD and PPD complete, with potential for PDUFA date as early as the third quarter of 2023 if priority review is received and other timelines meet expectations

Progressing nine ongoing studies across zuranolone, SAGE-718, SAGE-324 and early pipeline programs

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jan. 8, 2023-- Sage Therapeutics, Inc. (Nasdaq: SAGE), a biopharmaceutical company leading the way to create a world with better brain health, today announced that Chief Executive Officer, Barry Greene, will discuss the Company's progress in developing a leading brain health pipeline at the 41st Annual J.P. Morgan Healthcare Conference in San Francisco, California.

As part of this presentation, Mr. Greene will provide key updates on programs across Sage's depression, neuropsychiatry and neurology portfolios. Sage is advancing a portfolio of clinical programs featuring internally discovered novel chemical entities with the potential to become differentiated products designed to improve brain health by targeting the $GABA_A$ and NMDA receptor systems. Dysfunction in these systems is thought to be at the core of numerous neurological and neuropsychiatric disorders.

"It's time to begin a new era in the treatment of brain health disorders. We at Sage have a tremendous sense of urgency to create innovative medicines that address what matters most for people who currently lack adequate treatment options," said Barry Greene, Chief Executive Officer at Sage Therapeutics. "We enter 2023 having completed the submission of the rolling NDA for zuranolone in the treatment of major depressive disorder and postpartum depression with our collaborator Biogen. We've also made progress in initiating multiple studies across our pipeline, including SAGE-718 and SAGE-324. We believe that this momentum will help us achieve our mission to improve the lives of millions of people and advance the way brain health is viewed and treated."

Sage and its collaborator Biogen recently announced the submission of the zuranolone New Drug Application to the FDA for the treatment of major depressive disorder (MDD) and postpartum depression (PPD). Zuranolone, Sage's next-generation positive allosteric modulator (PAM) of $GABA_A$ receptors, is being evaluated as a potential rapid-acting treatment for MDD and PPD. If approved, zuranolone could represent the first oral, short course (14-day) medication for these indications. In the clinical development program to date, zuranolone has shown rapid and sustained improvement of depressive symptoms with a generally well-tolerated and consistent safety profile.

Sage and Biogen are focused on preparing for a potential launch of zuranolone for both MDD and PPD in 2023, if approved, with the ultimate goal of transforming the way depression is treated. Current efforts are focused on disease state education in MDD and PPD, scientific exchange and permitted interactions with payers. Sage expects these efforts and other permitted pre-launch activities to continue to broaden and ramp up in the coming year.

Sage continues to advance a robust clinical program for SAGE-718, the Company's first-in-class NMDA receptor PAM and lead neuropsychiatric drug candidate. SAGE-718 is in development as a potential oral therapy for cognitive disorders associated with NMDA receptor dysfunction, with multiple ongoing or planned Phase 2 studies across multiple disease areas, including its potential lead indication, Huntington's disease (HD), as well as Alzheimer's (AD) and Parkinson's diseases (PD). The company recently initiated LIGHTWAVE (CNA-202), a Phase 2 study of SAGE-718 in people with mild cognitive impairment and mild dementia due to AD and PURVIEW (CIH-301), a Phase 3 extension study in people with HD.

"We are proud of the progress we've made in advancing the SAGE-718 development program as we work to address impaired cognition, a main driver of disability in the indications we are studying, including Huntington's, Alzheimer's and Parkinson's diseases," said Laura Gault, M.D., Ph.D., Chief Medical Officer at Sage. "Our goal with SAGE-718 is to provide rapid, meaningful, and sustained symptomatic improvement in cognitive function early in disease so that patients can maintain independence longer."

Anticipated 2023 Key Milestones

The Company anticipates the following key milestones in 2023:

- Zuranolone:
  - Early:
    - FDA acceptance of rolling NDA submission for zuranolone in MDD and PPD
  - Mid:
    - Present additional data from the SHORELINE Study
  - Late:
    - PDUFA date for zuranolone in MDD and PPD, if accepted for review by the FDA
    - Commercial availability of zuranolone in MDD and PPD, if priority review is granted and zuranolone is approved

        - Initiate a lifecycle innovation study with zuranolone
    - Present additional analyses of data from LANDSCAPE and NEST clinical programs, including health economics and patient reported outcomes
- SAGE-718:
    - Progress recruitment in the ongoing DIMENSION, SURVEYOR, PURVIEW, PRECEDENT, and LIGHTWAVE Studies
    - Present additional analyses of data from clinical development program as well as disease state and burden of disease research in Huntington's, Parkinson's and Alzheimer's diseases
- SAGE-324:
    - Late:
        - Complete enrollment in the Phase 2b KINETIC 2 Study
    - Present additional analyses of data from clinical development program as well as disease state and burden of disease research in ET

About Sage Therapeutics

Sage Therapeutics is a biopharmaceutical company fearlessly leading the way to create a world with better brain health. Our mission is to pioneer solutions to deliver life-changing brain health medicines, so every person can thrive. For more information, please visit http://www.sagerx.com.

Forward-Looking Statements

Various statements in this release concern Sage's future expectations, plans and prospects, including without limitation our statements regarding: the potential for our NDA for zuranolone in MDD and PPD to be accepted and the possibility of priority review; the potential for approval and launch of zuranolone and potential timelines; our belief in the potential benefit and profile of zuranolone and in its potential to be successful and to meet an unmet need in the treatment of MDD and PPD; the potential for commercialization of zuranolone and our commercialization strategy and plans, including plans to help enable access; our expectations as to the types of MDD patients who may benefit from zuranolone, if approved; other planned activities and next steps for the zuranolone program; anticipated timelines for commencement of trials, completion of dosing, initiation of new activities and other plans for our other programs and early stage pipeline; our belief in the potential profile and benefit of our product candidates; potential indications for our product candidates; the potential for success of our programs, and the opportunity to help patients in various indications; the number of patients with the indications we are pursuing or may in the future pursue and the unmet need; and the mission and goals for our business and potential for long-term value creation.

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 FDA may find inadequacies and deficiencies in our NDA for zuranolone, including in the data we submit, despite prior discussions, and may decide not to accept the NDA for filing; even if the FDA accepts the NDA for filing, the FDA may find that the data included in the NDA are not sufficient for approval and may not approve the NDA in MDD or PPD, or both; the FDA may decide that the design, conduct or results of our completed and ongoing clinical trials for zuranolone, even if positive, are not sufficient for approval in MDD or PPD and may require additional trials or data which may significantly delay and put at risk our efforts to obtain approval and may not be successful; even if our NDA is successfully filed and accepted, the FDA may not grant priority review or meet expected review timelines for our NDA which would delay our launch timelines if zuranolone is approved; other decisions or actions of the FDA may affect our efforts with respect to zuranolone and our plans, progress, results and expected timelines; our expectations for timing of review of our NDA and of launch of zuranolone, if approved, may not be accurate; results of ongoing or future studies may impact our ability to obtain approval of zuranolone or impair the potential profile of zuranolone; success in earlier clinical trials of any of our other product candidates may not be repeated or observed in ongoing or future studies, and ongoing and future clinical trials may not meet their primary or key secondary endpoints which may substantially impair development; unexpected concerns may arise from additional data, analysis or results from any of our completed studies; we may encounter adverse events at any stage for any of product candidates that negatively impact further development, the potential for approval or the potential for successful commercialization or that require additional nonclinical and clinical work which may not yield positive results; we may encounter delays in initiation, conduct, completion of enrollment or completion of our ongoing and planned clinical trials, including as a result of slower than expected site initiation, slower than expected enrollment, the need or decision to expand the trials or other changes, that may impact our ability to meet our expected timelines and increase our costs; 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 or may impair the potential for successful development; we may not be successful in our efforts to gain regulatory approval of any products, even if successfully developed and approved; we may not achieve revenues from any future products, including zuranolone, if approved, at the levels we expect; the number of patients with the diseases or disorders for which our product candidates are being developed, the unmet need for additional treatment options and the potential use cases and market for our current or future products, including zuranolone, if approved, may be significantly smaller than we expect; zuranolone, if approved, or any of our other products that may be approved in the future, may not have the profile we expect in clinical practice after launch or may not achieve market acceptance for other reasons or we may encounter reimbursement-related or other market-related issues that impact the success of our commercialization efforts; the anticipated benefits of our ongoing collaborations, including the achievement of events tied to milestone payments or the successful development or commercialization of products and generation of revenue, may never be achieved; the need to align with our collaborators may hamper or delay our development and commercialization efforts or increase our costs; our business may be adversely affected and our costs may increase if any of our key collaborators fails to perform its obligations or terminates our collaboration; the internal and external costs required for our ongoing and planned activities, and the resulting impact on expense and use of cash, may be higher than expected which may cause us to use cash more quickly than we expect or change or curtail some of our plans or both; we may never be able to generate meaningful revenues from sales of our marketed product or to generate revenues at levels we expect or at levels necessary to justify our investment; our expectations as to sufficiency of cash to fund future operations and expense levels may prove not to be correct for these and other reasons such as changes in plans or actual events being different than our assumptions; we may be opportunistic in our future financing plans even if available cash is sufficient; additional funding may not be available on acceptable terms when we need it; and we may encounter technical and other unexpected hurdles in the development and manufacture of our product candidates or the commercialization of any marketed product which may delay our timing or change our plans, increase our costs or otherwise negatively impact our business; any of the foregoing or other

issues may negatively impact our value creation opportunity, as well as those risks more fully discussed in the section entitled "Risk Factors" in our most recent quarterly report, 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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