Sage Therapeutics Provides 2021 Corporate Strategy Update at J.P. Morgan Healthcare Conference

January 7, 2021

Catalyst rich 2021 includes expected topline readouts from ten clinical trials across the Company's depression, neurology and neuropsychiatry franchises and in COVID-related ARDS

Company committed to accelerating pipeline and expanding product engine with goal of delivering at least two IND-enabling product candidates per year by 2023

Sage to present at J.P. Morgan Healthcare Conference on January 12, 2021 at 10:50 am ET

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jan. 7, 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 Chief Executive Officer, Barry Greene, will discuss the Company's progress in becoming a leader in brain health in a corporate presentation at the 39 th Annual J.P. Morgan Healthcare Conference. As part of the presentation, Mr. Greene will highlight the Company's planned portfolio expansion and acceleration in 2021, including the anticipated advancement of SAGE-718, SAGE-689 and SAGE-904 into further phases of development. Today Sage also announced plans to advance two of its early development product candidates, SAGE-319 and SAGE-421, to preclinical studies.

"This year will be transformational for Sage, with numerous catalysts expected in early, mid and late 2021," said Barry Greene, Chief Executive Officer at Sage Therapeutics. "Brain health disorders represent one of the biggest challenges we face today, and with the planned expansion and acceleration of both our partnered and internal clinical pipeline this year, we are well-positioned in our efforts to deliver innovation to the millions of patients with these debilitating disorders. I believe that the upcoming milestones in 2021 will support our mission to bring medicines that matter to patients and propel us further on our journey to become the leading brain health company."

During his presentation, Mr. Greene will discuss the following corporate updates and milestones anticipated in the next 12-18 months:

Corporate Updates

Sage and Biogen recently announced that they have executed a global collaboration and license agreement to jointly develop and commercialize zuranolone (SAGE-217) for major depressive disorder (MDD), postpartum depression (PPD) and other disorders, and SAGE-324 for essential tremor and other disorders. The transaction, including the related purchase by Biogen of 6,241,473 shares of Sage Common Stock, closed in December 2020, following completion of review under the Hart-Scott-Rodino (HSR) Antitrust Improvements Act of 1976 in the U.S., and other customary closing conditions. In conjunction with the closing, Sage received $1.525 billion comprised of an $875 million up-front payment and $650 million for the equity investment. As of December 31, 2020, the Company had a cash balance of $2.1 billion (unaudited).

Depression Franchise

Sage's depression franchise features zuranolone, Sage's next-generation positive allosteric modulator (PAM) of GABA $_A$ receptors being evaluated in clinical development as a treatment for various affective disorders, and ZULRESSO® (brexanolone) CIV injection, approved by the U.S. Food and Drug Administration (FDA) as the first treatment specifically indicated for postpartum depression (PPD). Zuranolone has received breakthrough therapy designation from the FDA for the treatment of MDD.

The Company expects the following pivotal data readouts from the LANDSCAPE clinical program evaluating zuranolone in MDD and PPD in 2021:

- 1H 2021:
  - WATERFALL (MDD-301B) Study: A placebo-controlled Phase 3 trial evaluating a two-week course of zuranolone 50 mg in patients with MDD, with additional short-term follow-up.
- Mid 2021:
  - SHORELINE (MDD-303) Study 30 mg Cohort - Full Data: An open-label Phase 3 trial designed to naturalistically follow patients with MDD and evaluate the safety and tolerability of zuranolone 30 mg in adults for up to one year. The company announced topline interim data from this cohort in October 2020.
- Late 2021:
  - SKYLARK (PPD-301) Study: A placebo-controlled Phase 3 trial evaluating a two-week course of zuranolone 50 mg in women with PPD, with additional short-term follow-up.
  - CORAL (MDD-305) Study: A placebo-controlled Phase 3 trial evaluating a two-week course of zuranolone 50 mg, when co-initiated with a new open-label antidepressant, in patients with MDD, with additional short-term follow-up.
  - SHORELINE (MDD-303) Study 50 mg Cohort: An open-label Phase 3 trial designed to naturalistically follow patients with MDD and evaluate the safety and tolerability of zuranolone 50 mg in adults for up to one year.

Additional development plans for zuranolone will be confirmed as part of the Company's strategic collaboration with Biogen.

Neurology Franchise

SAGE-324, a next-generation PAM of $GABA_A$ receptors and Sage's lead neurology asset, is in development as a potential oral therapy for neurological conditions, such as essential tremor (ET), epilepsy and Parkinson's disease (PD).

- Early 2021:
  - KINETIC (324-ETD-201) Study: The Company expects topline data from the KINETIC Study, a placebo-controlled Phase 2 trial evaluating the safety and efficacy of SAGE-324 in patients with ET to read out in early 2021.
- Late 2021:
  - Sage expects to initiate the next placebo-controlled Phase 2 trial with SAGE-324 in ET in late 2021.

Additional development plans for SAGE-324 will be confirmed as part of the Company's strategic collaboration with Biogen.

Neuropsychiatry Franchise

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), PD and Alzheimer's disease (AD).

- Early 2021:
  - PARADIGM (718-CNP-201) Study**:** The Company anticipates topline data from the PARADIGM Study, a Phase 2a open-label trial evaluating SAGE-718 in patients with PD cognitive dysfunction in early 2021.
- Late 2021:
  - LUMINARY (718-CNA-201) Study**:** The Company expects to initiate dosing in the LUMINARY Study, a Phase 2a open-label trial evaluating SAGE-718 in patients with AD cognitive dysfunction and mild dementia in early 2021. Topline data from this trial are expected in late 2021.

Additionally, the Company expects to initiate a placebo-controlled Phase 2 trial with SAGE-718 in late 2021. Details of this trial will be informed by results from the Phase 2a studies.

Early Development

Sage expects to complete certain Phase 1 clinical studies for two compounds in its early development pipeline in 2021, SAGE-689 (single ascending dose) and SAGE-904 (single ascending dose and multiple ascending dose).

- **SAGE-689**: is an intramuscular $GABA_A$ receptor PAM in development as a potential therapy for disorders associated with acute GABA hypofunction.
- **SAGE-904:** is Sage's second NMDA receptor PAM product candidate in development as a potential oral therapy for disorders associated with NMDA hypofunction.

Results from the Phase 1 studies will inform further development of these compounds.

The company also announced plans to advance SAGE-319 and SAGE-421 to preclinical studies.

- **SAGE-319:** is an oral, extrasynaptic $GABA_A$ receptor preferring PAM that will be studied for potential use in disorders of social interaction.
- **SAGE-421**: is an oral, NMDA receptor PAM that will be studied for potential use in neurodevelopmental disorders and cognitive recovery and rehabilitation.

Other Development Opportunities

Sage initiated a Phase 3 trial with brexanolone in patients with advanced COVID-19 related acute respiratory distress syndrome (ARDS) in the fourth quarter of 2020 under the Coronavirus Treatment Acceleration Program (CTAP). The Company expects topline data from this trial in late 2021.

Webcast Information

Sage is scheduled to present at the 39th Annual J.P. Morgan Healthcare Conference on Tuesday, January 12, 2021 at 10:50 am ET. A live webcast of the presentation can be accessed on the investor page of Sage's website at investor.sagerx.com. A replay of the webcast will also be archived for up to 30 days on Sage's website following the conference.

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 timelines for initiation and completion of certain clinical trials and data read-outs; our plans for advancing, accelerating and expanding our development efforts and our product engine; our belief in the potential for upcoming catalysts and milestones to be transformational and to support our mission of bringing innovative medicines to patients; our views as to the potential profile and benefit of our product candidates; and our statements regarding 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: we may encounter delays in initiation, conduct, completion, or data analysis with respect to 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 time-lines; we may not be able to mitigate the impact of the COVID-19 pandemic on our clinical development timelines and the impact may be more significant than we expect and may negatively impact expected site initiation, enrollment or conduct of our clinical trials, or cause us to pause trials or not to be able to use data, in each case which may significantly impact our ability to meet our expected time-lines or may significantly impact the integrity or sufficiency of the data from our trials or cause us to have to change our plans; our clinical trials may not meeting their primary endpoints or key secondary endpoints; 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; ongoing and future non-clinical and clinical trial results may not support further development at all or may not be sufficient to move to the next stage of development or to file for or gain regulatory approval to market the product without further development work; 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 different or more severe adverse events at the higher doses we are studying in ongoing trials; we may encounter issues with the efficacy or durability of short-term treatment, or co-initiated treatment with zuranolone or safety and efficacy concerns with respect to retreatment that require additional studies be conducted; the FDA may ultimately decide that the design or results of our completed and planned clinical trials for any of our product candidates, even if positive, are not sufficient for regulatory approval in the indications that are the focus of our development plan; 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; we may not be successful in our development of any of our product candidates in any indication we are currently pursuing or may in the future pursue; we may encounter technical and other unexpected hurdles in the development and manufacture of our product candidates which may delay our timing or change our plans or increase our costs; 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20210107005221/en/

Investor:
Jeff Boyle
617-949-4256
Jeff.Boyle@sagerx.com

Media:
Maureen L. Suda
617-949-4289
maureen.suda@sagerx.com

Source: Sage Therapeutics, Inc.