# Sage Therapeutics to Provide Business Updates at 42nd Annual J.P. Morgan Healthcare Conference

January 8, 2024

***Excitement over December 2023 launch of ZURZUVAE™ (zuranolone), the first and only oral treatment indicated for adults with postpartum depression (PPD)***

***Continued progress on clinical pipeline, with topline data expected from multiple ongoing Phase 2 trials across 2024***

***Catalyst rich year supported by strong financial foundation and focused execution***

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jan. 8, 2024-- 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 key business drivers for 2024 at the 42nd Annual J.P. Morgan Healthcare Conference in San Francisco, California.

As part of this presentation, Mr. Greene will discuss commercialization of ZURZUVAE™ (zuranolone), the first and only once-daily 14-day oral treatment option for adults with postpartum depression (PPD) and will provide an update on the Company's progress in advancing its brain health pipeline.

"The landmark FDA approval of ZURZUVAE has fueled additional momentum in recognizing the urgency to treat PPD, which reinforces our belief that all women with PPD who are prescribed ZURZUVAE should be able to access it. While early, we are encouraged by the positive engagement we have had in the initial launch weeks, and we believe we are off to a great start – patients are being prescribed ZURZUVAE by multiple specialties, including OBGYNs, and we are seeing enthusiasm from prescribers to learn more," said Barry Greene, CEO at Sage Therapeutics. "We are also making progress across our pipeline and look forward to several clinical data milestones in the dalzanemdor (SAGE-718) and SAGE-324 programs this year. We head into 2024 poised for a catalyst-rich year further supported by a strong financial foundation and focused execution plans."

**Commercial availability of ZURZUVAE™ (zuranolone) underway to support women with PPD**

Sage and its collaborator, Biogen, are focused on establishing ZURZUVAE as the first line therapy and standard of care for women with PPD. The companies recently announced commercial availability of ZURZUVAE and the specialty pharmacy distribution model by which ZURZUVAE is shipped directly to patients who are prescribed the treatment. Sage and Biogen field sales teams are engaging in promotional dialogues with health care professionals (HCPs) who actively identify and treat women with PPD. Since commercial availability, HCPs, including OBGYNs, psychiatrists, and primary care physicians have started to prescribe ZURZUVAE in this indication. The companies are continuing active discussions with national, regional and government payors to advocate for broad and equitable access to ZURZUVAE for women with PPD with minimal restrictions and expect formulary discussions to continue over the course of 2024.

**Innovative brain health pipeline with potential for significant value creation**

Sage is advancing a portfolio of early-stage and clinical programs featuring internally discovered novel chemical entities targeting the $GABA_A$ and NMDA receptor systems. The Company expects several clinical data milestones in 2024 for dalzanemdor (SAGE-718) and SAGE-324.

**Dalzanemdor (SAGE-718),** the Company's first-in-class NMDA receptor positive allosteric modulator (PAM), is in development as a potential oral therapy for cognitive disorders associated with NMDA receptor dysfunction, including Huntington's disease (HD), Alzheimer's disease (AD) and Parkinson's disease (PD). In Q4 2023, the FDA granted Orphan Drug Designation to SAGE-718 for the treatment of HD, and the United States Adopted Name (USAN) Council assigned the nonproprietary name of "dalzanemdor" to this compound.

Topline data from ongoing Phase 2 studies are expected in 2024 across all indications, including the following anticipated read-outs:

- PRECEDENT study in people with mild cognitive impairment (MCI) associated with PD in early-2024

- SURVEYOR study in people with HD cognitive impairment in mid-2024

- LIGHTWAVE study in people with mild cognitive impairment and mild dementia due to AD in late-2024

- DIMENSION study in people with HD cognitive impairment in late-2024

**SAGE-324,** the Company's next-generation PAM of $GABA_A$ receptors, is in development as a potential oral therapy for movement disorders, such as essential tremor (ET). SAGE-324 is being developed in collaboration with Biogen Inc. Topline data from the Phase 2b KINETIC study in ET are expected in mid-2024.

Additional information about our clinical programs and early-stage pipeline can be found on https://www.sagerx.com/programs-research.

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 be available following the completion of the event and will be archived for up to 30 days.

**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 robust 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 Sage's future expectations, plans and prospects, including without limitation our statements regarding: our plans, expectations and goals for commercialization of ZURZUVAE as a treatment for women with PPD, including our goals for ZURZUVAE to become the first line treatment and standard of care in this indication and to enable access for women with this disease who are prescribed treatment; our belief in the potential of ZURZUVAE to be successful and to help women with PPD; anticipated timelines for completion of enrollment in clinical trials and reporting of results with respect to certain of our other programs; 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; our belief as to the key business drivers for our business and potential value creation opportunities; and the mission and goals 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: our launch and commercialization efforts in the U.S. with respect to ZURZUVAE for the treatment of women with PPD may not be successful, and we may be unable to generate revenues from sales of ZURZUVAE at the levels or on the timing we expect or at levels or on the timing necessary to support our goals; early positive signs from our engagements with healthcare professionals, patients and payors related to ZURZUVAE may not be a signal of the potential for future success; the number of women with PPD, the unmet need for additional treatment options, and the potential market for ZURZUVAE in women with PPD, may be significantly smaller than we expect; ZURZUVAE may not achieve the clinical benefit, clinical use or market acceptance in the treatment of PPD we expect or we may encounter reimbursement-related or other market-related issues that impact the success of our commercialization efforts, including our ability to achieve access goals; ZURZUVAE may never become the first line treatment and standard of care for women with PPD; we may encounter delays in initiation, conduct, completion of enrollment or completion and reporting of data with respect to any of our ongoing 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 may increase our costs; success in earlier clinical trials of any of our 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; decisions or actions of the FDA or the timing of meetings with the FDA may affect the timing, design, size, progress and cost of clinical trials or the timing of data read-outs or our ability to proceed with further development or may impair the potential for successful development or the timing or success of filing for and gaining regulatory approval; we may encounter adverse events at any stage that negatively impact further development and the potential for approval of our product candidates or the potential for successful commercialization of any our products or that require additional nonclinical and clinical work which may not yield positive results; the need to align with our collaborators may hamper or delay our development and commercialization efforts for the products or product candidates that are part of the collaboration or increase our costs; the anticipated benefits of our ongoing collaborations, including the receipt of milestone payments or the successful development or commercialization of products and generation of revenue, may never be achieved at the levels or timing we expect or at all; 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 change or curtail some of our plans or both; we may not be successful in our efforts to gain regulatory approval of products beyond ZURZUVAE and ZULRESSO; we may not achieve revenues from our products that may be successfully developed in the future, at levels we expect; additional funding may not be available on acceptable terms when we need it which could hamper our development and commercialization activities; any of the foregoing events could impair the drivers and value creation opportunities for our business; and we may encounter technical and other unexpected hurdles in the development and manufacture of our product candidates or the commercialization of any current or future marketed product 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, 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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**Investor Contact**
Ashley Kaplowitz
786-252-1419
ashley.kaplowitz@sagerx.com

**Media Contact**
Matthew Henson
917-930-7147
matthew.henson@sagerx.com

Source: Sage Therapeutics, Inc.