Sage Therapeutics and Biogen Announce Consistent Clinically Meaningful Data for Zuranolone Across the LANDSCAPE and NEST Clinical Development Programs Presented at the European College of Neuropsychopharmacology (ECNP) Congress

October 4, 2021

Improvement achieved in measurements of overall quality of life, functioning and general well-being achieved at Day 15 and sustained at Day 42

Consistent and differentiated safety and tolerability profile seen across clinical program

Sage to host conference call on October 4, 2021 at 8:00am ET

CAMBRIDGE, Mass. – October 4, 2021 – Sage Therapeutics, Inc. (Nasdaq: SAGE) and Biogen Inc. (Nasdaq: BIIB) today announced new data from the LANDSCAPE and NEST clinical development program evaluating the efficacy and safety of zuranolone for the treatment of major depressive disorder (MDD) and postpartum depression (PPD) presented at the 34th European College of Neuropsychopharmacology (ECNP) Congress, taking place October 2-5, 2021. Presentations include data from the WATERFALL Study, a Phase 3 placebo-controlled trial evaluating the efficacy and safety of zuranolone 50 mg in adults 18 to 64 years old with MDD as well as the open-label SHORELINE Study in MDD and cross-study analyses from across the LANDSCAPE and NEST programs. Collectively, the studies show reductions in depressive symptoms with zuranolone-treated patients such as consistent improvements in depressive mood, as well as rapid onset of significant effect by Day 3. Zuranolone has demonstrated a consistent safety profile in the totality of clinical data to date, with no evidence of withdrawal, weight gain, sexual dysfunction, euphoria, or sleep disruption; symptoms that are typically the cause of treatment discontinuation with current standard of care antidepressants. In pooled analyses from the LANDSCAPE and NEST programs of SF-36v2, a patient self-reported measure of general health, zuranolone treatment led to rapid improvement in quality of life and overall health across all functioning and well-being domains at Day 15 and across all domains at Day 42 (Day 45 in ROBIN Study).

Additional data presented summarized clinical data from the literature on onset of effect of current treatment options in MDD demonstrating there is a need for new treatment options with the potential for rapid response.

“The collection of data presented at ECNP showcases the LANDSCAPE and NEST programs, in totality, where we have seen a very consistent and differentiated profile for zuranolone. The efficacy data across the clinical development program have demonstrated a rapid onset of activity, consistent reductions in depressive symptoms and a two-week treatment regimen that may offer the potential to treat-as-needed. The data also include a robust safety database with more than 3,500 patients treated, showing that zuranolone has been well tolerated to date,” said Steve Kanes, M.D., PhD., chief medical officer at Sage Therapeutics. “We believe these data represent the potential for a benefit-risk profile for zuranolone that may be differentiated from the most prescribed depression drugs on the market, and may be welcomed by patients, if approved.”

“The data presented at ECNP further emphasize that zuranolone dosed once daily for two weeks has the potential to produce a rapid reduction of depressive symptoms within days for both major depressive disorder and postpartum depression and a differentiated, well-characterized safety profile,” said Katherine Dawson, M.D., head of the Therapeutics Development Unit at Biogen. “Collectively these data represent positive steps in Biogen’s journey to expand our footprint in neuropsychiatry and innovate for the millions of people who need new options to address mental health conditions.”

“The efficacy and safety data observed with zuranolone across the LANDSCAPE and NEST clinical program indicate that, if approved, it may offer the potential for people with MDD and PPD to experience a rapid reduction in their depressive symptoms without side effects such as weight gain, sexual dysfunction and sleep disruption that are often associated with treatments currently on the market,” said Anita H. Clayton, M.D., Chair of Psychiatry and Neurobehavioral Sciences, University of Virginia School of Medicine. “Patients in the trials are also indicating through the patient outcome measures that zuranolone helped with their overall well-being.”

Data presented at ECNP:

- **Oral Presentation:** Zuranolone in major depressive disorder: topline results from the Phase 3, multicenter, randomized, double-blind, placebo-controlled WATERFALL Study
- **Poster Presentation Title:** Zuranolone 30 mg in major depressive disorder: results through 1-year follow-up from the Phase 3, open-label, SHORELINE Study
- **Poster Presentation:** Exploring the rapidity of treatment effect for current treatment options for major depressive disorder

Conference Call Information
Sage will host a conference call and webcast Monday, October 4, 2021 at 8:00am ET to review the totality of the data presented at ECNP from the zuranolone clinical development program. Anita Clayton, M.D., Chair of Psychiatry and Neurobehavioral Sciences, University of Virginia School of Medicine will join the conference call to discuss data presented at the ECNP Congress in more detail.

The live webcast can be accessed on the investor page of Sage's website at investor.sagerx.com. A replay of the webcast will be available on Sage's website approximately two hours after the completion of the event and will be archived for up to 30 days.

About the Short-Form Health Survey (SF-36)
The Short Form health survey (SF-36) is an often-used, well-researched, and self-reported measure of general health. The SF-36 uses 36 questions, covering eight domains of health, to assess the general health status and quality of life at the individual level in clinical practice and research, and at the population level for health policy evaluations. The SF-36 has been used in thousands of research studies, and while it was originally designed as a generic health measure, it is also applied to specific disease populations. The SF-36 represents an international benchmark for health outcomes measurement and has been used as efficacy endpoints in clinical trials.

About Major Depressive Disorder (MDD)
Major depressive disorder (MDD) is a common but serious mood disorder in which people experience depressive symptoms that impair their social,

occupational, educational, or other important functioning, such as a depressed mood or loss of interest or pleasure in daily activities, consistently for at least a two-week period. It is estimated that approximately 19 million people in the U.S. and more than 250 million people worldwide suffer from MDD each year. While antidepressants are widely used to treat MDD, large-scale studies have demonstrated the need for additional therapies with a differentiated profile.

About Zuranolone
Zuranolone (SAGE-217/BIIB125) is a once-daily, two-week, investigational drug in development for the treatment of major depressive disorder (MDD) and postpartum depression (PPD). Zuranolone is an investigational oral neuroactive steroid (NAS) GABA-A receptor positive allosteric modulator (PAM). The GABA system is the major inhibitory signaling pathway of the brain and central nervous system and contributes to regulating brain function. Zuranolone has been granted Breakthrough Therapy Designation by the U.S. Food & Drug Administration.

Zuranolone is being evaluated as a potential rapid-acting treatment for PPD and MDD in the NEST and LANDSCAPE clinical trial programs. The two development programs include multiple studies examining use of zuranolone in several thousand patients with a variety of dosing, clinical endpoints, and treatment paradigms. The LANDSCAPE program includes five studies of zuranolone in patients with MDD. Data have been reported from three studies of zuranolone 30 mg in patients with MDD (MDD-201B, MOUNTAIN Study and the 30 mg cohort from the ongoing SHORELINE Study), and one study of zuranolone 50 mg in patients with MDD (WATERFALL Study) in addition to an interim cut of the zuranolone 50mg cohort of the ongoing SHORELINE Study. Two additional studies evaluating zuranolone 50 mg in patients with MDD are expected to read out by the end of 2021 (CORAL Study and another cut of the 50mg cohort of the SHORELINE Study).

The NEST Program includes two placebo-controlled studies of zuranolone in patients with PPD. Positive data from the ROBIN Study (zuranolone 30 mg) have been previously reported. The SKYLARK Study (zuranolone 50 mg) is anticipated to readout by mid-2022.

The programs are designed to generate data to support a potential NDA filing as efficiently as possible. If successful, LANDSCAPE and NEST may support paths to approval with three distinct opportunities to address patient needs: PPD, acute rapid response therapy in MDD when co-initiated with a new standard antidepressant, and as-needed treatment of MDD.

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.

About Biogen
At Biogen, our mission is clear: we are pioneers in neuroscience. Biogen discovers, develops and delivers worldwide innovative therapies for people living with serious neurological and neurodegenerative diseases as well as related therapeutic adjacencies. One of the world's first global biotechnology companies, Biogen was founded in 1978 by Charles Weissmann, Heinz Schaller, Kenneth Murray and Nobel Prize winners Walter Gilbert and Phillip Sharp. Today Biogen has the leading portfolio of medicines to treat multiple sclerosis, has introduced the first approved treatment for spinal muscular atrophy, commercializes biosimilars of advanced biologics and is focused on advancing research programs in multiple sclerosis and neuroimmunology, Alzheimer's disease and dementia, neuromuscular disorders, movement disorders, ophthalmology, neuropsychiatry, immunology, acute neurology and neuropathic pain.

We routinely post information that may be important to investors on our website at www.biogen.com. Follow us on social media - Twitter, LinkedIn, Facebook, YouTube.

Forward-Looking Statements

Sage Therapeutics Safe Harbor
Various statements in this release concern Sage's future expectations, plans and prospects, including without limitation statements regarding: the potential for future regulatory approval of zuranolone; our planned timing for reporting of data from ongoing clinical trials; the potential profile and benefit of zuranolone in MDD and PPD; regulatory filing plans and potential pathways and opportunities; planned next steps for the program; our estimates as to the number of patients with MDD; and the goals, opportunity and potential for zuranolone and 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: success in earlier clinical trials 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 or generate results sufficient to file for or gain regulatory approval to market a product without further development work; unexpected concerns may arise from additional data, analysis or results from any of our completed studies; 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 encounter delays in conduct of our clinical trials, including slower than expected site initiation or enrollment, that may impact our ability to meet our expected time-lines; the FDA may ultimately decide that the design, conduct or results of our completed, ongoing and planned clinical trials for zuranolone, even if positive, are not sufficient for regulatory filing or approval in the indications that are the focus of our development plan and may require additional trials or data which may significantly delay our efforts to obtain approval and may not be successful; other decisions or actions of the FDA or other regulatory agencies may affect the zuranolone program and our plans, progress or results; the actual size of the MDD patient population may be significantly lower than our estimates and, even if zuranolone is approved, it may only be approved or used to treat a subset of the relevant patient populations; we may encounter technical and other unexpected hurdles in the development and manufacture of zuranolone or our other product candidates which may delay our timing or change our plans; 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.

Biogen Safe Harbor
This news release contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, relating to the potential, benefits, safety and efficacy of zuranolone; the potential clinical effects of zuranolone; results from the WATERFALL and SHORELINE Studies of zuranolone; the clinical development program for zuranolone; clinical development programs, clinical trials and data readouts and presentations for zuranolone; the potential treatment of MDD and PPD; the potential of Biogen's commercial business and pipeline programs, including zuranolone; the anticipated benefits and potential of Biogen's collaboration arrangement with Sage; and risks and uncertainties associated with drug development and commercialization. These forward-looking statements may be accompanied by words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "potential," "possible," "will," "would" and other words and terms of similar meaning. Drug development and commercialization involve a high degree of risk and only a small number of research and development programs result in commercialization of a product. Results in early-stage clinical trials may not be indicative of full results or results from

later stage or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements, or the scientific data presented.

These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including without limitation, uncertainty of success in the development and potential commercialization of zuranolone; unexpected concerns may arise from additional data, analysis or results obtained during the WATERFALL and SHORELINE Studies or the other clinical studies of zuranolone; regulatory authorities may require additional information or further studies, or may fail or refuse to approve or may delay approval of Biogen's drug candidates, including zuranolone; the occurrence of adverse safety events; the risks of other unexpected hurdles, costs or delays; failure to protect and enforce data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; product liability claims; third party collaboration risks; and the direct and indirect impacts of the ongoing COVID-19 pandemic on our business, results of operations and financial condition. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from Biogen's expectations in any forward-looking statement. Investors should consider this cautionary statement as well as the risk factors identified in Biogen's most recent annual or quarterly report and in other reports Biogen has filed with the U.S. Securities and Exchange Commission. These statements are based on Biogen's current beliefs and expectations and speak only as of the date of this news release. Biogen does not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

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