Sage Therapeutics and Biogen Complete Rolling Submission of New Drug Application for Zuranolone in the Treatment of Major Depressive Disorder and Postpartum Depression

December 6, 2022

Zuranolone is being evaluated as a short course, rapid-acting, oral medication for major depressive disorder (MDD) and postpartum depression (PPD)

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Dec. 6, 2022-- Sage Therapeutics, Inc. (Nasdaq: SAGE) and Biogen Inc. (Nasdaq: BIIB) announced the completion of the rolling submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for zuranolone in the treatment of major depressive disorder (MDD) and postpartum depression (PPD). Zuranolone is an investigational drug being evaluated as a rapid-acting, once-daily, 14-day oral short course treatment in adults with MDD and PPD. The submission completes the NDA filing that was initiated earlier this year.

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In the clinical development program to date, zuranolone showed rapid and sustained improvement of depressive symptoms with a generally well-tolerated and consistent safety profile. Zuranolone, a neuroactive steroid, has a novel mechanism of action as a positive allosteric modulator of GABA-A receptors. In people with depression, it may help to rapidly rebalance dysregulated neuronal networks to help restore brain function. Zuranolone targets brain networks responsible for functions such as mood, arousal, behavior, and cognition.

“Based on the data in the LANDSCAPE and NEST programs, we believe that zuranolone has the potential to be a meaningful new therapy for depression,” said Priya Singhal, M.D., M.P.H., Head of Global Safety and Regulatory Sciences and Interim Head of R&D at Biogen. “We look forward to working with the FDA as this filing progresses.”

“Mental health is a highly underserved area with an urgent unmet need for innovative therapies. We need to rethink how MDD and PPD are treated. Existing treatments often take weeks to months to provide symptom relief, and patients may need to cycle through multiple treatment options to fully address their symptoms. People with MDD and PPD deserve better,” said Laura Gault, M.D., Ph.D., Chief Medical Officer at Sage. “We believe that zuranolone, if approved, could evolve the way depression is treated and this submission brings us one step closer to that goal.”

The NDA submission includes data from the LANDSCAPE and NEST development programs for zuranolone. The LANDSCAPE program includes five studies of zuranolone in adults with MDD (MDD-201B, MOUNTAIN, SHORELINE, WATERFALL, and CORAL Studies). The NEST program includes two studies of zuranolone in adult women with PPD (ROBIN and SKYLARK Studies).

Zuranolone was granted Fast Track Designation by the FDA in 2017 and Breakthrough Therapy in 2018 for MDD. The FDA also granted Fast Track Designation for PPD in 2022.

About zuranolone
Zuranolone (SAGE-217/BIIB125) is a once-daily, 14-day, investigational drug in development for the treatment of major depressive disorder (MDD) and postpartum depression (PPD). Zuranolone is an 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 Fast Track and Breakthrough Therapy Designation for MDD and Fast Track Designation for PPD by the U.S. Food & Drug Administration.

Zuranolone is being evaluated in the LANDSCAPE and NEST clinical development programs. The two development programs include multiple studies examining use of zuranolone in several thousand people with a variety of dosing, clinical endpoints, and treatment paradigms. The LANDSCAPE program includes five studies of zuranolone in people with MDD (MDD-201B, MOUNTAIN, SHORELINE, WATERFALL, and CORAL Studies). The NEST program includes two placebo-controlled studies of zuranolone in women with PPD (ROBIN and SKYLARK Studies). Additionally, Shionogi completed a Phase 2 study of zuranolone in Japan in people with MDD.

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 www.sagerx.com.

About Biogen
As pioneers in neuroscience, Biogen discovers, develops, and delivers worldwide innovative therapies for people living with serious neurological 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, Sir Kenneth Murray, and Nobel Prize winners Walter Gilbert and Phillip Sharp. Today, Biogen has a leading portfolio of medicines to treat multiple sclerosis, has introduced the first approved treatment for spinal muscular atrophy, and developed the first and only approved treatment to address a defining pathology of Alzheimer’s disease. Biogen is also commercializing biosimilars and focusing on advancing one of the industry’s most diversified pipelines in neuroscience that will transform the standard of care for patients in several areas of high unmet need.

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.

Sage Therapeutics Safe Harbor

Various statements in this release concern Sage's future expectations, plans and prospects, including without limitation our statements regarding: the potential profile and benefit of zuranolone in the treatment of MDD and PPD; our belief that the data from our clinical programs support the potential of zuranolone in the treatment of MDD and PPD; our mission of making zuranolone available as a new treatment option in the treatment of MDD and PPD; the potential for approval of zuranolone in the treatment of MDD and PPD; our estimates of the number of people with MDD and PPD; and other statements as to our mission and goals. 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; 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; the FDA may not grant priority review or meet expected review timelines for our NDA; other decisions or actions of the FDA or other regulatory agencies may affect our efforts with respect to zuranolone and our plans, progress or results; results of ongoing or future studies may impact our ability to obtain approval of zuranolone or impair the potential profile of zuranolone; unexpected concerns may arise from additional data, analysis or results from any of our completed studies; 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; the number of patients with MDD and PPD, the unmet need for additional treatment options and the potential profile and market for zuranolone in the treatment of MDD and PPD, if approved, may be significantly smaller than we expect; and we may encounter technical and other unexpected hurdles which may delay our timing or change our plans, increase our costs or otherwise negatively impact our efforts to gain approval of zuranolone and to make it available as a treatment option for MDD and PPD or to accomplish other aspects of our mission and goals; as well as those risks more fully discussed in the section entitled "Risk Factors" in our most recent quarterly report with the Securities and Exchange Commission (SEC), as well as discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the SEC. 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; 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 of 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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