Sage Therapeutics and Biogen Share Update on FDA Advisory Committee for Zuranolone

March 8, 2023

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Mar. 8, 2023-- Sage Therapeutics, Inc. (Nasdaq: SAGE) and Biogen Inc. (Nasdaq: BIIB) announced that the U.S. Food and Drug Administration (FDA) notified the companies that the agency does not currently plan to convene an advisory committee meeting to discuss the New Drug Application (NDA) for zuranolone in the treatment of major depressive disorder (MDD) and postpartum depression (PPD).

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20230307006059/en/

Zuranolone is an investigational drug being evaluated as a 14-day, rapid-acting, once-daily, oral treatment in adults with MDD and PPD. The application has been granted priority review and the FDA has assigned a Prescription Drug User Fee Act (PDUFA) action date of August 5, 2023.

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 central nervous system and contributes to regulating brain function.

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 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

Founded in 1978, Biogen is a leading global biotechnology company that has pioneered multiple breakthrough innovations including a broad portfolio of medicines to treat multiple sclerosis, the first approved treatment for spinal muscular atrophy, and two co-developed treatments to address a defining pathology of Alzheimer's disease. Biogen is advancing a pipeline of potential novel therapies across neurology, neuropsychiatry, specialized immunology and rare diseases and remains acutely focused on its purpose of serving humanity through science while advancing a healthier, more sustainable and equitable world.

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 FDA's plan not to convene an advisory committee meeting; the potential profile and benefit of zuranolone in the treatment of MDD and PPD; our expectations regarding the PDUFA date for our NDA; the potential for approval of zuranolone; and other statements as to our mission, goals and plans. 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 decide to convene an advisory committee at a future date despite its current plan not to hold an advisory committee meeting; the FDA may find that the data included in our NDA for zuranolone are not sufficient for approval and may not approve the NDA or may grant a more narrow or limited approval than we are seeking; the FDA 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 meet expected review timelines for our NDA or may extend the review period as a result of additional or supplemental information we submit or there may be other delays in such timelines; other decisions or actions of the FDA 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 or use that negatively impact further development or that require additional nonclinical and clinical work which may not yield positive results; the clinical profile of zuranolone in the treatment of MDD or PPD, if approved, may not be as we expect; and we may encounter technical and other unexpected hurdles which may delay our timing or change our plans or otherwise negatively impact our efforts to gain approval of zuranolone 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20230307006059/en/

MEDIA:
Sage
Kathryn Ritzinger
+1 646 872-2912
Kathryn.Ritzinger@sagerx.com

Biogen
Jack Cox
+ 1 210 544 7920
public.affairs@biogen.com

INVESTORS:
Sage
Helen Rubinstein
+1 315 382-3979
Helen.Rubinstein@sagerx.com

Biogen
Mike Hencke
+1 781 464 2442
IR@biogen.com

Source: Sage Therapeutics, Inc.