

Sage Therapeutics and Biogen to Host Investor Webcast on December 6, 2022 to Discuss Potential Commercialization Plans for Zuranolone

November 22, 2022

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 22, 2022-- Sage Therapeutics, Inc. (Nasdaq: SAGE) and Biogen Inc. (Nasdaq: BIIB) today announced that the companies will host a joint investor webcast to discuss the planned commercialization approach and opportunity for their investigational product, zuranolone, on Tuesday, December 6 at 8:00 a.m. ET.

Zuranolone is being evaluated as a potential rapid-acting, once-daily, oral two-week treatment for major depressive disorder (MDD) and postpartum depression (PPD). The webcast will cover the unmet medical need in MDD, review clinical data generated with zuranolone to date and provide more detail on the potential commercialization plans and opportunity in MDD, if zuranolone is approved.

Webcast Information

A live webcast of the presentation can be accessed on the investor page of Sage's website at <u>investor.sagerx.com</u>, where it will be available for up to 30 days, and the investor page of Biogen's website at <u>investors.biogen.com</u>.

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 pipeline in neuroscience that will transform the standard of care for patients in several areas of high unmet need.

In 2020, Biogen launched a bold 20-year, \$250 million initiative to address the deeply interrelated issues of climate, health, and equity. Healthy Climate, Healthy Lives™ aims to eliminate fossil fuels across the company's operations, build collaborations with renowned institutions to advance the science to improve human health outcomes, and support underserved communities.

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 for approval and commercialization of zuranolone and the potential commercial opportunity for zuranolone, if approved. 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 experience delays or unexpected hurdles in our efforts to complete our rolling new drug application (NDA) submission for zuranolone in MDD and PPD and we may not be able to complete the submission on the timeline we expect or at all; 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 in MDD or PPD, or both; 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; even if our NDA is successfully filed and accepted, 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, results and expected timelines; we may encounter adverse events from ongoing studies or future use of zuranolone or unexpected concerns from additional analysis of results of completed studies that negatively impact the potential for approval of zuranolone or the potential commercial opportunity; even if the NDA for zuranolone is approved, other decisions or actions of the FDA, such as decisions related to the scope and content of the approved label, may affect the commercial opportunity for zuranolone and our plans; even if zuranolone is approved, the unmet need for new treatment options in MDD and PPD, the number of patients with those disorders and related patient segment estimates and the market for zuranolone in those indications may be significantly smaller than we expect; zuranolone, if approved in MDD and PPD, may not achieve market acceptance for a number of reasons, including if the profile of zuranolone in clinical practice does not meet expectations or if competitive products meet treatment needs, or if we encounter reimbursement-related or other market-related issues that impact the success of our commercialization; we may never be able to generate meaningful revenues from sales of zuranolone, if approved, or to generate revenues at levels we expect; and we may encounter technical and other unexpected hurdles in the development and manufacture of our product candidates or the commercialization of any 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.

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/20221121005978/en/

Sage Investors

Helen Rubinstein 315-382-3979 helen.rubinstein@sagerx.com

Sage Media

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

Biogen Investors

Mike Hencke 781-464-2442 IR@biogen.com

Biogen Media

Jack Cox 210-544-7920 public.affairs@biogen.com

Source: Sage Therapeutics, Inc.