



## Sage Therapeutics Announces Discontinuation of the Collaboration with Biogen on the SAGE-324 Program

September 26, 2024

***Sage and Biogen will continue to partner on ZURZUVAE®, the first and only FDA-approved oral treatment for women with postpartum depression***

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Sep. 26, 2024-- Sage Therapeutics, Inc. (NASDAQ: Sage) today announced that Biogen has terminated its rights under the collaboration and license agreement with Sage specific to the SAGE-324 program. The companies recently announced negative results from the Phase 2 KINETIC 2 Study of investigational SAGE-324 for the chronic treatment of essential tremor (ET) and discontinued further clinical development of SAGE-324 in ET.

Sage and Biogen will continue to partner on ZURZUVAE® (zuranolone), the first and only FDA-approved oral treatment for women with postpartum depression (PPD) and will continue to work on their shared vision to help women suffering from PPD.

Under the terms of the collaboration and license agreement, the termination will be effective on February 17, 2025, and Sage will resume full ownership of the SAGE-324 asset at that time. Sage plans to continue to evaluate other potential indications, if any, for SAGE-324.

### **SELECT IMPORTANT SAFETY INFORMATION FOR ZURZUVAE:**

ZURZUVAE (zuranolone) CIV, is a neuroactive steroid gamma-aminobutyric acid A (GABA<sub>A</sub>) receptor positive modulator indicated for the treatment of postpartum depression in adults.

This does not include all the information needed to use ZURZUVAE safely and effectively. See full prescribing information for ZURZUVAE.

ZURZUVAE may cause serious side effects. The most common side effects of ZURZUVAE include sleepiness or drowsiness, dizziness, common cold, diarrhea, feeling tired, weak, or having no energy, and urinary tract infection. ZURZUVAE may decrease your awareness and alertness, which can affect your ability to drive safely or safely do other dangerous activities. Do not drive, operate machinery, or do other dangerous activities until at least 12 hours after taking each dose during your 14-day treatment course of ZURZUVAE. You may not be able to tell on your own if you can drive safely or tell how much ZURZUVAE is affecting you. ZURZUVAE may cause sleepiness, drowsiness, slow thinking, dizziness, confusion, and trouble walking. Because of these symptoms, you may be at a higher risk for falls during treatment with ZURZUVAE. Taking alcohol, other medicines that cause CNS depressant effects, or opioids while taking ZURZUVAE can make these symptoms worse and may also cause trouble breathing. Tell your healthcare provider if you develop any of these symptoms, or if they get worse during treatment with ZURZUVAE. Your healthcare provider may decrease your dose or stop ZURZUVAE treatment if you develop these symptoms. ZURZUVAE is a federal controlled substance (C-IV) because it contains zuranolone, which can be abused or lead to dependence. Tell your healthcare provider right away if you become pregnant or plan to become pregnant during treatment with ZURZUVAE. You should use effective birth control (contraception) during treatment with ZURZUVAE and for 1 week after the final dose. ZURZUVAE and other antidepressant medicines may increase the risk of suicidal thoughts and actions in people 24 years of age and younger. ZURZUVAE is not for use in children.

### **About SAGE-324**

SAGE-324 is an investigational oral neuroactive steroid (NAS) GABA<sub>A</sub> receptor positive allosteric modulator (PAM). NAS GABA<sub>A</sub> receptor PAMs bind to both synaptic and extrasynaptic GABA<sub>A</sub> receptors, enhancing inhibitory activity of the GABAergic system, the major inhibitory neurotransmission system in the brain. GABA is the primary inhibitory neurotransmitter in the central nervous system and plays a critical role in maintaining balanced neuronal activity in the brain. The safety and effectiveness of SAGE-324 have not been established.

### **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](http://www.sagerx.com) or engage with us on [Facebook](#), [LinkedIn](#), [Instagram](#), and [X](#).

### **Sage Forward-Looking Statements**

*Various statements in this release concern our future expectations, plans and prospects, including without limitation statements regarding: our plans to continue to evaluate potential indications for SAGE-324, our vision to help women with PPD with ZURZUVAE, our mission and goals, and the opportunity and potential 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: we may decide not to pursue any further development of SAGE-324 in any indication; the results of ongoing, planned or future clinical studies or nonclinical work with respect to any of our product candidates may be negative; results of earlier trials of any of our product candidates may not be replicated in ongoing or future trials; clinical and nonclinical data we generate in the course of any development program may not be sufficient to move to the next phase of development for an indication or may not support further development at all; with respect to our vision for ZURZUVAE, we may not achieve the clinical benefit, clinical use or level of market acceptance from healthcare*

*professionals, patients or payors for ZURZUVAE in the treatment of PPD we expect or we may encounter reimbursement-related or other market-related issues or issues with our distribution network that impact the success of our commercialization efforts, including our ability to achieve our vision for this product; 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 of our approved products or that require additional nonclinical and clinical work which may not yield positive results; 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 filed with the Securities and Exchange Commission, 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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