ZURZUVAE™ (zuranolone) CIV, a Landmark Oral Treatment for Women with Postpartum Depression (PPD), is Now Available in the U.S.

December 14, 2023

ZURZUVAE, the first and only oral, once-daily, 14-day treatment course, has shown to provide rapid improvements in depressive symptoms at Day 15 and as early as Day 3 for women with PPD

Patient support program, ZURZUVAE For You, and financial assistance available to eligible women with PPD prescribed ZURZUVAE

Patients will receive prescriptions directly at home via specialty pharmacy distribution model

CAMBRIDGE, Mass., Dec. 14, 2023 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) and Sage Therapeutics, Inc. (Nasdaq: SAGE) announced ZURZUVAE™ (zuranolone) 50 mg (two 25 mg capsules per day) CIV is now available by prescription for the treatment of postpartum depression (PPD) for adults in the United States, with product already at specialty pharmacies and delivered to patients. ZURZUVAE is the first and only oral, 14-day treatment course for adults with PPD that can provide rapid improvements in depressive symptoms at Day 15 and as early as Day 3.

“For women with PPD, delayed improvement in depressive symptoms can significantly worsen outcomes. Having an option like ZURZUVAE that can work at Day 15 and improve symptoms in as early as three days has the potential to make a profound difference in the lives of women with PPD,” said Dr. Kristina Deligiannidis, a principal investigator in the ZURZUVAE clinical development program and Professor, The Feinstein Institutes for Medical Research in Manhasset, New York. “This milestone is hopefully a catalyst for more systemic change for women with PPD including a much-needed increase in screening, diagnosis and treatment across physician specialties.”

“After having a baby, the post-birth follow-up appointment is usually the first time a woman has the opportunity to talk about how she is feeling. It shouldn’t matter if it takes place with her midwife, OBGYN or family practitioner – it’s critical we use these conversations to proactively discuss her mental health and take action to support women in need,” said Dr. Quinn Peeper, Obstetrician/Gynecologist at City Crescent Physicians in New Orleans. “A treatment like ZURZUVAE provides us with a new option to help address the needs of women with PPD.”

Biogen and Sage are prioritizing access through active discussions with national, regional and government payors to advocate for broad and equitable access to ZURZUVAE for women with PPD with minimal restrictions. While coverage decisions by insurers across all payor segments can take time, Biogen and Sage are focused on helping women who are prescribed ZURZUVAE gain access as quickly as possible. The companies also launched a patient support program, ZURZUVAE For You, which provides educational resources, help with understanding insurance coverage, and assistance navigating the prescription fulfillment process. The program also includes financial assistance, such as a copay assistance program, and product at no cost for eligible patients.

The companies are partnering with several of the leading national specialty pharmacies and ZURZUVAE will be shipped directly to women with PPD who are prescribed the treatment.

“It’s critical that as a society we recognize PPD is a serious medical condition. I have witnessed the devastating impact untreated PPD can have on women, only heightened by the fact that Black and Brown women and those living in a lower socioeconomic status are disproportionately impacted,” said Wendy N. Davis, Ph.D., PMH-C, Executive Director at Postpartum Support International. “PPD should not be treated as an afterthought. We need to embrace the care of women and increase access to effective care. Treatments like ZURZUVAE are a signal of hope that we're one step closer to prioritizing maternal mental health.”

PPD symptoms can be debilitating and are characterized by negative changes in mood and impaired function.[1,2] PPD impacts women of all races, ethnicity, socio-economic status and community,[3-5] though symptoms are more common among minority patient populations compared to white patients.[3,4] Black and Brown women, women who live in rural areas, or those on Medicaid may be more likely to receive inadequate postpartum care, compared to individuals in urban areas or with private health insurance.[5] Biogen and Sage are working with key stakeholders across states to help raise awareness of the importance of treating PPD rapidly and removing barriers to treatment.

“We are committed to working with healthcare providers so women with PPD do not face this isolating condition alone,” said Alisha A. Alaimo, President of Biogen’s North America Organization. “We are proud to offer the first oral therapy indicated specifically for women with PPD and we hope this milestone adds to the growing efforts, federally and among health organizations, to improve maternal mental health care.”

“We are immensely proud of the feedback following the approval of ZURZUVAE from those on the front lines who are advocating for and delivering maternal mental healthcare, as well as their commitment to making an impact collaboratively,” said Chris Benecchi, Chief Business Officer at Sage Therapeutics. “Innovations are only impactful if people can access them, and we will continue supporting the goal of broad and equitable access. Our support programs aim, where possible, to help women with PPD who are prescribed ZURZUVAE to have little to no copay, and to provide product at no cost for eligible patients with no insurance, as we believe that lack of insurance or financial means should not be a barrier to treatment access.”

For more information on ZURZUVAE and the patient support program, ZURZUVAE For You, HCPs and their patients can visit ZURZUVAE.com or call 844-987-9882.

Indication and Important Safety Information

What is ZURZUVAE?
ZURZUVAE is a prescription medicine used to treat adults with postpartum depression (PPD).
It is not known if ZURZUVAE is safe and effective in children.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about ZURZUVAE?

ZURZUVAE may cause serious side effects, including:

- **Decreased ability to drive or do other dangerous activities.** 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

- **Decreased awareness and alertness [central nervous system (CNS) depressant effects].** 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. Keep ZURZUVAE in a safe place to protect it from theft. Do not sell or give away ZURZUVAE, because it may harm others and is against the law.

Before taking ZURZUVAE, tell your healthcare provider about all of your medical conditions, including if you:

- drink alcohol
- have abused or been dependent on prescription medicines, street drugs, or alcohol
- have liver or kidney problems
- are pregnant or plan to become pregnant. ZURZUVAE may harm your unborn baby
- are breastfeeding or plan to breastfeed. ZURZUVAE passes into breast milk, and it is not known if it can harm your baby. Talk to your healthcare provider about the risks and benefits of breastfeeding and about the best way to feed your baby during treatment with ZURZUVAE

Females who are able to become pregnant:

- Tell your healthcare provider right away if you 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
- There is a pregnancy registry for females who are exposed to ZURZUVAE during pregnancy. The purpose of the registry is to collect information about the health of females exposed to ZURZUVAE and their baby. If you become pregnant during treatment with ZURZUVAE, talk to your healthcare provider about registering with the National Pregnancy Registry for Antidepressants at 1-844-405-6185 or visit online at https://womensmentalhealth.org/research/pregnancyregistry/antidepressants/

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. ZURZUVAE and some medicines may interact with each other and cause serious side effects. ZURZUVAE may affect the way other medicines work, and other medicines may affect the way ZURZUVAE works.

Especially tell your healthcare provider if you take antidepressants, opioids, or CNS depressants such as benzodiazepines.

What should I avoid while taking ZURZUVAE?

- **Do not** drive a car, operate machinery, or do other dangerous activities **until at least 12 hours after taking each dose of ZURZUVAE** because ZURZUVAE may make you feel sleepy, confused, or dizzy
- **Do not** drink alcohol or take other medicines that make you sleepy or dizzy while taking ZURZUVAE without talking to your healthcare provider

See "**What is the most important information I should know about ZURZUVAE?"**

ZURZUVAE may cause serious side effects, including:

See **"What is the most important information I should know about ZURZUVAE?"**

- **Increased risk of suicidal thoughts or actions.** 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**

How can I watch for and try to prevent suicidal thoughts and actions?

- Pay close attention to any changes, especially sudden changes in mood, behavior, thoughts, or feelings, or if you develop suicidal thoughts or actions. This is very important when an antidepressant medicine is started or when the dose is changed
- Tell your healthcare provider right away if you have any new or sudden changes in mood, behavior, thoughts, or feelings
- Keep all follow-up visits with your healthcare provider as scheduled. Call your healthcare provider between visits as needed, especially if you have concerns about symptoms

Tell your healthcare provider right away if you have any of the following symptoms, especially if they are new, worse, or worry you:

- attempts to commit suicide
- thoughts about suicide or dying
- new or worse depression
- feeling very agitated or restless
- trouble sleeping (insomnia)
- new or worse anxiety
- panic attacks
- new or worse irritability
- acting aggressive, being angry, or violent
- an extreme increase in activity and talking (mania)
- acting on dangerous impulses
- other unusual changes in behavior or mood

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

These are not all of the possible side effects of ZURZUVAE. Call your doctor for medical advice about side effects. You can report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full Prescribing Information, including **Boxed Warning** and Medication Guide.

About ZURZUVAE™ (zuranolone)
ZURZUVAE is a once-daily, oral, 14-day medicine for the treatment of adults with postpartum depression (PPD). ZURZUVAE is a 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.

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, two co-developed treatments to address a defining pathology of Alzheimer's disease, the first treatment to target a genetic form of ALS, the first oral treatment approved for postpartum depression, and the first approved treatment for Friedreich's ataxia. 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 - Facebook, LinkedIn, X, YouTube.

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.

Biogen Safe Harbor
This news release contains forward-looking statements, relating to the potential, benefits, safety and efficacy of ZURZUVAE; the potential of Biogen's commercial business and pipeline programs, including ZURZUVAE; 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 ZURZUVAE for PPD; 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; 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 impact of COVID-19 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 speak only as of the date of this news release. Biogen does not undertake any obligation to publicly update any forward-looking statements.

Sage Therapeutics Safe Harbor
Various statements in this release concern Sage's future expectations, plans and prospects, including without limitation our statements regarding: our plans for commercializing ZURZUVAE in the treatment of women with PPD; our expectations as to our patient support programs for ZURZUVAE; our goals and plans with respect to access and reimbursement coverage for women with PPD who are prescribed ZURZUVAE; statements regarding the unmet need in the treatment of PPD; our belief in the potential clinical benefit of ZURZUVAE in the treatment of PPD; and the mission and goals 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: our commercialization efforts in the U.S. with respect to ZURZUVAE for the treatment of women with PPD may not be successful, and we may be unable to generate revenues at the levels or on the timing we expect or at levels or on the timing necessary to support our goals; the number of women with PPD, the unmet need for additional treatment options, and the potential market for ZURZUVAE in this indication may be significantly smaller than we expect; ZURZUVAE may not achieve the clinical benefit, clinical use or market acceptance we expect in the treatment of women with PPD; we may not achieve broad access or reimbursement coverage with minimal restrictions for ZURZUVAE in the treatment

of women with PPD; we may encounter reimbursement-related or other market-related issues that impact the success of our commercialization efforts or access to ZURZUVAE in the treatment of women with PPD; we may encounter adverse events related to ZURZUVAE at any stage that negatively impact commercialization; the need to align with our collaborators may hamper or delay our commercialization efforts or increase our costs; our business may be adversely affected and our costs may increase if any of our key collaborators fails to perform its obligations or terminates our collaboration; our ongoing efforts and activities to successfully develop products in addition to ZURZUVAE may not be successful; 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.

References:

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