Biogen Receives European Commission Approval for ZURZUVAE® (zuranolone), the First and Only Treatment Approved for Women with Postpartum Depression in Europe

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- Postpartum depression is a leading cause of maternal mortality in Europe[1-2], and is one of the most common medical conditions associated with pregnancy[3-5]; up to 20% of women experience postpartum depressive symptoms[6-11]
- The approval of this new therapeutic approach introduces an oral, 14-day treatment specifically indicated for PPD
- The EC approval of ZURZUVAE is based on the SKYLARK study, which demonstrated rapid relief from depressive symptoms as early as day 3 and sustained through day 45 compared to placebo

CAMBRIDGE, Mass., Sept. 17, 2025 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) announced that the European Commission (EC) has granted marketing authorization for ZURZUVAE® (zuranolone) to treat post-partum depression (PPD) in adults following childbirth. ZURZUVAE is a once-daily, oral, 14-day treatment which represents a novel therapeutic approach, offering the first and only treatment indicated for PPD in the E.U.

"This approval is a major milestone in addressing a critical unmet need in maternal health for women in Europe, where postpartum depression is underdiagnosed and undertreated," said Priya Singhal, M.D., M.P.H., Head of Development at Biogen. "ZURZUVAE is a 14-day treatment course which can improve the symptoms of PPD as early as day 3. This is a significant step forward from the current standards of care and our team is committed to engaging with the medical community and local authorities as we work to secure access for eligible European patients."

PPD is one of the most common medical conditions associated with pregnancy.[3-5] Symptoms of PPD may include depressed mood, anxiety, affected ability to bond with the newborn, functional impairment of daily activities, feelings of guilt and worthlessness, doubts about motherhood, and thoughts of self- or infant harm.[3] Left untreated, PPD symptoms may persist beyond the postpartum period and can lead to prolonged maternal morbidities and repercussions on child development.[1, 12, 13]

In Europe, up to 20% of women with a recent pregnancy experience symptoms of PPD.[6-11] Because clinical guidelines for screening and management of depression during and after pregnancy vary across European countries, many cases may go undiagnosed and untreated.[5] Death by suicide during the perinatal period is a leading cause of maternal mortality in Europe.[1-2]

The EC's approval of ZURZUVAE is based on the SKYLARK study that evaluated ZURZUVAE which met its primary end point, a significant mean reduction from baseline in the 17-item Hamilton Rating Scale for Depression (HAMD-17), a common measure of depression severity, at day 15 as compared to placebo. All key secondary endpoints were also met, with significant reduction in depressive symptoms being seen as early as day 3 and sustained through day 45 compared to placebo. ZURZUVAE was generally well-tolerated. The most frequently reported side effects ≥ 5% and greater than placebo in patients treated with ZURZUVAE 50 mg were somnolence, dizziness, and sedation.

For detailed product information, please see the Summary of Product Characteristics on the European Medicines Agency website at www.ema.europa.eu.

The U.S. Food and Drug Administration (FDA) approved ZURZUVAE in August 2023 and the Drug Enforcement Agency (DEA) scheduled it as a Class IV controlled substance in October 2023. In August 2025, ZURZUVAE received regulatory approval in the U.K. by the Medicines and Healthcare products Regulatory Agency (MHRA).

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

ZURZUVAE was discovered by Sage Therapeutics, Inc., and in 2020 Biogen and Sage Therapeutics entered into a collaboration to jointly develop and commercialize ZURZUVAE in the U.S. As part of the agreement, Biogen received exclusive rights to develop and commercialize ZURZUVAE outside of the U.S., excluding Japan, Taiwan and South Korea. In July 2025, Supernus Pharmaceuticals, Inc. (Nasdaq: SUPN) completed its acquisition of Sage Therapeutics and is now the collaboration partner with whom Biogen is working in the U.S.

About Biogen
Founded in 1978, Biogen is a leading biotechnology company that pioneers innovative science to deliver new medicines to transform patients' lives and to create value for shareholders and our communities. We apply deep understanding of human biology and leverage different modalities to advance first-in-class treatments or therapies that deliver superior outcomes. Our approach is to take bold risks, balanced with return on investment to deliver long-term growth.

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.

Biogen Safe Harbor
This news release contains forward-looking statements, including, among others, relating to: the potential benefits, efficacy and safety of zuranolone (marketed as ZURZUVAE); our commitment to work to secure access for eligible patients in order to improve outcomes for, and address unmet needs of, patients with postpartum depression; the anticipated benefits, risks and potential of our collaboration arrangements; the potential of our commercial business and pipeline programs, including ZURZUVAE; and risks and uncertainties associated with drug development and commercialization. These forward-looking statements may be accompanied by such words as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could,"

“estimate,” “expect,” “forecast,” “goal,” “guidance,” “hope,” “intend,” “may,” “objective,” “outlook,” “plan,” “possible,” “potential,” “predict,” “project,” “prospect,” “should,” “target,” “will,” “would” or the negative of these words or 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. Given their forward-looking nature, these statements involve substantial risks and uncertainties that may be based on inaccurate assumptions and could cause actual results to differ materially from those reflected in such statements.

These forward-looking statements are based on management’s current beliefs and assumptions and on information currently available to management. Given their nature, we cannot assure that any outcome expressed in these forward-looking statements will be realized in whole or in part. We caution that these statements are subject to risks and uncertainties, many of which are outside of our control and could cause future events or results to differ materially from those stated or implied in this document, including, among others, uncertainty of our long-term success in developing, licensing, or acquiring other product candidates or additional indications for existing products; expectations, plans, prospects and timing of actions relating to product approvals, approvals of additional indications for our existing products, sales, pricing, growth, reimbursement and launch of our marketed and pipeline products; the potential impact of increased product competition in the biopharmaceutical and healthcare industry, as well as any other markets in which we compete, including increased competition from new originator therapies, generics, prodrugs and biosimilars of existing products and products approved under abbreviated regulatory pathways; our ability to effectively implement our corporate strategy; difficulties in obtaining and maintaining adequate coverage, pricing, and reimbursement for our products; the drivers for growing our business, including our dependence on collaborators and other third parties for the development, regulatory approval, and commercialization of products and other aspects of our business, which are outside of our full control; risks related to commercialization of biosimilars, which is subject to such risks related to our reliance on third-parties, intellectual property, competitive and market challenges and regulatory compliance; the risk that positive results in a clinical trial may not be replicated in subsequent or confirmatory trials or success in early stage clinical trials may not be predictive of results in later stage or large scale clinical trials or trials in other potential indications; risks associated with clinical trials, including our ability to adequately manage clinical activities, unexpected concerns that may arise from additional data or analysis obtained during clinical trials, regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of our drug candidates; and the occurrence of adverse safety events, restrictions on use with our products, or product liability claims; and any other risks and uncertainties that are described in reports we have filed with the U.S. Securities and Exchange Commission, which are available on the SEC’s website at www.sec.gov.

These statements speak only as of the date of this press release and are based on information and estimates available to us at this time. Should known or unknown risks or uncertainties materialize or should underlying assumptions prove inaccurate, actual results could vary materially from past results and those anticipated, estimated or projected. Investors are cautioned not to put undue reliance on forward-looking statements. A further list and description of risks, uncertainties and other matters can be found in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024 and in our subsequent reports on Form 10-Q. Except as required by law, we do not undertake any obligation to publicly update any forward-looking statements whether as a result of any new information, future events, changed circumstances or otherwise.

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