Zulresso®
(brexanolone) injection IV
for intravenous use 100mg/20mL

ZULRESSO® (brexanolone) Patient Brochure.

This brochure is intended for US patients and caregivers only

What is ZULRESSO?

ZULRESSO is a prescription medicine used to treat Postpartum Depression in individuals 15 years and older.
It is not known if ZULRESSO is safe and effective in individuals less than 15 years of age.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about ZULRESSO?
ZULRESSO can cause serious side effects, including:

- **Excessive sedation and sudden loss of consciousness.** ZULRESSO may cause you to feel very sleepy (excessive sedation) or pass out (loss of consciousness). Your healthcare provider should check you for symptoms of excessive sleepiness every 2 hours while you are awake.
  - During your ZULRESSO infusion, tell your healthcare provider right away if you feel like you cannot stay awake during the time you are normally awake or if you feel like you are going to pass out. Your healthcare provider may lower your dose or stop the infusion until symptoms go away.
  - You must have a caregiver or family member with you to help care for your child(ren) during your ZULRESSO infusion.
- Because of the risk of serious harm resulting from excessive sedation or sudden loss of consciousness, ZULRESSO is only available through a restricted program called the ZULRESSO REMS.

Please see additional Important Safety Information throughout and read the Medication Guide, including information on serious side effects, and discuss any questions you may have with your healthcare provider.

Postpartum depression (PPD) is one of the more common medical conditions that can happen during or after pregnancy. But it can be difficult to recognize.

Having a baby changes your body and your life in ways that may be hard to predict. Feeling exhausted, sad, moody, or tired within the first couple of weeks with your new baby can be common. However, postpartum depression (PPD) is different. If you're feeling depressed or you're experiencing a lack of interest or pleasure in normal activities, these can be signs of PPD.

Below is a list of signs and symptoms commonly associated with PPD. These are not the only ones, and you do not need to have all of them to experience PPD. If you're experiencing anything that is causing you concern, speak with your healthcare provider as soon as you can.

- Persistent sad, anxious, or "empty" mood
- Irritability
- Feelings of guilt, worthlessness, hopelessness, or helplessness
- Loss of interest or pleasure in hobbies and activities
- Fatigue or abnormal decrease in energy
- Feeling restless or having trouble sitting still
- Difficulty concentrating, remembering, or making decisions
- Difficulty sleeping (even when the baby is sleeping), awakening early in the morning, or oversleeping
- Abnormal appetite, weight changes, or both
- Aches or pains, headaches, cramps, or digestive problems that do not have a clear physical cause and do not ease even with treatment
- Trouble bonding or forming an emotional attachment with the new baby
- Persistent doubts about the ability to care for the new baby
- Thoughts about death, suicide, or harming oneself or the baby

If you are experiencing anything that causes concern, speak with your healthcare provider. They can tell you if it's PPD.

Please see additional Important Safety Information throughout and read the Medication Guide, including information on serious side effects, and discuss any questions you may have with your healthcare provider

Zulresso® (brexanolone) injection IV
for intravenous use 100mg/20mL

ZULRESSO® (brexanolone) may provide rapid improvement of depressive symptoms in 2.5 days (60 hours).

ZULRESSO is administered as a continuous intravenous infusion into the vein over 2.5 days (60 hours). ZULRESSO may cause you to feel very sleepy (excessive sedation) or pass out (loss of consciousness). Because of the risk of serious harm resulting from extreme sleepiness or passing out during treatment, ZULRESSO is only available through a restricted program called the ZULRESSO Risk Evaluation and Mitigation Strategy (REMS) in which a healthcare provider will carefully monitor you at a certified healthcare facility (also known as a Treating Center).

The most common side effects of ZULRESSO include: sleepiness, dry mouth, passing out, and flushing of the skin or face.
These are not all the side effects of ZULRESSO.

FAST RESULTS*

Moms treated with ZULRESSO experienced a greater improvement in depressive symptoms vs placebo as measured by a standard depression scale at the end of a 60 hour intravenous infusion.

MAINTAINED RESULTS*

In clinical studies in adults, moms who took ZULRESSO generally still felt better **30 days** after treatment began as measured by a standard depression scale. This 30-day measurement was also a preplanned part of the study.

**Individual results may vary.*

IMPORTANT SAFETY INFORMATION (continued)

Before receiving ZULRESSO, tell your healthcare provider about all your medical conditions, including if you:

- drink alcohol
- have kidney problems
- are pregnant or think you may be pregnant. It is not known if ZULRESSO will harm your unborn baby.
  - There is a pregnancy registry for women who are exposed to ZULRESSO during pregnancy. The purpose of the registry is to collect information about the health of women exposed to ZULRESSO and their baby. If you become pregnant during treatment with ZULRESSO, talk to your healthcare provider about registering with the National Pregnancy Registry for Antidepressants at 1-844-405-6185 or visit https://womensmentalhealth.org/clinical-and-researchprograms/pregnancyregistry/antidepressants/.
- are breastfeeding or plan to breastfeed. ZULRESSO passes into breast milk.

Talk to your healthcare provider about the risks and benefits of breastfeeding and about the best way to feed your baby while receiving ZULRESSO.

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

Please see additional Important Safety Information throughout and read the Medication Guide, including information on serious side effects, and discuss any questions you may have with your healthcare provider

Zulresso® (brexanolone) injection IV
for intravenous use 100mg/20mL

Understanding the treatment experience with ZULRESSO® (brexanolone).

ZULRESSO can cause excessive sedation and sudden loss of consciousness, which may cause serious harm. A healthcare provider will carefully monitor you for the duration of your infusion treatment in accordance with the REMS program.

If you're breastfeeding, talk to your healthcare provider about the best way to feed your baby while receiving ZULRESSO.

Consider bringing books, movies, and music to fill your time during your infusion.

Once your healthcare provider decides ZULRESSO is right for you, there may be a short wait time before starting treatment. Time to treatment may vary by individual Treating Center.

Preparing for your treatment

The thought of being away from family during treatment may feel overwhelming. Understanding the preparations you need to make may help you feel ready for your time away.

- **Prioritize** childcare arrangements for the duration of treatment, including at the Treating Center; someone will need to care for your child(ren) and be in the room with you if they visit
- **Plan** for extra support from loved ones for meal prep, transportation, and pet care, if needed
- **Pack** for your stay, including your ID, health insurance information, and toiletries

Please remember that your healthcare provider and the team at your Treating Center should always be your primary resources for any questions regarding your treatment.

IMPORTANT SAFETY INFORMATION (continued)

Especially tell your healthcare provider if you take other antidepressants, opioids, or Central Nervous System (CNS) depressants (such as benzodiazepines). Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine. Your healthcare provider will decide if other medicines can be taken with ZULRESSO.

How will I receive ZULRESSO?

ZULRESSO is given to you by continuous intravenous (IV) infusion into your vein. The infusion will last for a total of 60 hours (2.5 days).

What should I avoid while receiving ZULRESSO?

- ZULRESSO may make you feel dizzy and sleepy. Do not drive a car or do other dangerous activities after your ZULRESSO infusion until your feeling of sleepiness has completely gone away. See **"What is the most important information I should know about ZULRESSO?"**
- Do not drink alcohol while receiving ZULRESSO.

Please see additional Important Safety Information throughout and read the Medication Guide, including information on serious side effects, and discuss any questions you may have with your healthcare provider

SAGE CENTRAL® PATIENT SUPPORT

Sage Central® is available to provide patient support resources and information throughout your treatment.

Sage Central is a source for patient support resources and information. Once enrolled, you will have a dedicated team of case managers—known as Sage Central Navigators—who can provide information to help you throughout your treatment journey.

After you sign up with Sage Central, a Navigator will call you within 1 to 2 business days to welcome you and provide helpful information.

HOW CAN OUR NAVIGATORS HELP? THEY CAN:

- Answer questions about the treatment process
- Explain your insurance benefits and coverage options
- Provide information to help you prepare for your infusion
- Review financial assistance programs for eligible patients

Please remember that your healthcare provider should always be your primary resource for any questions regarding your treatment. Visit SageCentralSupport.com to learn more.

Call 844-4-SAGERX (844-472-4379) to connect with a Sage Central Navigator, Monday-Friday 8am-6pm ET

Scan the QR code to add Sage Central to your phone contacts

Please see additional Important Safety Information throughout and read the Medication Guide, including information on serious side effects, and discuss any questions you may have with your healthcare provider

SAGE CENTRAL® PATIENT SUPPORT

Learn about Sage Central Financial Assistance Programs for eligible patients.*

Zulresso® (brexanolone) injection IV for intravenous use 100mg/20mL

Concerns about the cost of ZULRESSO® (brexanolone) should not prevent you from seeking the treatment your healthcare provider has prescribed. Sage Central provides financial assistance options to eligible patients.

Once you've enrolled in Sage Central, you will be automatically enrolled in the financial assistance programs for which you may be eligible. Your continued eligibility is subject to the satisfaction of the terms and conditions of the financial assistance programs.

ZULRESSO DRUG COPAY ASSISTANCE PROGRAM

This program is designed to help reduce a patient's eligible out-of-pocket copay costs related to the drug. **If you have commercial insurance, you may be eligible for copay assistance to help reduce your out-of-pocket, drug-related copay costs up to $15,000**—regardless of income level and subject to certain terms and conditions and eligibility criteria.*

ZULRESSO INFUSION COPAY ASSISTANCE PROGRAM

This program is designed to help reduce a patient's eligible out-of-pocket copay costs related to the administration of the ZULRESSO infusion. **If you have commercial insurance, you may be eligible for copay assistance to help reduce your out-of-pocket, infusion-related copay costs up to $2,000**—regardless of income level and subject to certain terms and conditions and eligibility criteria.*

Residents of Massachusetts and Rhode Island are not eligible for infusion copay assistance.

FREE DRUG PROGRAM

This program provides ZULRESSO at no cost for eligible patients who would not otherwise have access to ZULRESSO and who meet certain income criteria. **If you are uninsured or underinsured and meet the financial eligibility criteria, you may qualify for the Free Drug Program.** Subject to terms and conditions and eligibility criteria.

See Terms & Conditions on pages 8 & 9

*ZULRESSO Drug Copay Assistance Program and ZULRESSO Infusion Copay Assistance Program are not available for prescriptions covered by Medicare, Medicaid, TriCare, or other federal- and state-funded programs.

Please see additional Important Safety Information throughout and read the Medication Guide, including information on serious side effects, and discuss any questions you may have with your healthcare provider

Zulresso®
(brexanolone) injection IV
for intravenous use 100mg/20mL

I remember just feeling better. It was as if there was a shift and the PPD symptoms, like my depressed mood, started to go away. From this moment on, I vowed I would fight PPD. I would fight for my family and most importantly, for myself.

– Lene, treated with ZULRESSO® (brexanolone)

This is one person's experience. Yours may be different.

Visit Zulresso.com to access additional ZULRESSO tools & resources

Lene has been compensated by Sage Therapeutics for her work as a ZULRESSO patient ambassador

IMPORTANT SAFETY INFORMATION (continued)

What are the possible side effects of ZULRESSO?
ZULRESSO can cause serious side effects, including:

- See **"What is the most important information I should know about ZULRESSO?"**
- **Increased risk of suicidal thoughts or actions.** ZULRESSO and other antidepressant medicines may increase suicidal thoughts and actions in some people 24 years of age and younger. Depression or other serious mental illnesses are the most important causes of suicidal thoughts or actions.

Please see additional Important Safety Information throughout and read the Medication Guide, including information on serious side effects, and discuss any questions you may have with your healthcare provider

Financial Assistance Programs Terms & Conditions.

ZULRESSO Drug Copay Assistance Program

To be eligible to participate in the ZULRESSO® Drug Copay Assistance Program (the "Drug Copay Program"), the patient must: (i) Have private, commercial health insurance; (ii) Reside in the United States or a U.S. territory; (iii) Be treated by a healthcare professional in the United States or a U.S. territory; (iv) Be 15 years of age or older; and (v) Be prescribed ZULRESSO® (brexanolone) injection for an on-label diagnosis. The Drug Copay Program will cover the patient's out-of-pocket costs (i.e., deductible, copay, or coinsurance obligations) for ZULRESSO up to a maximum of $15,000. The treating healthcare provider must itemize the out-of-pocket cost for the drug on the Copay Program Reimbursement Form for the patient to be eligible to receive financial assistance under the Drug Copay Program. The patient may not participate in the Drug Copay Program if the entire cost of the patients' ZULRESSO prescription is reimbursable by her private insurance plan or other private health or pharmacy benefit programs. The patient may not participate in the Drug Copay Program if the patient is eligible for a state or federally funded insurance program, including but not limited to Medicare, Medicaid, TRICARE, Veterans Affairs health care, a state prescription drug assistance program, or the Government Health Insurance Plan available in Puerto Rico (formerly known as "La Reforma de Salud"). This offer is not valid for cash paying patients. The patient must deduct the value of assistance received from the Drug Copay Program from any reimbursement request submitted to her private insurance plan, either directly by the patient or on her behalf. The patient is responsible for reporting her participation in the Drug Copay Program to any private insurer, health plan, or other third party who pays for or reimburses any part of the prescription. The patient should not participate in the Drug Copay Program if her insurer or health plan prohibits use of manufacturer coupons/copay assistance. The patient savings under the Drug Copay Program cannot be combined with any other savings, free trial or similar offer for the drug. Claims must be submitted in a timely manner. An Explanation of Benefits (EOB) from the patient's private insurance must be submitted within 180 days of the date of service for the patient to receive out-of-pocket assistance. The EOB must reflect the patient's out-of-pocket cost for ZULRESSO and submission of the claim by the patient's physician for the cost of the medication. The Drug Copay Program is not health insurance. This offer is not conditioned on any past or future purchases. Data related to the patient's participation in the Drug Copay Program may be collected, analyzed, and shared with Sage Therapeutics, Inc. ("Sage") for market research and other purposes related to assessing Sage's patient support programs. Data shared with Sage will be aggregated and de-identified; it will be combined with data related to other Drug Copay Program use and will not identify the patient. In the event that the Drug Copay Program is terminated, the EOB must be submitted no more than 90 days after the termination date and EOB must be within the patient's enrollment dates. Sage reserves the right to rescind, revoke or amend this offer without notice.

ZULRESSO Infusion Copay Assistance Program

To be eligible to participate in the ZULRESSO® Infusion Copay Assistance Program (the "Infusion Copay Program"), the patient must: (i) Have private, commercial health insurance; (ii) Reside in the United States or a U.S. territory; (iii) Be treated by a healthcare professional in the United States or a U.S. territory; (iv) Be 15 years of age or older; and (v) Be prescribed ZULRESSO® for an on-label diagnosis. The Infusion Copay Program will cover the patients' out-of-pocket costs (i.e., deductible, copay, or coinsurance obligations) associated with the infusion of ZULRESSO (administration, needles, tubing, infusion bags, syringes, infusion pump, preparation of medication, IV access and room and board) up to a maximum of $2,000. The treating healthcare provider must itemize the out-of-pocket infusion costs on the Copay Program Reimbursement Form for the patient to be eligible to receive financial assistance under the Infusion Copay Program. Expenses not specifically related to the infusion of ZULRESSO are not eligible for assistance. The patient may not participate in the Infusion Copay Program if all costs of the drug infusion are reimbursable by the patient's private insurance plan or other private health or pharmacy benefit programs. The patient may not participate in the Infusion Copay Program if the patient is eligible for a state or federally funded insurance program, including but not limited to Medicare, Medicaid, TRICARE, Veterans Affairs health care, a state prescription drug assistance program, or the Government Health Insurance Plan available in Puerto Rico (formerly known as "La Reforma de Salud"). Residents of the following states are not eligible to participate in the Infusion Copay Program: Massachusetts and Rhode Island. This offer is not valid for cash paying patients. Patient must deduct the value of assistance received from the Infusion Copay Program from any reimbursement request submitted to her private insurance plan, either directly by the patient or on her behalf. Patient is responsible for reporting her

ZULRESSO Infusion Copay Assistance Program (continued)

participation in the Infusion Copay Program to any private insurer, health plan, or other third party who pays for or reimburses any part of the prescription. The patient should not participate in the Infusion Copay Program if her insurer or health plan prohibits use of manufacturer-supported financial assistance. Claims must be submitted in a timely manner. An Explanation of Benefits (EOB) from the patient's private insurance must be submitted within 180 days of the date of service for the patient to receive out-of-pocket assistance. The EOB must reflect the patient's out-of-pocket cost for infusion of ZULRESSO and submission of the claim by the patient's physician for the infusion costs. The patient savings under the Infusion Copay Program cannot be combined with any other savings, free trial or similar offer for the drug infusion. The Infusion Copay Program is not health insurance. This offer is not conditioned on any past, present or future purchases. Data related to the patient's participation in the Infusion Copay Program may be collected, analyzed, and shared with Sage Therapeutics, Inc. ("Sage") for market research and other purposes related to assessing Sage's patient support programs. Data shared with Sage will be aggregated and de-identified; it will be combined with data related to other Infusion Copay Program use and will not identify the patient. In the event that the Infusion Copay Program is terminated, the EOB must be submitted no more than 90 days after the termination date and the EOB must be within the patient's enrollment dates. Sage reserves the right to rescind, revoke or amend this offer without notice.

Free Drug Program

To be eligible to participate in the ZULRESSO® Free Drug Program (the "FDP"), the patient must: (i) Be prescribed ZULRESSO® for an on-label diagnosis; (ii) Have household income less than or equal to 500% of the Federal Poverty Level (FPL); (iii) Be uninsured or rendered uninsured under any of the following circumstances: (a) Patient has no healthcare insurance, (b) Patient is insured but such insurance does not cover ZULRESSO, or (c) Patient is insured with coverage for ZULRESSO, but is ineligible for the ZULRESSO Copay Assistance Program, and cannot afford the medication (patient out-of-pocket costs are greater than $25); (iv) Reside in the United States or a U.S. territory; (v) Be treated by a healthcare professional in the United States or a U.S. Territory; and (vi) Be 15 years of age or older. Patients enrolled in Medicare, Medicaid or any other federal or state funded health plan may participate in the FDP if they receive the free product outside of their government-funded benefits. The treating healthcare provider must certify that based on his/her independent medical judgment, ZULRESSO is a medically appropriate treatment for the patient. The healthcare provider must certify not to bill the patient or the patient's insurer for the cost of ZULRESSO. If the patient is enrolled in any federal or state funded health plans, the healthcare provider must not bill any costs associated with ZULRESSO and corresponding treatment costs within a Diagnostic Related Group (DRG). The patient will be informed that she must not (i) seek reimbursement for the free drug from their health plan, and (ii) count the cost of the free drug towards her out-of-pocket spending requirements, if any, under her insurance. The free drug provided under the FDP is not conditioned on any past or future purchases. For any patient enrolled in a readily identifiable Medicare, Medicaid or other government funded plan, Sage will send a letter to the plan informing it that: (i) the patient is receiving free product from the ZULRESSO FDP outside of the patient's Medicare/Medicaid plan benefit, (ii) the patient and her physician have been informed that they must not seek reimbursement for the free drug from their health plan or count the cost of the free product towards the patient's out-of-pocket spending requirements, and (iii) the plan should discontinue any pending prior authorization or coverage appeal associated with the patient.

ZULRESSO® (brexanolone) is administered as a continuous intravenous infusion into the vein over 2.5 days (60 hours). In clinical studies in adults, moms who took ZULRESSO experienced a greater improvement in symptoms of postpartum depression vs placebo in 2.5 days. Symptoms were measured at the beginning of treatment using a standard depression scale and again at the end of treatment.

ZULRESSO may cause you to feel very sleepy (excessive sedation) or pass out (loss of consciousness). Because of the risk of serious harm resulting from excessive sedation or sudden loss of consciousness, ZULRESSO is only available through a restricted program called the ZULRESSO REMS.

Speak with your healthcare provider to see if ZULRESSO is the right treatment option for you.

IMPORTANT SAFETY INFORMATION (continued)

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.
- 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, other unusual changes in behavior or mood

The most common side effects of ZULRESSO include:

- Sleepiness, dry mouth, passing out, flushing of the skin or face.

These are not all the side effects of ZULRESSO.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see additional Important Safety Information throughout and read the Medication Guide, including information on serious side effects, and discuss any questions you may have with your healthcare provider

Sage Therapeutics®

Zulresso®
(brexanolone) injection IV
for intravenous use 100mg/20mL