Sage Therapeutics Announces Fourth Quarter and Full Year 2023 Financial Results and Highlights Pipeline and Business Progress

February 14, 2024

ZURZUVAE™ (zuranolone), the first-and-only oral treatment indicated for adults with postpartum depression (PPD), became commercially available mid-December; Sage achieved $0.8 million in collaboration revenue as of December 31, 2023, 50% of the net revenues Biogen reports for ZURZUVAE

Encouraging early launch results for ZURZUVAE with approximately 120 prescriptions in December

Catalyst rich 2024 with multiple topline data read-outs expected across dalzanemdor (SAGE-718) and SAGE-324 with potential for significant long-term value creation

Strong financial foundation with year-end 2023 cash, cash equivalents and marketable securities of $753 million

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Feb. 14, 2024-- Sage Therapeutics, Inc. (Nasdaq: SAGE), a biopharmaceutical company leading the way to create a world with better brain health, today reported business highlights and financial results for the fourth quarter and full year ended December 31, 2023.

“2023 was a pivotal year for Sage, with key accomplishments achieved across our pipeline, culminating with the recent encouraging launch of ZURZUVAE, the first-and-only once daily oral treatment for adults with postpartum depression. We are incredibly pleased with the early progress on the launch. I am proud of our team’s relentless work toward our goal of ZURZUVAE becoming the first line therapy for women with PPD and believe strongly in the potential for ZURZUVAE to make an impact in treating this devastating disease,” said Barry Greene, Chief Executive Officer at Sage Therapeutics. “Beyond our ongoing commercialization efforts for ZURZUVAE, we look forward to delivering on multiple anticipated catalysts in 2024, including topline data from our studies evaluating dalzanemdor and SAGE-324. We believe our work has the potential to make a difference in the lives of patients with brain health disorders, and we look forward to providing updates on our progress over the coming quarters.”

Key 2023 Highlights

U.S. Food and Drug Administration (FDA) Approval of ZURZUVAE (zuranolone) for the treatment of adults with PPD: In December 2023, Sage and its collaborator, Biogen, announced the commercial availability of ZURZUVAE indicated for the treatment of adults with PPD following its approval by the FDA in August 2023. Efforts to establish ZURZUVAE as the first line therapy and standard of care for women with PPD are underway.

- In November 2023, ZURZUVAE received a Schedule IV classification from the U.S. Drug Enforcement Administration (DEA). Schedule IV drugs, substances or chemicals are defined as drugs with a low potential for abuse and low risk of dependence.

Continued advancement across innovative brain health pipeline with potential for significant long-term value creation: Sage continued to progress enrollment across multiple Phase 2 studies in its clinical-stage pipeline which includes dalzanemdor (SAGE-718) and SAGE-324.

- Dalzanemdor (SAGE-718):
  - Sage completed enrollment in the Phase 2 PRECEDENT placebo-controlled study of dalzanemdor in people with mild cognitive impairment due to Parkinson’s Disease. Topline data from the study are expected in early 2024.
  - The United States Adopted Name (USAN) Council assigned the nonproprietary name of “dalzanemdor” to investigational SAGE-718.
  - Dalzanemdor was granted Orphan Drug Designation for the treatment of Huntington’s Disease by the FDA and by the European Medicines Agency (EMA).
- SAGE-324:
  - In December 2023, Sage and its collaborator, Biogen, completed screening in the Phase 2b KINETIC 2 placebo-controlled study of SAGE-324 in essential tremor. In January 2024, the study completed enrollment. Topline data are expected in mid-2024.

Fourth Quarter 2023 Portfolio Updates

Sage is advancing a portfolio of clinical-stage programs featuring internally discovered novel chemical entities with the potential to become differentiated products designed to improve brain health by targeting the $GABA_A$ and NMDA receptor systems. Dysfunction in these systems is thought to be at the core of numerous neurological and neuropsychiatric disorders.

Postpartum Depression Commercial Products

ZURZUVAE was approved by the FDA in August 2023 as the first-and-only oral treatment specifically indicated for adults with PPD.

ZURZUVAE was made commercially available in December 2023. ZURZUVAE is being developed and commercialized in collaboration with Biogen Inc. Sage also commercializes ZULRESSO® (brexanolone) CIV injection in the treatment of PPD.

ZURZUVAE

Sage and its collaborator, Biogen, are focused on the goal of establishing ZURZUVAE as the first line therapy and standard of care for women with PPD. ZURZUVAE was made commercially available in December 2023. The companies are utilizing a specialty pharmacy distribution model by which ZURZUVAE is shipped directly to women with PPD who are prescribed the treatment.

Initial launch data reflects demand from an estimated 10 days when patients could access health care professional (HCP) offices. As of December 31, 2023, the following results had been achieved:

- $0.8 million in collaboration revenue from ZURZUVAE, representing 50% of the net revenues recorded when Biogen shipped ZURZUVAE to the distributors. ZURZUVAE net revenues in December 2023 principally represent initial efforts of preparing the channel for the full launch in the first quarter of 2024.
- Approximately 120 prescriptions written by various physician types, including psychiatrists, OBGYNs, and primary care physicians (PCPs).
- In December, 50 prescriptions shipped and were delivered.

Sage and Biogen field sales teams are engaging in promotional dialogues with HCPs who actively identify and treat women with PPD. In December, prescriptions were primarily written by OBGYNs and psychiatrists, who prescribed in approximately equal numbers. There were also a small number of prescriptions from PCPs.

The companies are advancing discussions with national, regional and government payors to advocate for broad and equitable access to ZURZUVAE for women with PPD with minimal restrictions and expect formulary discussions to continue over the course of 2024. In the early launch, the vast majority of prescriptions were covered by payers.

At commercial availability, Sage and Biogen 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. In December, the commercially insured patients using the ZURZUVAE savings card paid no copay.

The Company expects the following milestones for ZURZUVAE in 2024:

- Early 2024:
  - Broader complement of capabilities for commercializing ZURZUVAE in the treatment of women with PPD
- 2024:
  - Present additional analyses of data from NEST clinical program, including health economics and patient reported outcomes

Pipeline

Dalzanemdor (SAGE-718), the Company's first-in-class NMDA receptor positive allosteric modulator (PAM), is in development as a potential oral therapy for cognitive impairment associated with neurodegenerative disorders. Dalzanemdor has received Fast Track Designation and Orphan Drug Designation (ODD) from the FDA, and Orphan Drug Designation from the European Medicines Agency (EMA) for the potential treatment of Huntington's Disease. Dalzanemdor has also been awarded an Innovation Passport Designation for cognitive impairment associated with HD and entry into the Innovative Licensing and Access Pathway (ILAP) by the U.K. Medicines and Healthcare products Regulatory Agency (MHRA). SAGE-324, the Company's next-generation PAM of GABAA receptors, is in development as a potential oral therapy for movement disorders, such as essential tremor (ET). SAGE-324 is being developed in collaboration with Biogen Inc.

Dalzanemdor (SAGE-718)

Sage is advancing a robust clinical program for dalzanemdor with multiple ongoing Phase 2 studies, including the DIMENSION and SURVEYOR Studies in people with cognitive impairment associated with Huntington's Disease (HD), the lead indication for dalzanemdor, the PRECEDENT Study in people with mild cognitive impairment (MCI) associated with Parkinson's Disease (PD) and the LIGHTWAVE Study in people with MCI and mild dementia due to Alzheimer's Disease (AD).

In January 2024, the ILAP Steering Group awarded an Innovative Passport Designation to dalzanemdor for cognitive impairment associated with HD. Innovation Passport Designation supports enhanced coordination of development activities, including access to a range of development tools and other potential benefits. Eligibility for the designation is based on a set of criteria including the potential to treat a life-threatening or serious condition for which there is significant unmet need. ILAP does not necessarily lead to a faster development pathway or regulatory review process and does not increase the likelihood of regulatory approval.

Ongoing studies in the dalzanemdor clinical program include:

- DIMENSION (CIH-201) Study: The DIMENSION Study is a double-blind, placebo-controlled Phase 2 study in people with cognitive impairment associated with HD. The study is designed to evaluate the efficacy of once-daily dalzanemdor dosed over three months, with a target enrollment of approximately 178 people. The DIMENSION Study is enrolling across 40 clinical sites.
- SURVEYOR (CIH-202) Study: The SURVEYOR Study is a double-blind, placebo-controlled Phase 2 study in people with cognitive impairment associated with HD. The SURVEYOR Study is being conducted with the goal of generating evidence

linking changes in cognition to real-world functioning and is not designed or powered to demonstrate a statistically significant difference between dalzanemdor and placebo.

- PURVIEW (CIH-301) Study: The PURVIEW Study is an open-label Phase 3 safety study of dalzanemdor in people with cognitive impairment associated with HD. The study is designed to evaluate the long-term safety profile and long-term functioning compared to HD natural history studies of those treated for one year or more.
- PRECEDENT (CNP-202) Study: The PRECEDENT Study is a double-blind, placebo-controlled Phase 2 study in people with MCI due to PD. The study is designed to evaluate the safety and efficacy of dalzanemdor dosed over 6 weeks.
- LIGHTWAVE (CNA-202) Study: The LIGHTWAVE Study is a double-blind, placebo-controlled Phase 2 study of dalzanemdor in people with MCI and mild dementia due to AD. The study is designed to evaluate the safety and efficacy of dalzanemdor dosed over a 12-week period.

The Company expects the following milestones for dalzanemdor in 2024:

- Early 2024:
  - Report topline data from PRECEDENT Study in people with MCI associated with PD
- Mid-2024:
  - Report topline data from SURVEYOR Study in people with HD cognitive impairment
- Late 2024:
  - Report topline data from LIGHTWAVE Study in people with MCI and mild dementia due to AD
  - Report topline data from DIMENSION Study in people with HD cognitive impairment
- 2024:
  - Present additional analyses of data from clinical development program as well as disease state and burden of disease research in HD, PD and/or AD

SAGE-324

Sage and its collaborator, Biogen, have completed enrollment in the Phase 2b KINETIC 2 placebo-controlled study of SAGE-324 in ET, which follows positive results from the completed KINETIC Study of SAGE-324 in ET. KINETIC 2 is a Phase 2b dose-ranging study with the primary goal of defining the dose for SAGE-324 with an efficacy and tolerability profile that maintains plasma concentrations needed for sustained tremor symptom control in treating ET. Topline data from the KINETIC 2 Study are expected in mid-2024.

Sage is also enrolling patients in a Phase 2 long-term open-label safety study, to evaluate the long-term safety and tolerability of SAGE-324 in ET. The primary endpoint is incidence of treatment-emergent adverse events.

The Company expects the following milestones for SAGE-324 in 2024:

- Mid-2024:
  - Report topline data from Phase 2b KINETIC 2 Study in people with ET
- 2024:
  - Present additional analyses of data from clinical development program as well as disease state and burden of disease research in ET

FINANCIAL RESULTS FOR THE FOURTH QUARTER AND FULL YEAR 2023

- **Cash Position:** Cash, cash equivalents and marketable securities as of December 31, 2023 were $753 million compared to $876 million at September 30, 2023.
- **Revenue:** Collaboration revenue from sales of ZURZUVAE was $0.8 million in the fourth quarter of 2023, the first quarter of sales. Reported collaboration revenue is 50% of the net revenues Biogen reports for ZURZUVAE. ZURZUVAE net revenues in December 2023 principally represent initial efforts of preparing the channel for the full launch in the first quarter of 2024. License and milestone revenue was $75.0 million in the fourth quarter of 2023 and for the year ended December 31, 2023, compared to no such revenues in the same periods of 2022. The $75.0 million milestone payment was earned in the fourth quarter of 2023 upon the first commercial sale of ZURZUVAE in PPD and was received from Biogen in January 2024. Net revenue from sales of ZULRESSO was $2.0 million in the fourth quarter of 2023, compared to $2.9 million in the same period of 2022. For the year ended December 31, 2023, net revenue from sales of ZULRESSO was $10.5 million compared to $7.7 million in the same period of 2022.
- **R&D Expenses:** Research and development expenses were $64.3 million, including $4.7 million of non-cash stock-based compensation expense, in the fourth quarter of 2023 compared to $89.3 million, including $4.9 million of non-cash stock-based compensation expense, for the same period in 2022. For the fourth quarter of 2023, the decrease in R&D expenses as compared to the same period in 2022 was primarily related to reorganization cost savings measures including reduced headcount, budgeted expenditures and reprioritization of early-stage pipeline programs. For the year ended December 31, 2023, R&D expenses were $356.2 million, including $24.8 million of non-cash stock-based compensation expense, compared to $326.2 million, including $25.9 million of non-cash stock-based compensation expense, for the same period in 2022. For the year, the increase in R&D expenses was primarily due to increased headcount, and spending on zuranolone (ZURZUVAE) and Sage's wholly owned pipeline, including dalzanemdor (SAGE-718) and other programs.

The reimbursement from Biogen to Sage for R&D expenses pursuant to the Sage/Biogen Collaboration and License Agreement was $76.2 million in 2023 compared to $73.2 million in the same period of 2022.

- **SG&A Expenses:** Selling, general and administrative expenses were $55.1 million, including $8.3 million of non-cash stock-based compensation expense, in the fourth quarter of 2023, compared to $67.3 million, including $10.4 million of non-cash stock-based compensation expense, for the same period in 2022. For the fourth quarter of 2023, the decrease in SG&A expenses as compared to the same period in 2022 was primarily related to reorganization cost savings measures including reduced headcount and budgeted expenditures. For the year ended December 31, 2023, SG&A expenses were $274.5 million, including $47.7 million of non-cash stock-based compensation expense, compared to $227.7 million, including $35.7 million of non-cash stock-based compensation expense, for the same period in 2022. The increase in SG&A expenses year-over year was primarily due to hiring employees in the first half of 2023 to support ongoing permitted pre-launch and launch-readiness activities with respect to ZURZUVAE, in anticipation of commercialization of ZURZUVAE**,** and stock-based compensation expense related to the vesting of certain milestones. The reimbursement from Sage to Biogen for SG&A expenses pursuant to the Sage/Biogen Collaboration and License Agreement was $16.5 million in 2023 compared to $2.2 million of reimbursement from Biogen to Sage in the same period of 2022. The primary reason for the decrease in net reimbursement from Biogen to Sage was an increase in the collaboration costs incurred by Biogen in anticipation of the commercialization of ZURZUVAE.
- **Restructuring Expenses:** Restructuring expenses were $33.4 million for the year ended December 31, 2023 due to the August 2023 corporate reorganization, with the majority of expense incurred during the third quarter of 2023. No restructuring expenses were incurred in the same period of 2022.
- **Net Loss:** Net loss was $32.7 million for the fourth quarter of 2023 compared to $147.1 million for the same period in 2022. For the year ended December 31, 2023, net loss was $541.5 million compared to $532.8 million for the same period in 2022.

FINANCIAL GUIDANCE

- Based upon the Company's current operating plan, Sage anticipates that its existing cash, cash equivalents and marketable securities, along with the milestone payment received in January 2024, anticipated funding from ongoing collaborations, and estimated revenues, will support its operations into 2026.
- The Company does not anticipate receipt of any milestone payments from collaborations in the remainder of 2024.
- The Company anticipates operating expenses will decrease in 2024 relative to 2023.
- With the availability of ZURZUVAE as an additional treatment for women with PPD, the Company anticipates ZULRESSO revenues will decrease over time.

Conference Call Information

Sage will host a conference call and webcast today, Wednesday, February 14, at 8:00 a.m. ET to review its fourth quarter and full year 2023 financial results and discuss recent corporate updates. The live webcast can be accessed on the investor page of Sage's website at investor.sagerx.com. A replay of the webcast will be available on Sage's website following the completion of the event and will be archived for up to 30 days.

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 or engage with us on Facebook, LinkedIn, Instagram, and X.

Forward-Looking Statements

Various statements in this release concern Sage's future expectations, plans and prospects, including without limitation our statements regarding: our plans, expectations and goals for commercialization of ZURZUVAE as a treatment for women with PPD, including our goals for ZURZUVAE to become the first line treatment and standard of care in this indication; our belief in the potential for ZURZUVAE and our belief that ZURZUVAE will be successful in helping women with PPD; anticipated timelines for completion of enrollment in clinical trials and reporting of results with respect to certain of our other programs; our belief in the potential profile and benefit of our product candidates; potential indications for our product candidates; the potential for success of our programs, and the opportunity to help patients in various indications; our belief as to the key catalysts for our business and potential value creation; 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 launch and 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 from sales of ZURZUVAE at the levels or on the timing we expect or at levels or on the timing necessary to support our goals; early positive signs from launch or from our engagements with healthcare professionals, patients and payors related to ZURZUVAE may not be a signal of the potential for future success; the number of women with PPD, the unmet need for additional treatment options, and the potential market for ZURZUVAE in women with PPD, may be significantly smaller than we expect; ZURZUVAE may not achieve the clinical benefit, clinical use or level of market acceptance from healthcare professionals, patients or payors 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 access goals; ZURZUVAE may never become the first line treatment and standard of care for women with PPD; we may encounter delays in initiation, conduct, completion of enrollment or completion and reporting of data

with respect to any of our ongoing clinical trials, including as a result of slower than expected site initiation, slower than expected enrollment, the need or decision to expand the trials or other changes, that may impact our ability to meet our expected timelines and may increase our costs; success in earlier clinical trials of any of our product candidates may not be repeated or observed in ongoing or future studies, and ongoing and future clinical trials may not meet their primary or key secondary endpoints which may substantially impair development; unexpected concerns may arise from additional data, analysis or results from any of our completed studies; decisions or actions of the FDA or the timing of meetings with the FDA may affect the timing, design, size, progress and cost of clinical trials or the timing of data read-outs or our ability to proceed with further development or may impair the potential for successful development or the timing or success of filing for and gaining regulatory approval; 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 our products or that require additional nonclinical and clinical work which may not yield positive results; the need to align with our collaborators may hamper or delay our development and commercialization efforts for the products or product candidates that are part of the collaboration or increase our costs; the anticipated benefits of our ongoing collaborations, including the receipt of payments or the successful development or commercialization of products and generation of revenue, may never be achieved at the levels or timing we expect or at all; 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; the internal and external costs required for our ongoing and planned activities, and the resulting impact on expense and use of cash, may be higher than expected which may cause us to change or curtail some of our plans or both; we may not be successful in our efforts to gain regulatory approval of products beyond ZURZUVAE and ZULRESSO; we may not achieve revenues from our products that may be successfully developed in the future, at levels we expect; additional funding may not be available on acceptable terms when we need it which could hamper our development and commercialization activities; any of the foregoing events could impair the value creation opportunities for our business; and we may encounter technical and other unexpected hurdles in the development and manufacture of our product candidates or the commercialization of any current or future 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 annual or 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.

Financial Tables

Sage Therapeutics, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	December 31, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	$ 753,184	$ 1,272,494
Total assets	882,277	1,356,449
Total liabilities	82,747	103,850
Total stockholders' equity	799,530	1,252,599

Sage Therapeutics, Inc. and Subsidiaries
Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Product revenue, net	$ 1,985	$ 2,865	$ 10,454	$ 7,686
License and milestone revenue - related party	75,000	-	75,000	-
Collaboraion revenue - related party	824	-	824	-
Other Collaboration revenue	163	-	177	-
Total revenue	77,972	2,865	86,455	7,686
Operating costs and expenses:				
Cost of goods sold	819	143	2,159	813
Research and development	64,330	89,295	356,235	326,163
Selling, general and administrative	55,109	67,329	274,524	227,699
Restructuring	(212)	-	33,386	-
Total operating costs and expenses	120,046	156,767	666,304	554,675
Loss from operations	(42,074)	(153,902)	(579,849)	(546,989)
Interest income, net	9,467	6,793	38,743	14,190
Other income (expense), net	(99)	(37)	(383)	15
Net loss	$ (32,706)	$ (147,146)	$ (541,489)	$ (532,784)

Net loss per share - basic and diluted	$ (0.55)	$ (2.47)	$ (9.05)	$ (8.98)
Weighted average shares outstanding - basic and diluted	59,990,004	59,494,613	59,836,441	59,306,094

SELECT IMPORTANT SAFETY INFORMATION FOR ZURZUVAE

ZURZUVAE (zuranolone) CIV, is a neuroactive steroid gamma-aminobutyric acid (GABA) A 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, including decreased 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. 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 central nervous system (CNS) depressant effects including sleepiness, drowsiness, slow thinking, dizziness, confusion, and trouble walking. Taking alcohol, other medicines that cause CNS depressant effects such as benzodiazepines, or opioids while taking ZURZUVAE can make these symptoms worse and may also cause trouble breathing. ZURZUVAE is a federally controlled substance schedule 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. 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.

SELECT IMPORTANT SAFETY INFORMATION for ZULRESSO

ZULRESSO (brexanolone) CIV, is a neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator indicated for the treatment of postpartum depression in individuals 15 years and older.

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

WARNING: EXCESSIVE SEDATION AND SUDDEN LOSS OF CONSCIOUSNESS
See full prescribing information for complete boxed warning
Patients are at risk of excessive sedation or sudden loss of consciousness during administration of ZULRESSO.

Because of the risk of serious harm, patients must be monitored for excessive sedation and sudden loss of consciousness and have continuous pulse oximetry monitoring. Patients must be accompanied during interactions with their child(ren).

ZULRESSO is available only through a restricted program called the ZULRESSO REMS.

WARNINGS AND PRECAUTIONS
Suicidal Thoughts and Behaviors: Consider changing the therapeutic regimen, including discontinuing ZULRESSO, in patients whose PPD becomes worse or who experience emergent suicidal thoughts and behavior.

ADVERSE REACTIONS: Most common adverse reactions (incidence ≥5% and at least twice the rate of placebo) were sedation/somnolence, dry mouth, loss of consciousness, and flushing/hot flush.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** ZULRESSO may cause fetal harm. Healthcare providers are encouraged to register patients by calling the National Pregnancy Registry for Antidepressants at 1-844-405-6185 or visiting online at https://womensmentalhealth.org/clinical-and-researchprograms/pregnancyregistry/antidepressants/
- **Renal Impairment:** Avoid use of ZULRESSO in patients with end stage renal disease (ESRD)

To report SUSPECTED ADVERSE REACTIONS, contact Sage Therapeutics, Inc. at 1-844-4-SAGERX (1-844-472-4379) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
Please see accompanying full Prescribing Information including Boxed Warning.

View source version on businesswire.com: https://www.businesswire.com/news/home/20240214365148/en/

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