Sage Therapeutics Submits New Drug Application to U.S. FDA for Intravenous Brexanolone in the Treatment of Postpartum Depression

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Brexanolone IV submission is the Company's first New Drug Application

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Apr. 23, 2018-- Sage Therapeutics (NASDAQ: SAGE), a clinical-stage biopharmaceutical company developing novel medicines to treat life-altering central nervous system (CNS) disorders, today announced the Company has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for its lead product candidate, an intravenous formulation of brexanolone (SAGE-547), for the treatment of postpartum depression (PPD).

Brexanolone IV received Breakthrough Therapy Designation in September 2016, underscoring the significant unmet need in women with PPD. Breakthrough Therapy Designation is intended to offer a potentially expedited development path and review for promising drug candidates intended to treat serious conditions, including increased interaction and guidance from the FDA.

The NDA submission is supported by data from the Hummingbird Program. This clinical program included three multicenter, randomized, double-blind, parallel-group, placebo-controlled trials (Study 202A, Study 202B and Study 202C), each designed to evaluate the safety and effectiveness of brexanolone in women with moderate or severe PPD, aged between 18 and 45 years who were ≤6 months postpartum at screening in the United States.

About FDA Breakthrough Therapy Designation
The FDA's Breakthrough Therapy Designation is intended to expedite the development and review of a drug candidate that is planned for use, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. The benefits of Breakthrough Therapy Designation include the same benefits as Fast Track Designation, plus an organizational commitment involving the FDA's senior managers with more intensive guidance from the FDA. Breakthrough Therapy Designation does not change the standards for approval.

About Postpartum Depression
Postpartum depression (PPD) is a distinct and readily identified major depressive disorder that is the most common medical complication of childbirth, affecting a subset of women typically commencing in the third trimester of pregnancy or within four weeks after giving birth. PPD may have devastating consequences for a woman and for her family, which may include significant functional impairment, depressed mood and/or loss of interest in her newborn, and associated symptoms of depression such as loss of appetite, difficulty sleeping, motor challenges, lack of concentration, loss of energy and poor self-esteem. Suicide is the leading cause of maternal death following childbirth. In the U.S., estimates of new mothers identified with PPD each year vary by state from 8 to 20 percent, with an overall average of 11.5 percent. More than half of these cases may go undiagnosed without proper screening. There are no FDA approved therapies for PPD and there is a high unmet medical need for improved pharmacological therapy in PPD.

About Brexanolone (SAGE-547)
Brexanolone (SAGE-547) is an allosteric modulator of both synaptic and extrasynaptic $GABA_A$ receptors. Allosteric modulation of neurotransmitter receptor activity results in varying degrees of desired activity rather than complete activation or inhibition of the receptor. Sage's proprietary intravenous (IV) formulation of brexanolone is being developed for the treatment of postpartum depression (PPD) and has been granted Breakthrough Therapy Designation by the FDA and PRIority MEdicines (PRIME) designation from the European Medicines Agency (EMA) in PPD.

About Sage Therapeutics
Sage Therapeutics is a clinical-stage biopharmaceutical company committed to developing novel medicines to transform the lives of patients with life-altering central nervous system (CNS) disorders. Sage has a portfolio of novel product candidates targeting critical CNS receptor systems, GABA and NMDA. Sage's lead program, a proprietary IV formulation of brexanolone (SAGE-547), has completed Phase 3 clinical development for postpartum depression. Sage is developing its next generation modulators, including SAGE-217 and SAGE-718, in various CNS disorders. For more information, please visit www.sagerx.com.

Forward-Looking Statements
Various statements in this release concern Sage's future expectations, plans and prospects, including without limitation our statements regarding or implying: the potential for approval of brexanolone IV in the treatment of PPD; the potential for expedited development and review of brexanolone IV in PPD as a result of the Breakthrough Therapy Designation from the FDA; our expectations regarding the possible acceptance of our NDA filing; our estimates of the prevalence of PPD; and our view as to the potential for brexanolone IV and the other product candidates in our portfolio. 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: the FDA may decide not to accept for filing our NDA for brexanolone IV in PPD; the clinical and non-clinical data we have generated with our proprietary formulation of brexanolone to date may be determined by the FDA, despite prior advice, to be insufficient to file for or gain regulatory approval to launch and commercialize our product in PPD and the FDA may determine that additional trials or data are necessary in order to file for or obtain approval; the FDA may find fault with the data generated at particular clinical site or sites or with the activities of our trial monitor or may disagree with our analyses of the results of our trials or identify issues with our manufacturing or quality systems, and any such findings or issues could require additional data or analyses or changes to our systems that could delay or prevent us from gaining approval of brexanolone IV;

we may not achieve expedited development or review of brexanolone IV as a result of the Breakthrough Therapy Designation from the FDA; the actual size of the PPD patient population may be significantly lower than our estimates and, even if brexanolone IV is successfully approved for PPD, it may only be approved or used to treat a subset of the PPD population; we may encounter unexpected safety or tolerability issues with brexanolone IV in ongoing clinical trials; we may not be able to successfully demonstrate the efficacy and safety of any of our other product candidates at each stage of development; success in early stage clinical trials may not be repeated or observed in ongoing or future studies of ourproduct candidates; ongoing and future clinical results may not support further development or be sufficient to gain regulatory approval to market our product candidates;and we may encounter technical and other unexpected hurdles in the development and manufacture of our product candidates; as well as those risks more fully discussed in the section entitled "Risk Factors" in our most recent Annual Report on Form 10-K, and 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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