

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property  
Organization  
International Bureau

(43) International Publication Date  
24 August 2023 (24.08.2023)



(10) International Publication Number  
**WO 2023/158668 A1**

(51) International Patent Classification:

*A61K 31/135* (2006.01) *A61K 31/58* (2006.01)  
*A61K 31/137* (2006.01) *A61K 45/06* (2006.01)  
*A61K 31/343* (2006.01) *A61P 25/22* (2006.01)  
*A61K 31/381* (2006.01) *A61P 25/24* (2006.01)

LV, MC, ME, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI,  
SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN,  
GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— with international search report (Art. 21(3))

(21) International Application Number:

PCT/US2023/013098

(22) International Filing Date:

15 February 2023 (15.02.2023)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

63/310,581 16 February 2022 (16.02.2022) US  
63/337,828 03 May 2022 (03.05.2022) US  
63/482,200 30 January 2023 (30.01.2023) US

(71) Applicant: **SAGE THERAPEUTICS, INC.** [US/US]; 215  
First Street, Cambridge, MA 02142 (US).

(72) Inventors: **LASSER, Robert, Alfonso**; 215 First Street,  
Cambridge, MA 02142 (US). **DOHERTY, James**; 215  
First Street, Cambridge, MA 02142 (US). **JONAS, Jef-**  
**frey, Martin**; 215 First Street, Cambridge, MA 02142  
(US). **KANES, Stephen, Jay**; 215 First Street, Cambridge,  
MA 02142 (US). **GUNDUZ-BRUCE, Handan**; 215 First  
Street, Cambridge, MA 02142 (US). **BULLOCK, Amy, E.**;  
215 First Street, Cambridge, MA 02142 (US). **MARIANO,**  
**Timothy, Y.**; 215 First Street, Cambridge, MA 02142 (US).

(74) Agent: **DOYLE, Kathryn, D.** et al.; Honigman LLP, 650  
Trade Centre Way, Suite 200, Kalamazoo, MI 49002 (US).

(81) Designated States (*unless otherwise indicated, for every  
kind of national protection available*): AE, AG, AL, AM,  
AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ,  
CA, CH, CL, CN, CO, CR, CU, CV, CZ, DE, DJ, DK, DM,  
DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,  
HN, HR, HU, ID, IL, IN, IQ, IR, IS, IT, JM, JO, JP, KE,  
KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU,  
LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG,  
NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS,  
RU, RW, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH,  
TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS,  
ZA, ZM, ZW.

(84) Designated States (*unless otherwise indicated, for every  
kind of regional protection available*): ARIPO (BW, CV,  
GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ,  
TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU,  
TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE,  
DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU,

(54) Title: NEUROACTIVE STEROIDS FOR TREATMENT OF CNS-RELATED DISORDERS

(57) Abstract: The present disclosure relates to methods of treating major depressive disorder (MDD) or postpartum depression (PPD) in a subject in need thereof with a combination of Compound (1) and an additional antidepressant, followed by continued administration of the additional antidepressant.

WO 2023/158668 A1