

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

(19) World Intellectual Property
Organization

International Bureau

(43) International Publication Date
25 May 2023 (25.05.2023)



(10) International Publication Number
WO 2023/089132 A1

(51) International Patent Classification:

A61K 31/4045 (2006.01) *A61K 45/06* (2006.01)
A61K 9/00 (2006.01) *A61P 25/18* (2006.01)
A61K 9/08 (2006.01) *A61P 25/22* (2006.01)
A61K 9/19 (2006.01) *A61P 25/24* (2006.01)
A61K 47/12 (2006.01) *A61P 25/30* (2006.01)

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.

(21) International Application Number:

PCT/EP2022/082486

(22) International Filing Date:

18 November 2022 (18.11.2022)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

PCT/EP2021/082227

110143066 18 November 2021 (18.11.2021) EP
2119021.0 18 November 2021 (18.11.2021) TW
17/574,424 24 December 2021 (24.12.2021) GB
12 January 2022 (12.01.2022) US
PCT/EP2022/055324
02 March 2022 (02.03.2022) EP

(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, 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).

Declarations under Rule 4.17:

- as to the identity of the inventor (Rule 4.17(i))
- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))

Published:

- with international search report (Art. 21(3))
- in black and white; the international application as filed contained color or greyscale and is available for download from PATENTSCOPE

(71) Applicant: **SMALL PHARMA LTD** [GB/GB]; 6-8 Bonhill Street, London EC2A 4BX (GB).

(72) Inventors: **RANDS, Peter**; C/O Small Pharma Ltd 6-8 Bonhill Street, London EC2A 4BX (GB). **ROUTLEDGE, Carol**; C/o Small Pharma Ltd 6-8 Bonhill Street, London EC2A 4BX (GB). **LAYZELL, Marie**; C/O Small Pharma Ltd 6-8 Bonhill Street, London EC2A 4BX (GB). **JAMES, Ellen**; C/O Small Pharma Ltd 6-8 Bonhill Street, London EC2A 4BX (GB). **JOEL, Zelah**; C/O Small Pharma Ltd 6-8 Bonhill Street, London EC2A 4BX (GB). **BENWAY, Tiffanie**; C/O Small Pharma Ltd 6-8 Bonhill Street, London EC2A 4BX (GB). **GOOD, Meghan**; C/O Small Pharma Ltd 6-8 Bonhill Street, London EC2A 4BX (GB).

(74) Agent: **PATENT BOUTIQUE LLP**; 10A Printing House Yard Hackney Road, London E2 7PR (GB).

(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,

(54) Title: INJECTABLE AND INHALABLE FORMULATIONS

(57) Abstract: The present invention relates to aqueous pharmaceutical formulations, methods for their production, and uses thereof. The aqueous pharmaceutical formulations comprise a salt of an optionally substituted dimethyltryptamine compound and water, with a pH from 5 to 6.5, preferably from about 5 to about 6, and a concentration of the optionally substituted dimethyltryptamine compound of about 10 mg/ml or greater as the freebase equivalent. These formulations can comprise an effective dose of an optionally substituted dimethyltryptamine compound for use in psychedelic assisted therapy within a volume of 5 ml or less. Such formulations are surprisingly suitable both for intramuscular injection and nebulised inhalation, being both stable and clinically acceptable, and have potential uses in the treatment of psychiatric or neurological disorders.



WO 2023/089132 A1