

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

(19) World Intellectual Property
Organization
International Bureau

(43) International Publication Date
04 May 2023 (04.05.2023)



(10) International Publication Number
WO 2023/076414 A1

- (51) **International Patent Classification:**
A61K 31/485 (2006.01) *A61P 25/28* (2006.01)
A61K 31/49 (2006.01)
- (21) **International Application Number:**
PCT/US2022/047919
- (22) **International Filing Date:**
26 October 2022 (26.10.2022)
- (25) **Filing Language:** English
- (26) **Publication Language:** English
- (30) **Priority Data:**
63/272,471 27 October 2021 (27.10.2021) US
63/275,091 03 November 2021 (03.11.2021) US
- (71) **Applicant: AVANIR PHARMACEUTICALS, INC.**
[US/US]; 30 Enterprise, Suite 200, Aliso Viejo, California
92656 (US).
- (72) **Inventor: DUBE, Sanjay;** 30 Enterprise, Suite 200, Aliso
Viejo, California 92656 (US).
- (74) **Agent: DORIGO, Andrea et al.;** Fish & Richardson P.C.,
PO Box 1022, Minneapolis, Minnesota 55440-1022 (US).
- (81) **Designated States** (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,

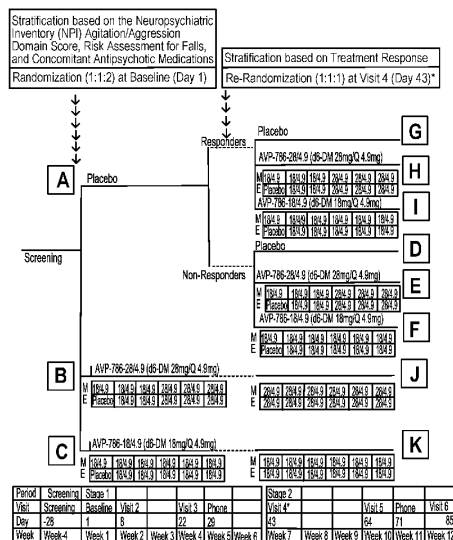
AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ,
CA, CH, CL, CN, CO, CR, CU, CV, CZ, DE, DJ, DK, DM,
DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,
HN, HR, HU, ID, IL, IN, IQ, IR, IS, IT, JM, JO, JP, KE,
KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU,
LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, 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,
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 applicant's entitlement to apply for and be granted a
patent (Rule 4.17(ii))
— as to the applicant's entitlement to claim the priority of the
earlier application (Rule 4.17(iii))

(54) **Title:** METHODS OF TREATING AGITATION ASSOCIATED WITH ALZHEIMER'S DISEASE



(57) **Abstract:** In some embodiments provided herein is a method of treating agitation associated with Alzheimers disease in a subject, comprising administering to the subject therapeutically effective amounts of deuterated [d6]-dextromethorphan hydrobromide (d6-DM) and quinidine sulfate, wherein the subject is a patient that has been diagnosed as having Alzheimers disease, wherein the method comprises determining the Cohen-Mansfield agitation inventory (CMAI) total score in the patient prior to said administration

E = evening dose; M = morning dose.
Study medication (active or placebo) was administered as capsules, 1 in the morning and 1 in the evening, approximately 12 hours apart.
* Visit 4 (Day 43) stratification for the placebo arm is based on treatment response criteria followed by re-randomization (1:1:1).

FIG. 1

[Continued on next page]

Published:

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