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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
02 October 2025 (02.10.2025)

WIPO | PCT

(10) International Publication Number
WO 2025/207664 A1

(51) International Patent Classification:
A61K 31/5375 (2006.01) *A61P 25/20* (2006.01)

(21) International Application Number:
PCT/US2025/021386

(22) International Filing Date:
25 March 2025 (25.03.2025)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

63/569,684	25 March 2024 (25.03.2024)	US
63/573,409	02 April 2024 (02.04.2024)	US
63/738,431	23 December 2024 (23.12.2024)	US

(71) Applicant: **AXSOME THERAPEUTICS, INC.** [US/US]; One World Trade Center, 22nd Floor, New York, New York 10007 (US).

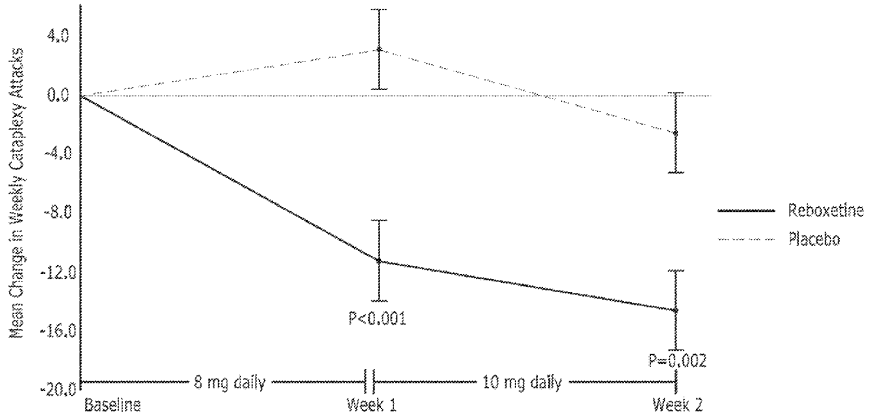
(72) Inventor: **TABUTEAU, Herriot**; One World Trade Center, 22nd Floor, New York, New York 10007 (US).

(74) Agent: **SPENCE, Erica A.** et al.; 525 B Street, Suite 2200, San Diego, California 92101 (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, MU, 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, UY, 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, SC, 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,

(54) Title: USE OF REBOXETINE TO TREAT NARCOLEPSY



Primary Endpoint	Reboxetine	Placebo	P-value
Overall Change in Average Weekly Cataplexy Attacks	-13.0	-0.3	<0.001
Week 2 Change in Average Weekly Cataplexy Attacks	-14.6	-2.6	0.002

FIG. 5

(57) Abstract: Polymorph forms of reboxetine, and their therapeutic uses, are described herein. Also described herein are methods of treating narcolepsy with cataplexy, comprising administering reboxetine (including esreboxetine) to a human being in need thereof. Reboxetine (including esreboxetine) may also be used in the manufacture of a medicament for the treatment of narcolepsy with cataplexy. Also disclosed herein are kits comprising a pharmaceutical composition comprising reboxetine (including esreboxetine) and instructions to use the pharmaceutical composition to treat narcolepsy with cataplexy in a human being.

WO 2025/207664 A1

[Continued on next page]

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).

Published:

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