(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 2025/207408 A1

(51) International Patent Classification:
A61K 39/395 (2006.01) *A61K 9/00* (2006.01)
A61K 47/22 (2006.01) *A61P 27/02* (2006.01)
A61K 47/26 (2006.01) *A61P 5/14* (2006.01)

(21) International Application Number:
PCT/US2025/020774

(22) International Filing Date:
20 March 2025 (20.03.2025)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
63/567,673 20 March 2024 (20.03.2024) US
63/682,181 12 August 2024 (12.08.2024) US
63/727,078 02 December 2024 (02.12.2024) US

(71) Applicant: **ACELYRIN, INC.** [US/US]; 4149 Liberty Canyon Road, Agoura Hills, California 91301 (US).

(72) Inventors: **GROVER, Anita**; 23371 Mulholland Dr., Los Angeles, California 91364 (US). **MPOFU, Shephard**; 4149 Liberty Canyon Road, Agoura Hills, California 91301 (US). **NGUYEN, Anh**; 4149 Liberty Canyon Road, Agoura Hills, California 91301 (US). **NYBORG, Andrew, C.**; 4149 Liberty Canyon Road, Agoura Hills, California 91301 (US). **WANI, Amit S.**; 4149 Liberty Canyon Road, Agoura Hills, California 91301 (US).

(74) Agent: **SCHOEN, Adam M.** et al.; Brown Rudnick LLP, One Financial Center, Boston, Massachusetts 02111 (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, 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))*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

(54) Title: METHODS AND COMPOSITIONS COMPRISING LONIGUTAMAB FOR TREATING TED

	3 mg/kg Q3W (n=6)	6 mg/kg Q3W (n=6)	9 mg/kg Q3W (n=6)	12 mg/kg Q3W (n=5)	Overall (n=23)	3 mg/kg Q3W (n=6)	6 mg/kg Q3W (n=6)	9 mg/kg Q3W (n=6)	12 mg/kg Q3W (n=5)	Overall (n=23)	Total (n=46)
Number of TEAEs	9	9	2	10	2	11	11	7	1	1	59
Number of related TEAEs	1	0	0	0	0	5	2	0	1	0	10
Number of serious TEAEs	0	0	0	0	0	0	0	0	0	0	0
Number of TEAEs leading to study discontinuation	0	0	0	0	0	0	0	0	0	0	0
Participants with at least 1 TEAE, n (%)	3 (50)	4 (66.7)	2 (33.3)	3 (60)	1 (12.5)	3 (50)	3 (50)	4 (66.7)	1 (16.7)	1 (12.5)	25 (39.7)
Participants with a related TEAE	1 (16.7)	0	0	0	0	1 (16.7)	1 (16.7)	0	1 (16.7)	0	4 (6.3)
Participants with a serious TEAE	0	0	0	0	0	0	0	0	0	0	0
Participants with a TEAE leading to study discontinuation	0	0	0	0	0	0	0	0	0	0	0

[a] participants were screened for cohort 5 in error; the sixth participant was screening ineligible and only 5 patients were enrolled in cohort 5. [b] subsequent TEAE treatment-emergent subsequent.

FIG. 1

(57) Abstract: The present disclosure is generally directed to pharmaceutical compositions comprising lonigutamab and methods of making and using such compositions for the treatment of thyroid eye disease (TED).

WO 2025/207408 A1