

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

CORRECTED VERSION

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
31 January 2019 (31.01.2019)

(10) International Publication Number
WO 2019/023564 A8

(51) International Patent Classification:
A61K 39/395 (2006.01) *C07K 16/18* (2006.01)

TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

(21) International Application Number:
PCT/US2018/044071

(22) International Filing Date:
27 July 2018 (27.07.2018)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/537,741 27 July 2017 (27.07.2017) US

Published:

- with international search report (Art. 21(3))
- with sequence listing part of description (Rule 5.2(a))

(48) Date of publication of this corrected version:

26 December 2019 (26.12.2019)

(15) Information about Correction:
see Notice of 26 December 2019 (26.12.2019)

(71) Applicant: **ALEXION PHARMACEUTICALS, INC.**
[US/US]; 121 Seaport Boulevard, Boston, Massachusetts
02210 (US).

(72) Inventors: **ORTIZ, Stephan**; 31 Dover Court, Guilford, CT 06437 (US). **GENTILE, Jillian**; 29 Wolf Hill Road, Southington, CT 06489 (US). **PHILOMINATHAN, Leena**; 130 Copper Beech Drive, Cheshire, CT 06410 (US). **ROUTHIER, Eric**; 307 Route 148, Killingworth, CT 06419 (US). **MASON, Bruce**; 31 Lenore Drive, Madison, CT 06443 (US).

(74) Agent: **REMILLARD, Jane, E.** et al.; Nelson Mullins Riley & Scarborough LLP, One Post Office Square, Boston, MA 02109-2127 (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, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, 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, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, 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, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM,

(54) Title: HIGH CONCENTRATION ANTI-C5 ANTIBODY FORMULATIONS

(57) Abstract: The present disclosure relates to stable aqueous solutions comprising a high concentration of an anti-C5 antibody (e.g., ravulizumab) and methods for preparing the solutions. The disclosure also provides methods for treating or preventing complement-associated disorders, such as paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS), using the solutions. Also featured were therapeutic kits containing one or more of the solutions and a means for administering the solutions to a patient in need such a treatment.