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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
21 September 2023 (21.09.2023)

WIPO | PCT

(10) International Publication Number
WO 2023/177416 A1

(51) International Patent Classification:
A61K 31/44 (2006.01) *A61K 9/107* (2006.01)
A61K 9/06 (2006.01) *A61K 47/10* (2017.01)

(21) International Application Number:
PCT/US2022/040336

(22) International Filing Date:
15 August 2022 (15.08.2022)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
63/319,586 14 March 2022 (14.03.2022) US
63/370,143 02 August 2022 (02.08.2022) US

(71) Applicant: **ARCUTIS BIOTHERAPEUTICS, INC.** [US/US]; 3027 Townsgate Road, #300, Westlake Village, California 91361 (US).

(72) Inventors: **OSBORNE, David W.**; 4215 Creekside Court, Fort Collins, Colorado 80525 (US). **TOFIG, Babak N.**; c/o Arcutis Biotherapeutics, Inc., 3027 Townsgate Road, #300, Westlake Village, California 91361 (US).

(74) Agent: **POSTAL, Brett A.**; Rothwell. Figg, Ernst & Manbeck, P.C., 901 New York Avenue, NW, Suite 900 East, Washington, District of Columbia 20001 (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, 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, 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, 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, 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:
— *of inventorship (Rule 4.17(iv))*

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

WO 2023/177416 A1

(54) Title: SELF-PRESERVING TOPICAL PHARMACEUTICAL COMPOSITIONS COMPRISING DIETHYLENE GLYCOL MONOETHYL ETHER

(57) Abstract: Self-preserving topical pharmaceutical compositions comprising diethylene glycol monoethyl ether (DEGEE) maintained at an acidic pH. The pH of the formulation can be maintained at a pH of less than 6.3, or alternatively less than 6.0. The topical pharmaceutical compositions disclosed herein are self-preserving and can satisfy European Pharmacopeia Efficacy of Antimicrobial Preservation Criteria A without the addition of a traditional antimicrobial preservative. Certain pharmaceutical composition further comprise an emulsifier blend of cetearyl alcohol, dicetyl phosphate, and ceteth-10 phosphate, which is manufactured by Croda under the tradename Crodafos™ CES.