

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

(19) World Intellectual Property
Organization
International Bureau

(43) International Publication Date
27 February 2025 (27.02.2025)



(10) International Publication Number
WO 2025/043187 A1

(51) International Patent Classification:

A61K 9/28 (2006.01) A61P 35/02 (2006.01)
A61K 31/706 (2006.01) A61K 31/7068 (2006.01)
A61K 31/453 (2006.01)

(21) International Application Number:

PCT/US2024/043662

(22) International Filing Date:

23 August 2024 (23.08.2024)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

63/578,566 24 August 2023 (24.08.2023) US

(71) Applicant: OTSUKA PHARMACEUTICAL CO., LTD.

[JP/JP]; 2-9, Kanda-Tsukasamachi, Chiyoda-Ku, Tokyo 101-8535 (JP).

(72) Inventors: DAVAR, Nipun; c/o Otsuka Pharmaceutical

Co., Ltd., 2-9, Kanda-Tsukasamachi, Chiyoda-Ku, Tokyo 101-8535 (JP). KOU, Jim; c/o Otsuka Pharmaceutical Co., Ltd., 2-9, Kanda-Tsukasamachi, Chiyoda-Ku, Tokyo 101-8535 (JP). JAIN, Rachna; c/o Otsuka Pharmaceutical Co., Ltd., 2-9, Kanda-Tsukasamachi, Chiyoda-Ku, Tokyo 101-8535 (JP). OGANESIAN, Aram; c/o Otsuka Pharmaceutical Co., Ltd., 2-9, Kanda-Tsukasamachi, Chiyoda-Ku,

Tokyo 101-8535 (JP). SANO, Yuri; c/o Otsuka Pharmaceutical Co., Ltd., 2-9, Kanda-Tsukasamachi, Chiyoda-Ku, Tokyo 101-8535 (JP). KEER, Harold; c/o Otsuka Pharmaceutical Co., Ltd., 2-9, Kanda-Tsukasamachi, Chiyoda-Ku, Tokyo 101-8535 (JP).

(74) Agent: TANNER, Lorna L. et al.; SHEPPARD MULLIN RICHTER & HAMPTON LLP, 650 Town Center Drive, 10th Floor, Costa Mesa, California 92626-1993 (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, 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,

(54) Title: FIXED DOSE COMBINATIONS OF CEDAZURIDINE AND AZACITIDINE

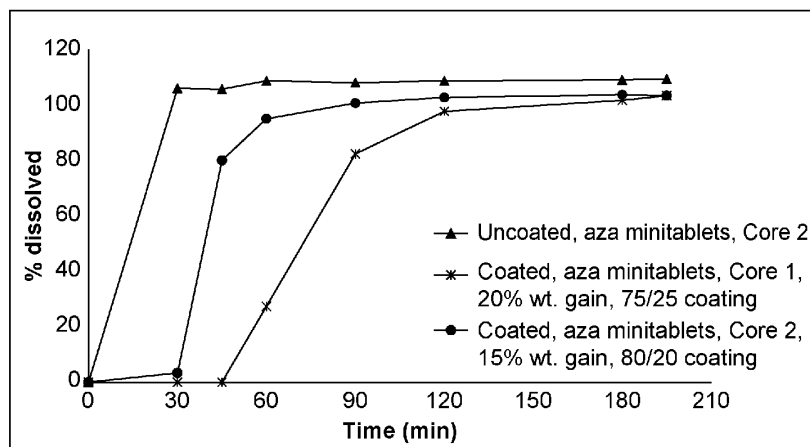


FIG. 1

(57) Abstract: The present disclosure relates generally to pharmaceutical dosage forms comprising azacitidine and cedazuridine.

[Continued on next page]

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 the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Published:

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