

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

(19) World Intellectual Property
Organization
International Bureau

(43) International Publication Date
24 October 2024 (24.10.2024)



(10) International Publication Number
WO 2024/220731 A1

(51) International Patent Classification:

A61K 31/635 (2006.01) A61K 9/20 (2006.01)
A61K 9/10 (2006.01) A61P 35/00 (2006.01)

(21) International Application Number:

PCT/US2024/025295

(22) International Filing Date:

18 April 2024 (18.04.2024)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

63/460,201	18 April 2023 (18.04.2023)	US
63/470,621	02 June 2023 (02.06.2023)	US
PCT/US2023/025791		
	20 June 2023 (20.06.2023)	US
63/540,884	27 September 2023 (27.09.2023)	US
63/612,840	20 December 2023 (20.12.2023)	US

(71) Applicant: **INCYCLIX BIO, LLC.** [US/US]; 600 Park Offices Drive, Suite 355, Research Triangle Park, NC 27709 (US).

(72) Inventors: **STRUM, Jay, Copeland**; c/o Incyclix Bio, LLC., 600 Park Offices Drive, Suite 355, Research Triangle Park, NC 27709 (US). **SMITH, Alexander**; c/o Incyclix Bio, LLC., 600 Park Offices Drive, Suite 355, Research Triangle Park, NC 27709 (US). **ROBERTS, Patrick, Joseph**; c/o Incyclix Bio, LLC., 600 Park Offices Drive, Suite 355, Research Triangle Park, NC 27709 (US).

(74) Agent: **BELLOWS, Brent, R.** et al.; Knowles Intellectual Property Strategies, LLC, 400 Perimeter Center Terrace, Suite 200, Atlanta, GA 30346 (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, 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 applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
- 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))

(54) Title: ADVANTAGEOUS HUMAN DOSAGE REGIMENS FOR ADMINISTRATION OF INX-315

(57) Abstract: Dosages and regimens based on the discovery of unexpectedly high and sustained exposure of INX-315 in humans in need thereof which results in increased efficacy per dose and minimizes adverse events during treatment, including by minimizing the ratio of Cmax to Cmin, resulting in a decrease in an initial drug spike after administration.

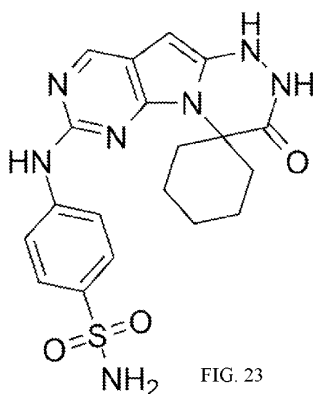


FIG. 23

WO 2024/220731 A1