

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

(19) World Intellectual Property
Organization
International Bureau

(43) International Publication Date
15 June 2023 (15.06.2023)



(10) International Publication Number
WO 2023/107525 A1

(51) International Patent Classification:

A61K 31/519 (2006.01) *A61K 45/06* (2006.01)
A61K 31/506 (2006.01) *A61P 35/02* (2006.01)
A61K 31/565 (2006.01) *A61P 35/00* (2006.01)

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

(21) International Application Number:

PCT/US2022/052071

(22) International Filing Date:

07 December 2022 (07.12.2022)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

63/288,179 10 December 2021 (10.12.2021) US
63/321,218 18 March 2022 (18.03.2022) US

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))
- 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))

(71) Applicant: **ELI LILLY AND COMPANY** [US/US]; Lilly Corporate Center, Indianapolis, Indiana 46285 (US).

(72) Inventors: **LITCHFIELD, Lacey Morgan**; c/o ELI LILLY AND COMPANY, P.O. Box 6288, Indianapolis, Indiana 46206-6288 (US). **MORATO GUIMARAES, Claudia**; c/o ELI LILLY AND COMPANY, P.O. Box 6288, Indianapolis, Indiana 46206-6288 (US).

(74) Agent: **PLETCHER, Joseph M.** et al.; ELI LILLY AND COMPANY, P.O. Box 6288, Indianapolis, Indiana 46206-6288 (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, 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, 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, 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,

(54) Title: CDK4 AND 6 INHIBITOR IN COMBINATION WITH FULVESTRANT FOR THE TREATMENT OF HORMONE RECEPTOR-POSITIVE, HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR 2-NEGATIVE ADVANCED OR METASTATIC BREAST CANCER IN PATIENTS PREVIOUSLY TREATED WITH A CDK4 AND 6 INHIBITOR

(57) Abstract: Disclosed are methods, uses, and combinations for treating hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) advanced or metastatic breast cancer in patients previously treated with a CDK4 and 6 inhibitor, the methods, uses, and combinations including the administration of a CDK4 and 6 inhibitor in combination with fulvestrant. The methods uses and combinations may include a CDK4 and 6 inhibitor such as palbociclib, ribociclib, or abemaciclib with fulvestrant.

WO 2023/107525 A1