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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
02 December 2021 (02.12.2021)

WIPO | PCT

(10) International Publication Number
WO 2021/242912 A1

(51) International Patent Classification:
A61K 31/4745 (2006.01) *A61P 35/00* (2006.01)
A61K 31/337 (2006.01)

(21) International Application Number:
PCT/US2021/034332

(22) International Filing Date:
26 May 2021 (26.05.2021)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
63/030,800 27 May 2020 (27.05.2020) US

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(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, IT, 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,

(54) **Title:** CONCOMITANT ADMINISTRATION OF GLUCOCORTICOID RECEPTOR MODULATOR RELACORILANT AND PACLITAXEL, A DUAL SUBSTRATE OF CYP2C8 AND CYP3A4

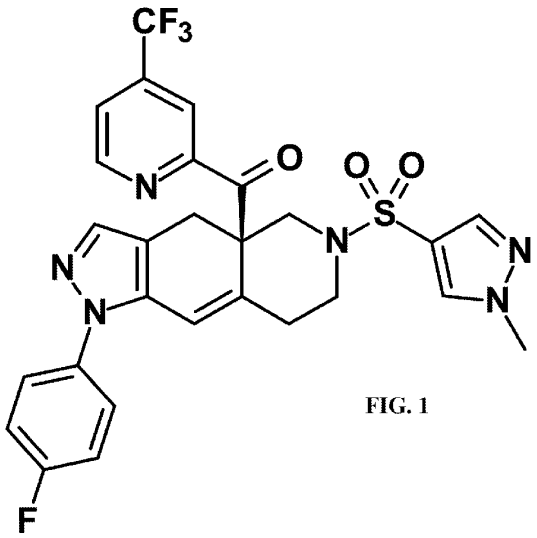


FIG. 1

(57) **Abstract:** Many drugs useful in treating cancer are metabolized by CYP2C8 enzymes, by CYP3A4 enzymes, or both. The effects of concomitant administration of relacorilant and paclitaxel, a drug used to treat cancer that is a substrate for both CYP2C8 and CYP3A4, are disclosed herein. Relacorilant potently inhibited CYP2C8 and CYP3A4 in *in vitro* tests, indicating that co-administration of relacorilant and paclitaxel would increase paclitaxel plasma exposure more than 5-fold *in vivo*, requiring significant reductions in paclitaxel doses when co-administering paclitaxel with relacorilant. Surprisingly, paclitaxel plasma exposure increased only by about 80% instead of the expected more than 5-fold increase expected with concomitant relacorilant and paclitaxel administration. Applicant discloses safe methods of co-administering relacorilant and paclitaxel by reducing the dose of paclitaxel to about half the paclitaxel

WO 2021/242912 A1

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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, 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).

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

dose used when paclitaxel is administered alone. Relacorilant and such reduced doses of paclitaxel may be co-administered to treat cancer, e.g., ovarian or pancreatic cancer.