



(51) International Patent Classification:

A61K 31/337 (2006.01) A61P 35/00 (2006.01)
A61K 31/55 (2006.01)

(21) International Application Number:

PCT/JP2024/080177

(22) International Filing Date:

02 October 2024 (02.10.2024)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

63/587,628 03 October 2023 (03.10.2023) US

(71) Applicant: **TAKEDA PHARMACEUTICAL COMPANY LIMITED** [JP/JP]; 1-1, Doshomachi 4-chome, Chuo-ku, Osaka-shi, Osaka, 5408645 (JP).

(72) Inventors: **AUERBACH, Alan**; 10880 Wilshire Blvd, Suite 2150, Los Angeles, CA 90024 (US). **NIU, Huifeng**; 15 Heather Lane, Southborough, MA 01772 (US).

(74) Agent: **ISHIKAWA Toru** et al.; ORION I.P. Office, Promity Fuchinobe Bldg. 5th Floor, 1-9-15, Kanumadai, Chuo-ku, Sagamihara-shi, Kanagawa, 2520233 (JP).

(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,

(54) Title: ALISERTIB AND PACLITAXEL FOR TREATING SMALL CELL LUNG CANCER

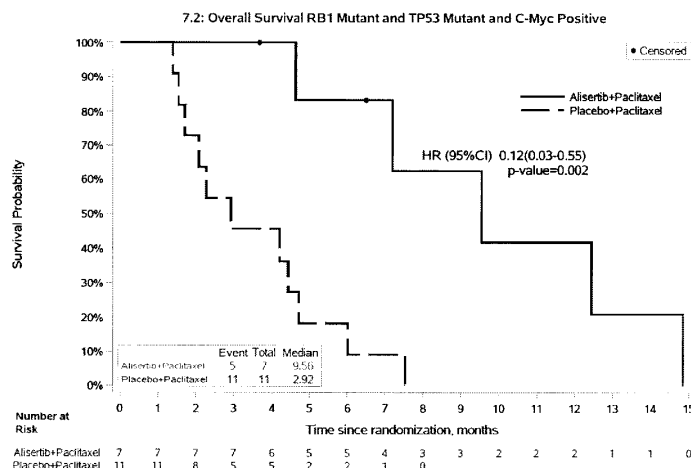


FIG. 7B

(57) Abstract: Provided are methods for the treatment of small cell lung cancer (SCLC) comprising administering alisertib. Also provided herein are methods for the treatment of small cell lung cancer (SCLC) comprising administering alisertib and a taxane, such as paclitaxel. Specific patient populations are contemplated in the methods and compositions disclosed herein, including patients with certain biomarkers and/or genetic profiles as well as resistant or refractory patients with certain biomarkers and/or genetic profiles.

[Continued on next page]

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).

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))*