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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
15 December 2005 (15.12.2005)

PCT

(10) International Publication Number
WO 2005/117877 A1

(51) International Patent Classification[7]: A61K 31/4745, 31/517, 31/5377, 31/519, 31/4706, A61P 35/00

(21) International Application Number:
PCT/EP2005/005639

(22) International Filing Date: 25 May 2005 (25.05.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/576,503 3 June 2004 (03.06.2004) US

(71) Applicant *(for all designated States except US)*: **F.HOFFMANN-LA ROCHE AG** [CH/CH]; Grenzacherstrasse 124, CH-4070 Basel (CH).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **CHEN, Jianping** [US/US]; 10 Kerri Lane, Lincoln Park, NJ 07035 (US). **HIGGINS, Brian** [US/US]; 69-14 Utopia Parkway, Fresh Meadows, NY 11365 (US). **KOLINSKY, Kenneth** [US/US]; 22 Vreeland Avenue, Bloomingdale, NJ 07403 (US).

(74) Agent: **KLEIN, Thomas**; Grenzacherstrasse 124, CH-4070 Basel (CH).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 2005/117877 A1

(54) Title: TREATMENT WITH IRINOTECAN (CPT-11) AND AN EGFR-INHIBITOR

(57) Abstract: The present invention provides a method for manufacturing a medicament for treating tumors or tumor metastases, characterized in that a therapeutically effective amount of an EGFR kinase inhibitor and irinotecan is used, with or without additional agents or treatments, such as other anti-cancer drugs or radiation therapy. The invention also encompasses a pharmaceutical composition that is comprised of an EGFR kinase inhibitor and irinotecan combination in combination with a pharmaceutically acceptable carrier. A preferred example of an EGFR kinase inhibitor that can be used in practising this invention is the compound erlotinib HCl (also known as Tarceva™).