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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
24 February 2005 (24.02.2005)

PCT

(10) International Publication Number
WO 2005/016347 A1

(51) International Patent Classification[7]: A61K 31/517, 31/506, A61P 35/00, A61K 31/00

(21) International Application Number:
PCT/IB2004/002580

(22) International Filing Date: 6 August 2004 (06.08.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/495,919 18 August 2003 (18.08.2003) US

(71) Applicant *(for all designated States except US)*: **PFIZER PRODUCTS INC.** [US/US]; Eastern Point Road, Groton, CT 06340 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **BHATTACHARYA, Samit, Kumar** [IN/US]; Pfizer Global Research and Development, Eastern Point Road, Groton, CT 06340 (US). **CONNELL, Richard, Damian** [US/US]; Pfizer Global Research and Development, Eastern Point Road, Groton, CT 06340 (US). **MOYER, James, Dale** [US/US]; Pfizer Global Research and Development, Eastern Point Road, Groton, CT 06340 (US). **JANI, Jitesh, Pranlal** [US/US]; Pfizer Global Research and Development, Eastern Point Road, Groton, CT 06340 (US). **NOE, Dennis, Alan** [US/US]; Pfizer Global Research and Development, Eastern Point Road, Groton, CT 06340 (US). **STEYN, Stefanus, Johannes** [ZA/US]; Pfizer Global Research and Development, Eastern Point Road, Groton, CT 06340 (US).

(74) Agent: **FULLER, Grover, F., Jr.**; Pfizer Inc., 201 Tabor Road, NJ, Morris Plains, 07950 (US).

(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, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, 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, IT, 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.

(54) Title: DOSING SCHEDULE FOR ERBB2 ANTICANCER AGENTS

(57) Abstract: The invention is directed to methods for the a method for treating overexpression of the erbB2 in a mammal in need of treatment by administering to the mammal a therapeutically effective amount of a first inhibitor of an erbB2 receptor and then, after an interval of less than 24 hours, administering to the mammal from one to six therapeutically effective amounts of the same or different inhibitor of the erbB2 receptor. The invention is also directed to a slow daily infusion of the erbB2 inhibitor. The overexpression of the erbB2 receptor can result in abnormal cell growth and lead to cancer. By the methods of the invention, the efficacy and safety of the inhibitors is increased. The invention is also directed to kits for facilitating the dose administration method of the invention.

WO 2005/016347 A1