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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
20 October 2005 (20.10.2005)

PCT

(10) International Publication Number
WO 2005/097167 A1

(51) International Patent Classification[7]: A61K 38/18, A61P 7/06

(21) International Application Number: PCT/US2005/009873

(22) International Filing Date: 24 March 2005 (24.03.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/556,923 26 March 2004 (26.03.2004) US

(71) Applicant *(for all designated States except US)*: **JANSSEN PHARMACEUTICA NV** [BE/BE]; Turnhoutseweg 30, B-2340 Beerse (BE).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **CHEUNG, Wing, K.** [US/US]; 21 Crosswood Way, Warren, New Jersey 07059 (US).

(74) Agents: **JOHNSON, Philip, S.** et al.; Johnson & Johnson, One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933 (US).

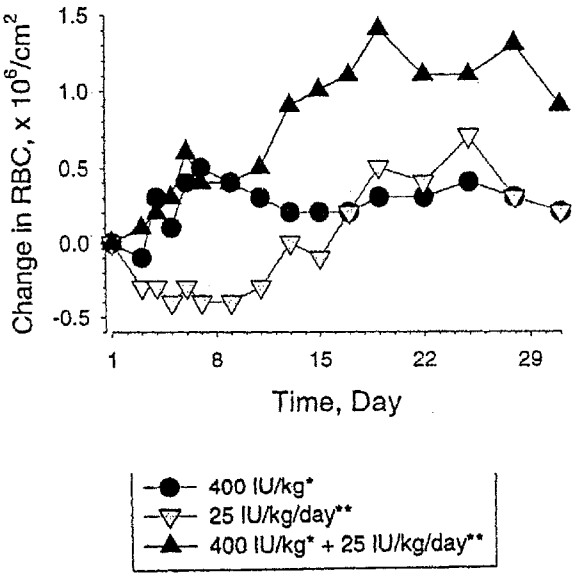
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, 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, 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*

[Continued on next page]

(54) Title: COMBINATION DOSING REGIMEN FOR ERYTHROPOIETIN



(57) Abstract: The present invention provides a combination dosing regimen for erythropoietin (EPO). More particularly, the present dosing regimen includes administration of at least a first dosing segment comprising a first exposure to EPO capable of stimulating the production of reticulocytes followed by a second exposure to EPO capable of sustaining the maturation of the reticulocytes into neocytes, and ultimately, red blood cells. Advantageously, the dosing segment may be cycled or repeated, any number of times and according to any desired time scheme, in order to provide or maintain any desired total red blood cell count and/or hemoglobin concentration. Methods of treatment employing the combination dosing regimen, as well as kits are also provided.

WO 2005/097167 A1

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.