



(11)

**EP 2 005 954 B8**

(12)

**CORRECTED EUROPEAN PATENT SPECIFICATION**

(15) Correction information:

**Corrected version no 1 (W1 B1)**

**Corrections, see**

**Bibliography INID code(s) 73**

(48) Corrigendum issued on:

**28.11.2012 Bulletin 2012/48**

(45) Date of publication and mention

of the grant of the patent:

**24.10.2012 Bulletin 2012/43**

(21) Application number: **07737319.9**

(22) Date of filing: **22.02.2007**

(51) Int Cl.:

**A61K 31/196** <sup>(2006.01)</sup> **A61K 31/198** <sup>(2006.01)</sup>

**A61K 31/20** <sup>(2006.01)</sup> **A61K 31/337** <sup>(2006.01)</sup>

**A61K 31/513** <sup>(2006.01)</sup> **A61K 31/53** <sup>(2006.01)</sup>

**A61K 31/573** <sup>(2006.01)</sup> **A61K 31/704** <sup>(2006.01)</sup>

**A61K 33/36** <sup>(2006.01)</sup> **A61P 35/00** <sup>(2006.01)</sup>

**A61P 43/00** <sup>(2006.01)</sup>

(86) International application number:

**PCT/JP2007/053326**

(87) International publication number:

**WO 2007/108272 (27.09.2007 Gazette 2007/39)**

(54) **KIT FOR CANCER THERAPY AND PHARMACEUTICAL COMPOSITION FOR CANCER THERAPY**

**KIT FÜR DIE KREBSTHERAPIE UND PHARMAZEUTISCHE ZUSAMMENSETZUNG ZUR KREBSTHERAPIE**

**KIT POUR LA THÉRAPIE DU CANCER ET COMPOSITION PHARMACEUTIQUE POUR LA THÉRAPIE DU CANCER**

(84) Designated Contracting States:

**AT BE BG CH CY CZ DE DK EE ES FI FR GB GR  
HU IE IS IT LI LT LU LV MC NL PL PT RO SE SI  
SK TR**

(30) Priority: **23.03.2006 JP 2006080691**

**13.02.2007 JP 2007032777**

(43) Date of publication of application:

**24.12.2008 Bulletin 2008/52**

(60) Divisional application:

**11184021.1 / 2 404 596**

(73) Proprietor: **TMRC Co., Ltd.**

**Tokyo 105-0013 (JP)**

(72) Inventor: **EKIMOTO, Hisao**

**Tokyo 115-0042 (JP)**

(74) Representative: **Jones, Helen M.M. et al**

**Gill Jennings & Every LLP  
The Broadgate Tower  
20 Primrose Street  
London EC2A 2ES (GB)**

(56) References cited:

**EP-A- 0 396 184 WO-A2-2004/093856**

**WO-A2-2005/027842 WO-A2-2005/039490**

**JP-A- 07 215 882 JP-A- 11 012 175**

**JP-A- 2000 506 489 JP-A- 2004 528 316**

**JP-A- 2005 512 961**

- **DEBRUYNE F M J ET AL: "Ketoconazole high dose (H.D.) in advanced prostatic cancer : A comparison of two dosage regimens" JOURNAL OF STEROID BIOCHEMISTRY, PERGAMON PRESS PLC, GB, vol. 28, 1 January 1987 (1987-01-01), page 81, XP023420229 ISSN: 0022-4731 [retrieved on 1987-01-01]**
- **HO A D ET AL: "Combination of low-dose cytarabine and 13-cis retinoic acid in the treatment of myelodysplastic syndromes" LEUKEMIA RESEARCH, NEW YORK,NY, US, vol. 11, no. 11, 1 January 1987 (1987-01-01), pages 1041-1044, XP022921542 ISSN: 0145-2126 [retrieved on 1987-01-01]**

Note: Within nine months of the publication of the mention of the grant of the European patent in the European Patent Bulletin, any person may give notice to the European Patent Office of opposition to that patent, in accordance with the Implementing Regulations. Notice of opposition shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

**EP 2 005 954 B8**

- "986 PUBLICATION Clinical study of combining arsenic trioxide (As<sub>2</sub>O<sub>3</sub>), all-trans retinoic acid (ATRA) and idarubicin (IDA) for induction therapy on the patients with relapsed acute promyelocytic leukemia(APL)" EUROPEAN JOURNAL OF CANCER. SUPPLEMENT, PERGAMON, OXFORD, GB, vol. 3, no. 2, 1 October 2005 (2005-10-01), page 284, XP005133100 ISSN: 1359-6349
- GANSLMAYER MARION ET AL: "The combination of tamoxifen and 9cis retinoic acid exerts overadditive anti-tumoral efficacy in rat hepatocellular carcinoma" JOURNAL OF HEPATOLOGY, vol. 40, no. 6, June 2004 (2004-06), pages 952-956, XP009118834 ISSN: 0168-8278
- LEUNG MUN-FAI ET AL: "The combined differentiating effect of retinoic acid and vincristine on acute promyelocytic leukemia" LEUKEMIA RESEARCH, vol. 21, no. 1, 1997, pages 81-84, XP009118839 ISSN: 0145-2126
- JOZAN SUZANNE ET AL: "Cytotoxic effect of interferon-alpha2a in combination with all-trans retinoic acid or cisplatin in human ovarian carcinoma cell lines" ANTI-CANCER DRUGS, vol. 9, no. 3, March 1998 (1998-03), pages 229-238, XP009118840 ISSN: 0959-4973
- GANSLMAYER MARION ET AL: "Combined tamoxifen and retinoids affect intratumoral apoptosis rate in a rat HCC model" GASTROENTEROLOGY, vol. 126, no. 4, Suppl. 2, April 2004 (2004-04), page A597, XP009118835 & DIGESTIVE DISEASE WEEK/105TH ANNUAL MEETING OF THE AMERICAN-GASTROENTEROLOGICAL-ASSOCIATION; NEW ORLEANS, LA, USA; MAY 16 20, 2004 ISSN: 0016-5085
- CLERICI CARLO ET AL: "Treatment with all-trans retinoic acid plus tamoxifen and vitamin E in advanced hepatocellular carcinoma" ANTICANCER RESEARCH, vol. 24, no. 2C, March 2004 (2004-03), pages 1255-1260, XP009118836 ISSN: 0250-7005
- ANZANO M A ET AL: "CHEMOPREVENTION OF MAMMARY CARCINOGENESIS IN THE RAT: COMBINED USE OF RALOXIFENE AND /-CIS-RETINOIC ACID" JOURNAL OF THE NATIONAL CANCER INSTITUTE, OXFORD UNIVERSITY PRESS, GB, vol. 88, no. 2, 17 January 1996 (1996-01-17), pages 123-125, XP002054376 ISSN: 0027-8874
- EMI N.: 'Kyusei Zen Kotsudui Kyusei Hakketsubyo ni Taisuru Shinki Chiryoho' BESSATSU IGAKU NO AYUMI 15 September 2005, pages 446 - 448, XP003017982
- SAHARA N. ET AL.: 'Am-80, A Hissan ni yoru Kyusei Zen Kotsudui Kyusei Hakketsubyo no Chiryō' RINSHOI vol. 31, no. 12, 10 December 2005, pages 1920 - 1923, XP003017983
- NANRI T. ET AL.: 'Kyusei Zen Kotsudui Hakketsubyo (Actepromyelocytic leukemia)' HEMATOLOGY & ONCOLOGY vol. 52, no. 1, 28 January 2006, pages 10 - 19, XP003017984
- KAWAKITA T. ET AL.: 'Kyusei Zen Kotsudui Kyusei Hakketsubyo Chiryō no Saikin no Hatten (Recent advances in the treatment of acute promyelocytic leukemia)' BIO CHIMICA vol. 20, no. 13, 10 December 2005, pages 1153 - 1158, XP003017985
- YANADA M. ET AL.: '<<Hyojunteki Chiryōho to sono Mondaiten>>, Kyusei Zen Kotsudui Kyusei Hakketsubyo' NAIKA vol. 92, no. 3, 01 September 2003, pages 464 - 469, XP003017986
- KAGECHIKA H.: 'Gosei Tetinoids to sonorinsho Oyo (Synthetic tetinoids and their clinical applications)' HEMATOLOGY & ONCOLOGY vol. 51, no. 3, 28 September 2005, pages 277 - 282, XP003017987
- TALLMAN M.S. ET AL.: 'Retinoids in Cancer Treatment' J. CLIN. PHARMACOL. vol. 32, no. 10, October 1992, pages 868 - 888, XP001000254
- KUROKI T. ET AL.: 'Koganzei no Sayo Kiko' IWANAMI KOZA GENDAI IGAKU NO KISO 10 DAI 7 KAI HAIHON SAIBO ZOSHOKU TO GAN, KABUSHIKI KAISHA IWANAMI SHOTEN 29 June 1999, pages 199 - 212, XP003017988
- KALEMKERIAN G.P. ET AL.: 'Activity of Fenretinide plus chemotherapeutic agents in small-cell lung cancer cell lines' CANCER CHEMOTHER. PHARMACOL. vol. 43, no. 2, February 1999, pages 145 - 150, XP002950455
- FORMELLI F. ET AL.: 'Synthetic retinoid Fenretinide is effective against a human ovarian carcinoma xenograft and potentiates Cisplatin activity' CANCER RESEARCH vol. 53, no. 22, 15 November 1993, pages 5374 - 5376, XP008130036
- SHUDO K. ET AL.: 'kan Shuyo Chiroyozai toshite no Gosei Retinoid Kaihatsu-TAK-101 no Kiso to Rinsho eno Tenbo (Synthetic retinoid development as hepatic tumor therapeutic agent. Basis of TAK-101 and prospect of its clinical application)' THE JOURNAL OF CLINICAL SCIENCE vol. 33, no. 6, June 1997, pages 721 - 727, XP003017990