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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
22 November 2001 (22.11.2001)

PCT

(10) International Publication Number
WO 01/87334 A1

(51) International Patent Classification[7]: A61K 39/395, 31/5685, 31/4196, A61P 35/00 // (A61K 39/395, 31:5685) (A61K 39/395, 31:4196)

(21) International Application Number: PCT/EP01/04468

(22) International Filing Date: 19 April 2001 (19.04.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09/571,355 15 May 2000 (15.05.2000) US

(71) Applicants *(for all designated States except US)*: **PHARMACIA & UPJOHN S.P.A.** [IT/IT]; Via Robert Koch, 1.2, I-20152 Milan (IT). **PHARMACIA & UPJOHN COMPANY** [US/US]; 301 Henrietta Street, Kalamazoo, MI 49001 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **MASSIMINI, Giorgio** [IT/IT]; Via Padre Carlo Vigevano, 26, I-20081 Abbiategrasso_(Milan) (IT). **PISCITELLI, Gabriella** [IT/IT]; Via Tantardini, 7, I-20136 Milan (IT). **PURANDARE, Dinesh** [IN/US]; 6 Macintosh Road, Branchburg, NJ 08876 (US).

(74) Agent: **LONGONI, Alessandra**; Pharmacia & Upjohn S.p.A, Patent Department, Viale Pasteur, 10, I-20014 Nerviano_(Milan) (IT).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EE, 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, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

**Published:**
— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

*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.*

*162162*

*G00002*

WO 01/87334 A1

(54) Title: AROMATASE INHIBITORS AND MONOCLONAL ANTI-HER2 ANTIBODIES AS ANTITUMORS AGENTS

(57) Abstract: A method of treating a human being suffering from an hormone-dependent disorder characterized by the overexpression of HER2 comprising administering to said human being an aromatase inhibitor e.g. exemestane, fadrozole, letrozole and anastrozole and an antibody against HER2 e.g. trastuzumab, in amounts effective to produce a superadditive or synergistic therapeutic effect.