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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
12 September 2003 (12.09.2003)

PCT

(10) International Publication Number
WO 03/074025 A2

(51) International Patent Classification[7]: A61K 9/00, 31/485

(21) International Application Number: PCT/EP03/02004

(22) International Filing Date: 27 February 2003 (27.02.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
02004786.6 1 March 2002 (01.03.2002) EP
02023589.1 23 October 2002 (23.10.2002) EP

(71) Applicant *(for all designated States except US)*: **CHIESI FARMACEUTICI S.P.A.** [IT/IT]; Via Palermo, 26/A, I-43100 Parma (IT).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **DAVIES, Rebecca, Jaine** [GB/IT]; Via Palermo 26/A, I-43100 Parma (IT). **GANDERTON, David** [GB/IT]; Via Palermo 26/A, I-43100 Parma (IT). **LEWIS, David, Andrew** [GB/IT]; Via Palermo 26/A, I-43100 Parma (IT). **MEAKIN, Brian, John** [GB/IT]; Via Palermo 26/A, I-43100 Parma (IT). **CHURCH, Tanya, Kathleen** [GB/IT]; Via Palermo 26/A, I-43100 Parma (IT). **BRAMBILLA, Gaetano** [IT/IT]; Via Palermo, 26/A, I-43100 Parma (IT). **FERRARIS, Alessandra** [IT/IT]; Via palermo 26/A, I-43100 Parma (IT).

(74) Agents: **MINOJA, Fabrizio** et al.; Bianchetti Bracco Minoja S.r.l., Via Rossini, 8, I-20122 Milano (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, EC, 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, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

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

Published:
— *without international search report and to be republished upon receipt of that 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 03/074025 A2

(54) Title: PRESSURISED METERED DOSE INHALERS CONTAINING SOLUTIONS OF BETA-2 AGONISTS

(57) Abstract: The present invention relates to a pharmaceutical formulation for use in the administration of 2(1H)-quinolinone derivatives long-acting β_2-agonists by inhalation. In particular this invention relates to a chemically stable highly efficient TA 2005 HFA solution formulation to be administered by pressurised metered dose inhalers (pMDIs) characterized by a deep lung penetration. The invention also relates to methods for the preparation of said formulation and to its use in respiratory diseases such as asthma and chronic obstructive pulmonary disease (COPD).