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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
24 March 2011 (24.03.2011)

PCT

(10) International Publication Number
WO 2011/033105 A1

(51) International Patent Classification:
A61K 39/395 (2006.01) *C07K 16/30* (2006.01)
A61P 35/00 (2006.01) *C07K 16/46* (2006.01)
C07K 16/28 (2006.01)

(21) International Application Number:
PCT/EP2010/063795

(22) International Filing Date:
20 September 2010 (20.09.2010)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

09170715.8	18 September 2009 (18.09.2009)	EP
61/243,651	18 September 2009 (18.09.2009)	US
10164596.8	1 June 2010 (01.06.2010)	EP
61/344,147	1 June 2010 (01.06.2010)	US

(71) Applicant *(for all designated States except US)*: **MICROMET AG** [DE/DE]; Staffelseestr. 2, 81477 Munich (DE).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **ZUGMEIER, Gerhard** [DE/DE]; Micromet AG, Staffelseestr. 2, 82477 Munich (DE). **KUFER, Peter** [DE/DE]; Micromet AG, Staffelseestr. 2, 81477 Munich (DE). **RÜTTINGER, Dominik** [DE/DE]; Micromet AG, Staffelseestr. 2, 81477 Munich (DE). **KAUBITZSCH, Sabine** [DE/DE]; Micromet AG, Staffelseestr. 2, 81477 Munich (DE).

(74) Agents: **KOCH, Andreas** et al.; Schiweck, Weinzierl & Koch, Landsbergerstrasse 98, 80339 Munich (DE).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

WO 2011/033105 A1

(54) Title: DOSAGE REGIMEN FOR ADMINISTERING AN EPCAMXCD3 BISPECIFIC ANTIBODY

(57) Abstract: The present invention relates to a method (dosage regimen) for administering an EpCAMxCD3 bispecific antibody to a human patient, comprising (a) administering continually a first dose of said antibody for a first period of time; and consecutively (b) administering continually a second dose of said antibody for a second period of time, wherein said second dose exceeds said first dose. The methods of the invention (and likewise the dosage regimen of the invention) are also suitable for treating EpCAM positive epithelial cancer cells in a human patient, or for ameliorating and/or preventing a medical condition mediated by the continued administration of an EpCAMxCD3 bispecific antibody to a human patient. The present invention also relates to the use of an EpCAMxCD3 bispecific antibody for the preparation of a pharmaceutical composition to be used in a method as defined in any one of the preceding claims. A pharmaceutical package or kit comprising the first dose and the second dose as defined in the methods/dosage regimen of the present invention is disclosed as well.