



(12) Translation of
European patent specification

(11) NO/EP 3294769 B1

NORWAY

(19) NO
(51) Int Cl.
C07K 16/28 (2006.01)
A61K 31/573 (2006.01)
A61K 39/00 (2006.01)
A61P 35/00 (2006.01)

Norwegian Industrial Property Office

(45)	Translation Published	2021.04.19
(80)	Date of The European Patent Office Publication of the Granted Patent	2021.01.13
(86)	European Application Nr.	16723349.3
(86)	European Filing Date	2016.05.13
(87)	The European Application's Publication Date	2018.03.21
(30)	Priority	2015.05.13, EP, 15167597
(84)	Designated Contracting States:	AL ; AT ; BE ; BG ; CH ; CY ; CZ ; DE ; DK ; EE ; ES ; FI ; FR ; GB ; GR ; HR ; HU ; IE ; IS ; IT ; LI ; LT ; LU ; LV ; MC ; MK ; MT ; NL ; NO ; PL ; PT ; RO ; RS ; SE ; SI ; SK ; SM ; TR
(73)	Proprietor	MorphoSys AG, Semmelweisstrasse 7, 82152 Planegg, Tyskland
(72)	Inventor	LECLAIR, Stéphane, Schulstrasse 12 ½, 82131 Gauting, Tyskland ENDELL, Jan, Barer Str. 36, 80333 München, Tyskland HÄRTLE, Stefan, Biberfeldstrasse 3, 82291 Mammendorf, Tyskland
(74)	Agent or Attorney	PLOUGMANN VINGTOFT, Postboks 1003 Sentrum, 0104 OSLO, Norge

(54)	Title	TREATMENT FOR MULTIPLE MYELOMA (MM)
(56)	References Cited:	WO-A1-2012/041800 Anonymous: "History of Changes for Study: NCT01421186 A Phase I/IIa Study of Human Anti-CD38 Antibody MOR03087 (MOR202) in Relapsed/Refractory Multiple Myeloma Archive History for NCT01421186 https", , 18 March 2015 (2015-03-18), XP055539141, Retrieved from the Internet: URL: https://clinicaltrials.gov/ct2/history/NCT01421186?V_9=View#StudyPageTop [retrieved on 2019-01-08] CUESTA-MATEOS: FRONT IMMUNOL, vol. 8, 2018, page 1936, Stephen A Beers ET AL: "Blood Spotlight Influence of immunoglobulin isotype on therapeutic antibody function", , 13 January 2016 (2016-01-13), XP055617716, DOI: 10.1182/blood-2015-09- Retrieved from the Internet: URL: http://www.bloodjournal.org/content/bloodjournal/127/9/1097.full.pdf [retrieved on 2019-09-03] Marc S Raab ET AL: "A phase I/IIa study of the human anti-CD38 antibody MOR202 (MOR03087) in relapsed or refractory multiple myeloma (rrMM)", , 2 June 2015 (2015-06-02),

XP055286751, Retrieved from the Internet: URL: https://www.morphosys.com/sites/default/files/phone-conferences/downloads/asco_mor202_poster_final_for_print_21.05.15.pdf [retrieved on 2016-07-07]
 BLOOD, vol. 130, no. 8, 2017, pages 974-981,
 N ENGL J MED, vol. 375, 2016, pages 1319-1331,
 NIELS W.C.J. VAN DE DONK ET AL: "CD38 Antibodies in Multiple Myeloma: Mechanisms of Action and Modes of Resistance", FRONTIERS IN IMMUNOLOGY, vol. 9, 20 September 2018 (2018-09-20), XP055611801, DOI: 10.3389/fimmu.2018.02134
 KATHARINA TEILUF ET AL: "[alpha]-Radioimmunotherapy with ²¹³Bi-anti-CD38 immunoconjugates is effective in a mouse model of human multiple myeloma", ONCOTARGET, vol. 6, no. 7, 10 December 2014 (2014-12-10), pages 4692-4703, XP055286741, DOI: 10.18632/oncotarget.2986
 Michael Karl Bauer: "CD38: A Unique Target In Multiple Myeloma", , 28 March 2014 (2014-03-28), XP055538985, Retrieved from the Internet: URL: <https://ir.genmab.com/static-files/96108e16-8308-4ace-afc5-d7ef2689ddc6> [retrieved on 2019-01-08]
 CURR HEMATOL MALIG REP, vol. 4, 2017, pages 344-357,
 HARTLEPP ET AL: "800 POSTER MOR202 - a fully human antibody targeting CD38 for the treatment of multiple myeloma and other forms of blood-borne malignancies", EUROPEAN JOURNAL OF CANCER. SUPPLEMENT, PERGAMON, OXFORD, GB, vol. 5, no. 4, 1 September 2007 (2007-09-01), page 117, XP022333014, ISSN: 1359-6349, DOI: 10.1016/S1359-6349(07)70533-5
 PROCEED. AM. SOC. CLIN. ONCOL. (ASCO) ANN. MEETING; 2-7 JUNE 2016, CHICAGO, IL; ABSTRACT 8012, 2016,

Enclosed is a translation of the patent claims in Norwegian. Please note that as per the Norwegian Patents Acts, section 66i the patent will receive protection in Norway only as far as there is agreement between the translation and the language of the application/patent granted at the EPO. In matters concerning the validity of the patent, language of the application/patent granted at the EPO will be used as the basis for the decision. The patent documents published by the EPO are available through Espacenet (<http://worldwide.espacenet.com>) or via the search engine on our website here: <https://search.patentstyret.no/>

Patentkrav

- 1.** Et antistoff spesifikt for CD38 som omfatter en variabel tung kjede med sekvensen QVQLVESGGGLVQPGGSLRLSCAASGFTFSSYYMNWVRQAPGKGLEWVSGISGDPSNTYY ADSVKGRFTISRDN SKNTLYLQMNSLRAEDTAVYYCARDLPLVYTG FAYWGQGT LVTVSS (SEKV ID NR: 8) og en variabel lett kjede med sekvensen DIELTQPPSVSVAPGQTARISCSGDNLRHYYVYWYQKPGQAPVLVIYGDSKRPSGIPE RFSGSNSGNTATLTISGTQAEDEADYYCQTYTGGASLVFGGGTKLTVLGQ (SEKV ID NR: 9) og en IgG1 Fc-region for anvendelse i behandlingen av multippelt myelom, hvor nevnte antistoff blir administrert i en dose på 16 mg/kg eller mer én gang i uken (q1w) over minst åtte uker, og hvor nevnte antistoff blir administrert i kombinasjon med deksametason.
- 2.** Antistoffet for anvendelse i henhold til krav 1, hvor nevnte antistoff blir administrert intravenøst.
- 3.** Antistoffet for anvendelse i henhold til et hvilket som helst av de foregående kravene, hvor nevnte antistoff blir administrert intravenøst over en periode på to timer.
- 4.** Antistoffet for anvendelse i henhold til et hvilket som helst av de foregående kravene, hvor deksametason blir dosert ved 20 mg eller 40 mg én gang i uken (q1W).