



(12) Translation of
European patent specification

(11) NO/EP 2766039 B1

NORWAY

(19) NO
(51) Int Cl.
A61K 39/395 (2006.01)
A61K 31/42 (2006.01)
A61K 31/519 (2006.01)
A61K 31/655 (2006.01)
A61K 45/06 (2006.01)
A61P 19/02 (2006.01)
C07K 16/28 (2006.01)

Norwegian Industrial Property Office

(21)	Translation Published	2018.05.14
(80)	Date of The European Patent Office Publication of the Granted Patent	2017.11.22
(86)	European Application Nr.	12769684.7
(86)	European Filing Date	2012.10.10
(87)	The European Application's Publication Date	2014.08.20
(30)	Priority	2012.07.20, EP, 12305889 2011.10.11, US, 201161545864 P
(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
	Designated Extension States:	BA; ME
(73)	Proprietor	Sanofi Biotechnology, 54 rue La Boétie, 75008 Paris, FR-Frankrike Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591-6707, US-USA
(72)	Inventor	HUANG, Xiaohong, 876 Writer Ct., Vernon Hills, IL 60061, US-USA JASSON, Martine, c/o SanofiPatent Department 54 rue La Boétie, F-75008 Paris, FR-Frankrike MARKS, Vanessa, c/o SanofiPatent Department 54 rue La Boétie, F-75008 Paris, FR-Frankrike RADIN, Allen, c/o REGGENERON PHARMACEUTICALS Inc. 777 Old Saw Mill River Road, Tarrytown New York 10591-6707, US-USA
(74)	Agent or Attorney	TANDBERG INNOVATION AS, Postboks 1570 Vika, 0118 OSLO, Norge
(54)	Title	COMPOSITIONS FOR THE TREATMENT OF RHEUMATOID ARTHRITIS AND METHODS OF USING THE SAME

(56) References

Cited:

REICHERT JANICE M: "Antibody-based therapeutics to watch in 2011", MABS, vol. 3, no. 1, January 2011 (2011-01), pages 76-99, XP002688560,, Sanofi: "Evaluation of SAR153191(REGN88)(Sarilumab) on Top of Methotrexate in Rheumatoid Arthritis Patients (RA-MOBILITY)", ClinicalTrials.gov (U.S. National Institutes of Health) , 2 February 2010 (2010-02-02), XP002688561, Retrieved from the Internet: URL:<http://www.clinicaltrials.gov/ct2/show/NCT01061736?term=sarilumab&rank=5> [retrieved on 2012-12-05], RADIN1 A ET AL: "Safety and effects on markers of inflammation of subcutaneously administered regn88/sar153191 (regn88), an interleukin-6 receptor inhibitor, in patients with rheumatoid arthritis: findings from phase 1 studies", ANNALS OF THE RHEUMATIC DISEASES, vol. 69, no. Suppl. 3, 1 January 2010 (2010-01-01), page 99, XP008158577, BRITISH MEDICAL ASSOCIATION, LONDON, GB ISSN: 0003-4967, RADIN AR ET AL: "REGN88/SAR153191 a fully human interleukin-6 receptor monoclonal antibody, reduces acute phase reactants in patients with rheumatoid arthritis: preliminary observations", LY2439821, A HUMANIZED ANTI-INTERLEUKIN-17 MONOCLONAL ANTIBODY, IN THE TREATMENT OF PATIENTS WITH RHEUMATOID ARTHRITIS: A PHASE I RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PROOF-OF-CONCEPT STUDY,, 1 January 2010 (2010-01-01), page S1121, XP008158581, ISSN: 1529-0131, Sanofi and Regeneron present results from pivotal phase 3 studies of sarilumab at american college of rheumatology annual meeting, BIOLOGICAL ABSTRACTS, vol. 23 1 November 2014 (2014-11-01), Philadelphia, PA, US, abstract no.: 2823, Roy Fleischmann, Dennis L. Decktor, Chunpeng Fan, Hubert Van Hoogstraten and Mark C Genovese: "Comparable Efficacy with Sarilumab Plus Methotrexate in Biologic-Experienced and Biologic-Naïve Patients with Moderate-to-Severe Rheumatoid Arthritis from a Phase 3, Randomized, Double-Blind, Placebo-Controlled, International Study", page S1232,, Tarrytown Paris ET AL: "Sanofi and Regeneron Report Positive Phase 2b Trial Results with Sarilumab in Rheumatoid Arthritis",, 12 July 2011 (2011-07-12), XP055165299, Retrieved from the Internet: URL:<http://investor.regeneron.com/common/download/download.cfm?companyid=REGN&fileid=482054&filekey=687FE312-DCDE-4686-8C7D-828898B48C7D&filename=590869.pdf> [retrieved on 2015-01-27], Sanofi and Regeneron announce positive topline results from phase 3 studies with sarilumab in patients with rheumatoid arthritis, Sanofi: "Effect of SAR153191 (REGN88) With Methotrexate in Patients With Active Rheumatoid Arthritis Who Failed TNF-alpha Blockers", ClinicalTrials.gov (U.S. National Institutes of Health) , 7 October 2010 (2010-10-07), XP002688562, Retrieved from the Internet: URL:<http://www.clinicaltrials.gov/ct2/show/NCT01217814?term=sarilumab&rank=1> [retrieved on 2012-12-05]

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. Antistoff for bruk i en fremgangsmåte ved behandling av revmatoid artritt i et individ, omfattende å administrere til individet en virksom mengde av antistoffet og metotreksat, hvor antistoffet omfatter det variable området til den tunge kjeden til sekvens SEKV. ID NR.:2 og det variable området til den lette kjeden til sekvens SEKV. ID NR.:3 og antistoffet blir administrert i mellom 100 mg og 200 mg per to uker, og hvor individet (1) tidligere ble behandlet for revmatoid artritt gjennom 10 administering av metotreksat, og (2) tidligere resultatløst ble behandlet for revmatoid artritt gjennom administrering av en TNF- α -antagonist valgt fra gruppen bestående av etanercept, infliximab, adalimumab, golimumab og certolizumab pegol.
2. Antistoff for bruk ifølge krav 1, hvor individet tidligere ble resultatløst 15 behandlet for revmatoid artritt gjennom administrering av metotreksat.
3. Antistoff for bruk ifølge krav 2, hvor metotreksat blir administrert med mellom 6 til 25 mg per uke.
- 20 4. Antistoff for bruk ifølge ethvert av kravene 1 til 3, hvor antistoffet blir administrert med 150 mg per to uker eller 200 mg per to uker.
5. Antistoff for bruk ifølge ethvert av kravene 1-4, hvor individet oppnår en 20% forbedring i American College of Rheumatologys kjernesett-sykdomsindeks etter 12 25 uker med behandling.
6. Antistoff for bruk ifølge ethvert av kravene 1-4, hvor individet oppnår en 50% forbedring i American College of Rheumatologys kjernesett-sykdomsindeks etter 12 uker med behandling.
- 30 7. Antistoff for bruk ifølge ethvert av kravene 1-4, hvor individet oppnår en 70% forbedring i American College of Rheumatologys kjernesett-sykdomsindeks etter 12

uker med behandling.

8. Antistoff for bruk ifølge ethvert av kravene 1 til 3, hvor individet har blitt behandlet med anti-TNF- α -antagonisten i minst 3 måneder i løpet av de siste 2 år eller
5 individet var intolerant mot minst én TNF- α -antagonist.
9. Antistoff for bruk ifølge ethvert av kravene 1 til 8, hvor antistoffet er sarilumab.
10. Antistoff for bruk ifølge ethvert av kravene 1 til 9, hvor antistoffet blir
10 administrert subkutant til individet.