(12) **Translation of European patent specification**

(11) **NO/EP 4058060 B1**

NORWAY

(19) NO
(51) Int Cl.
A61K 39/395 (2006.01)
A61P 37/00 (2006.01)

Norwegian Industrial Property Office

(45)	Translation Published	2025.05.05
(80)	Date of The European Patent Office Publication of the Granted Patent	2025.02.19
(86)	European Application Nr.	20804531.0
(86)	European Filing Date	2020.11.11
(87)	The European Application's Publication Date	2022.09.21
(30)	Priority	2019.11.11, US, 201962933672 P 2020.05.29, US, 202063031848 P 2020.10.08, US, 202063089345 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
	Designated validation states	MA ; TN
(73)	Proprietor	Astrazeneca AB, 151 85 Södertälje, Sverige
(72)	Inventor	BERGLIND, Anna, AstraZeneca AB, 151 85 Södertälje, Sverige ABREU, Gabriel, AstraZeneca AB, 151 85 Södertälje, Sverige PINEDA, Lilia, AstraZeneca Pharmaceuticals LP 1800 Concord Pike, Wilmington, Delaware 19850, USA TUMMALA, Raj, AstraZeneca Pharmaceuticals LP 1800 Concord Pike, Wilmington, Delaware 19850, USA ASKANASE, Anca, Department of Medicine Division of Rheumatology Columbia University College of Physicians & Surgeons 161 Fort Washington Avenue, New York, NY 10032, USA RICHEZ, Christophe, Rheumatology Department CHU de Bordeaux-GH Pellegrin and UMR CNRS 5164 Bordeaux University 146 rue Léo-Saignat, 33076 Bordeaux, Frankrike MORAND, Eric, Centre for Inflammatory Disease Level 5, Block E Monash Medical Centre Monash University 246 Clayton Road, Clayton, Victoria 3168, Australia BRUCE, Ian, Centre for Epidemiology Versus Arthritis Second floor Stopford Building The University of Manchester Oxford Road, Manchester M13 9PT, Storbritannia BROHAWN, Philip, AstraZeneca UK Limited 1 Francis Crick Avenue Cambridge Biomedical Campus, Cambridge Cambridgeshire CB2 0AA, Storbritannia FURIE, Richard, Division of Rheumatology Zucker School of Medicine at Hofstra/Northwell Great Neck 500 Hofstra Blvd, Hempstead, NY 11549, USA BAE, Sang-Cheol, Department of Rheumatology Hanyang University Hospital for Rheumatic Diseases 222-1 Wangsimni-ro, Seongdong-gu, Seoul 04763, Sør-Korea TANAKA, Yoshiya, The First Department of Internal Medicine School of Medicine University of Occupational and Environmental Health 1-1, Iseigaoka, Kitakyushu, 807-8555, Japan WERTH, Victoria, University of Pennsylvania, Philadelphia, Pennsylvania 19104, USA

VOLLENHOVEN, Ronald Van, Department of Rheumatology Amsterdam Rheumatology and Immunology Center PO Box 7057, 1007 MB Amsterdam, Nederland
ISENBERG, David, Centre for Rheumatology, University College London Rayne Building 4th Floor 5 University Street, London WC1E 6JF, Storbritannia
VITAL, Ed, NIHR Leeds Biomedical Research Centre at Leeds Teaching Hospitals NHS Trust Chapeltown Road, Leeds LS7 4SA, Storbritannia
KAHLENBERG, Michelle, Division of Rheumatology, University of Michigan, Ann Arbor, Michigan 48109-5422, USA
KALYANI, Rubana, MedImmune, LLC, One MedImmune Way, Gaithersburg, Maryland 20878, USA
KALUNIAN, Kenneth, University of California San Diego Health 8910 Villa La Jolla Drive, La Jolla, California 92037, USA

(74) Agent or Attorney: Novagraaf Brevets, Bâtiment O2, 2 rue Sarah Bernhardt CS90017, 92665 ASNIÈRES-SUR-SEINE CEDEX, Frankrike

---

(54) Title: **TYPE I INTERFERON INHIBITION IN SYSTEMIC LUPUS ERYTHEMATOSUS**

(56) References Cited:
WO-A1-2020/165437
WO-A1-2017/031288
BROHAWN PZ ET AL: "Type I interferon gene signature test-low and -high patients with systemic lupus erythematosus have distinct gene expression signatures", LUPUS, vol. 28, no. 13, 29 October 2019 (2019-10-29), GB, pages 1524 - 1533, XP093057738, ISSN: 0961-2033, Retrieved from the Internet <URL:http://journals.sagepub.com/doi/full-xml/10.1177/0961203319885447> DOI: 10.1177/0961203319885447
RICHARD FURIE ET AL: "A Phase 3 Randomized Controlled Trial of Anifrolumab in Patients with Moderate to Severe Systemic Lupus Erythematosus", 23 October 2019 (2019-10-23), XP055767135, Retrieved from the Internet <URL:https://acrabstracts.org/abstract/a-phase-3-randomized-controlled-trial-of-anifrolumab-in-patients-with-moderate-to-severe-systemic-lupus-erythematosus/> [retrieved on 20210120]
RICHARD FURIE ET AL: "Anifrolumab, an Anti-Interferon-[alpha] Receptor Monoclonal Antibody, in Moderate-to-Severe Systemic Lupus Erythematosus : ANIFROLUMAB IN MODERATE-TO-SEVERE SLE", ARTHRITIS & RHEUMATOLOGY (HOBOKEN), vol. 69, no. 2, 28 January 2017 (2017-01-28), US, pages 376 - 386, XP055652780, ISSN: 2326-5191, DOI: 10.1002/art.39962
ERIC MORAND ET AL: "Efficacy and Safety of Anifrolumab in Patients with Moderate to Severe Systemic Lupus Erythematosus: Results of the Second Phase 3 Randomized Controlled Trial", 23 October 2019 (2019-10-23), XP055767128, Retrieved from the Internet <URL:https://acrabstracts.org/abstract/efficacy-and-safety-of-anifrolumab-in-patients-with-moderate-to-severe-systemic-lupus-erythematosus-results-of-the-second-phase-3-randomized-controlled-trial/> [retrieved on 20210120]

PATENTKRAV

1. Inhibitor av IFN-reseptor (IFNR) av type I for anvendelse i en fremgangsmåte for behandling av systemisk lupus erythematosus (SLE) i et individ med behov derav, fremgangsmåten omfattende administrering til individet av en terapeutisk effektiv mengde av inhibitoren av interferon (IFN)-reseptor (IFNR) av type I, hvori ved baseline har individet en IFN-gensignatur (IFNGS) av lav type I, hvori IFNR-inhibitoren reduserer SLE-sykdomsaktivitet i individet, hvori IFNR-inhibitoren er anifrolumab, og hvori IFNGS til individet ved baseline kan måles ved en 4-gen kvantitativ polymerasekjedereaksjonsbasert test, hvori testen måler IFI27-, IFI44-, lFI44L- og RSAD2-ekspresjon i fullblodet til individet.

2. IFNR-inhibitoren for anvendelsen ifølge et hvilket som helst foregående krav, hvori den reduserende SLE-sykdomsaktiviteten i individet omfatter en BILAG-basert kompositttlupusvurdering (BICLA)-respons i individet.

3. IFNR for anvendelsen ifølge et hvilket som helst foregående krav, hvori individet har moderat til alvorlig SLE.

4. IFNR-inhibitoren for anvendelsen ifølge krav 5, hvori fremgangsmåten omfatter administrering av en dose på 300 mg av IFNR-inhibitoren til individet.

5. IFNR-inhibitoren for anvendelsen ifølge krav 5 eller 6, omfattende administrering av en dose av IFNR-inhibitoren til individet hver 4. uke.

6. IFNR-inhibitoren for anvendelsen ifølge et hvilket som helst foregående krav, hvori IFNR-inhibitoren administreres til individet intravenøst.

7. IFNR-inhibitoren for anvendelsen ifølge et hvilket som helst av kravene 1 til 5, hvori IFNR-inhibitoren administreres subkutant til individet.

8. IFNR-inhibitoren for anvendelsen i et hvilket som helst foregående krav, hvori individet er positivt for anti-dsDNA, anti-nukleære eller anti-Smith-antistoffer ved baseline.
