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(54) Title **ANTI-C5 ANTIBODIES AND USES THEREOF**

(56) References Cited:

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EDWIN K.S. WONG ET AL: "Anticomplement C5 therapy with eculizumab for the treatment of paroxysmal nocturnal hemoglobinuria and atypical hemolytic uremic syndrome", TRANSLATIONAL RESEARCH, vol. 165, no. 2, 1 February 2015 (2015-02-01), pages 306-320, XP055358380, NL ISSN: 1931-5244, DOI: 10.1016/j.trsl.2014.10.010

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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/

Claims

1. An antibody or antigen-binding fragment thereof that binds specifically to complement factor 5 (C5) protein, wherein the antibody or antigen-binding fragment thereof comprises a heavy chain variable region (HCVR) comprising the amino acid sequence set forth in SEQ ID NO: 98, and a light chain variable region (LCVR) comprising the amino acid sequence set forth in SEQ ID NO: 106.

2. The antibody or antigen-binding fragment thereof of claim 1, comprising a heavy chain and a light chain, wherein the heavy chain comprises the amino acid sequence set forth in SEQ ID NO: 353 and/or the light chain comprises the amino acid sequence set forth in SEQ ID NO: 354.

3. The antibody or antigen-binding fragment thereof of claim 1 or claim 2, comprising a heavy chain and a light chain, wherein the heavy chain comprises the amino acid sequence set forth in SEQ ID NO: 353, and the light chain comprises the amino acid sequence set forth in SEQ ID NO: 354.

4. The antibody or antigen-binding fragment thereof of any one of claims 1-3, which is a full antibody molecule.

5. A pharmaceutical composition comprising an antibody or antigen-binding fragment thereof of any one of claims 1-4 and a pharmaceutically acceptable carrier or diluent.

6. A reusable pen delivery device comprising the pharmaceutical composition of claim 5.

7. An autoinjector delivery device comprising the pharmaceutical composition of claim 5.

8. An isolated polynucleotide molecule comprising a nucleotide sequence that encodes a HCVR of an antibody or antigen-binding fragment thereof as set forth in any one of claims 1-4 and a nucleotide sequence that encodes a LCVR of an antibody or antigen-binding fragment thereof as set forth in any one of claims 1-4.

9. A recombinant expression vector comprising the polynucleotide molecule of claim 8.

10. A cell comprising the recombinant expression vector of claim 9.

11. The antibody or antigen-binding fragment thereof of any one of claims 1-4 for use in a method of preventing, treating or ameliorating at least one symptom or indication of a disease or disorder selected from the group consisting of atypical hemolytic uremic syndrome (aHUS), paroxysmal nocturnal hemoglobinuria (PNH), age-related macular degeneration, geographic atrophy, uveitis, neuromyelitis optica, multiple sclerosis, stroke, Guillain Barre Syndrome, traumatic brain injury, Parkinson's disease, a disorder of inappropriate or undesirable complement activation, a hemodialysis complication, hyperacute allograft rejection, xenograft rejection, interleukin-2 induced toxicity during IL-2 therapy, an inflammatory disorder, inflammation of an autoimmune disease, Crohn's disease, adult respiratory distress syndrome, thermal injury, a burn, frostbite, a post-ischemic reperfusion condition, myocardial infarction, capillary leak syndrome, obesity, diabetes,

Alzheimer's disease, schizophrenia, epilepsy, atherosclerosis, vasculitis, bullous pemphigoid, C3 glomerulopathy, membraneproliferative glomerulonephritis, diabetic nephropathy, Alport's syndrome, progressive kidney failure, a proteinuric kidney disease, renal ischemia-reperfusion injury, lupus nephritis, balloon angioplasty, post-pump syndrome in cardiopulmonary bypass or renal bypass, renal ischemia, mesenteric artery reperfusion after aortic reconstruction, infectious disease, sepsis, an immune complex disorder, an autoimmune disease, a renal disorder, rheumatoid arthritis, systemic lupus erythematosus (SLE), SLE nephritis, proliferative nephritis, hemolytic anemia, asthma, chronic obstructive pulmonary disease (COPD), emphysema, pulmonary embolism, pulmonary infarct, pneumonia, and myasthenia gravis.

12. The antibody or antigen-binding fragment thereof for use according to claim 11, wherein:

(a) the method of treatment is prophylactic;

(b) the method comprises administering the antibody or antigen-binding fragment thereof in combination with a second therapeutic agent; optionally wherein the second therapeutic agent is selected from the group consisting of an anti-coagulant, an antiinflammatory drug, an antihypertensive, an immunosuppressive agent, a lipid-lowering agent, an anti-CD20 agent such as rituximab, an anti-TNF agent such as infliximab, an anti-seizure agent, a C3 inhibitor, a second anti-C5 antibody, and an anti-thrombotic agent; or

(c) the method comprises administering the antibody or antigen-binding fragment thereof subcutaneously, intravenously, intradermally, intraperitoneally, orally, intramuscularly or intracranially.