

Claims:

1. An anti-FcRn antibody or antigen binding fragment thereof for use in the treatment or prevention of myasthenia gravis (MG) in a human in need thereof, wherein at least three doses of the antibody or antigen binding fragment is to be administered to the human,
5 wherein each dose is independently selected from 4mg/kg, 7mg/kg, 10mg/kg, 15mg/kg and 20mg/kg.
2. Use of an anti-FcRn antibody or antigen binding fragment thereof for the manufacture of a medicament for the treatment or prevention of myasthenia gravis (MG), wherein at least three doses of the antibody or binding fragment thereof is to be administered,
10 wherein each dose is independently selected from 4mg/kg, 7mg/kg, 10mg/kg, 15mg/kg and 20mg/kg.
3. An anti-FcRn antibody or antigen binding fragment thereof or a use according to any one of claims 1 to 2, wherein the antibody or binding fragment thereof comprises:
 - a. a heavy chain or heavy chain fragment having a variable region, wherein said
15 variable region comprises three CDRs having the sequences given in SEQ ID NO: 1 for CDR H1, SEQ ID NO: 2 for CDR H2 and SEQ ID NO: 3 for CDR H3, and
 - b. a light chain or light chain fragment having a variable region, wherein said
20 variable region comprises three CDRs having the sequences given in SEQ ID NO: 4 for CDR L1, SEQ ID NO: 5 for CDR L2 and SEQ ID NO: 6 for CDR L3,
4. An anti-FcRn antibody or antigen binding fragment thereof or a use according to any one of claims 1 to 3, wherein the antibody or antigen binding fragment thereof is humanized.
5. An anti-FcRn antibody or antigen binding fragment thereof or a use according to any one
25 of claims 1 to 4 wherein the anti-FcRn antibody or binding fragment thereof comprises a heavy chain comprising the sequence given in SEQ ID NO:29 or a sequence specific to FcRn at least 80% identical thereto.
6. An anti-FcRn antibody or antigen binding fragment thereof or a use according to any one of claims 1 to 5 wherein the anti-FcRn antibody or binding fragment thereof comprises a
30 light chain comprising the sequence given in SEQ ID NO:15 or a sequence specific to FcRn at least 80% identical thereto.
7. An n anti-FcRn antibody or antigen binding fragment thereof or a use according to claim 5 or 6 wherein the anti-FcRn antibody or binding fragment thereof comprises a heavy chain variable domain sequence having the sequence given in SEQ ID NO:29 and a light
35 chain variable domain sequence comprising the sequence given in SEQ ID NO:15.
8. An anti-FcRn antibody or a use according to any one of claims 1 to 7, wherein the antibody is a full length antibody, optionally wherein the full length antibody is selected from the group consisting of an IgG1, IgG4 and IgG4P.
9. An anti-FcRn antibody or a use according to claim 7 or claim 8 wherein the anti-FcRn
40 antibody has a heavy chain comprising the sequence given in SEQ ID NO:72 or SEQ ID

NO:87 or SEQ ID NO:43 and a light chain comprising the sequence given in SEQ ID NO:22, optionally wherein the anti-FcRn antibody is UCB7665 (rozanolixizumab).

10. An anti-FcRn antibody or antigen binding fragment thereof or a use according to any one of claims 1 to 9 having a binding affinity for human FcRn of 100pM or less, optionally wherein the binding affinity for human FcRn is 100pM or less when measured at pH6 and at pH7.4.
11. An anti-FcRn antibody or antigen binding fragment thereof or a use according to any one of claims 1 to 10 wherein the antibody or antigen binding fragment is provided as a pharmaceutical composition comprising one or more of a pharmaceutically acceptable excipient, diluent or carrier, optionally wherein the pharmaceutical composition further comprises one or more other active ingredients.
12. An anti-FcRn antibody or antigen binding fragment thereof or a use according to any one of claims 1 to 11, wherein each dose is 4 mg/kg or 7mg/kg or 10mg/kg or 15mg/kg or 20mg/kg, or wherein each dose is 7mg/kg or 10mg/kg.
13. An anti-FcRn antibody or antigen binding fragment thereof or a use according to any one of claims 1 to 12, wherein each dose is to be administered weekly, optionally wherein at least 4, 5 or 6 doses are to be administered weekly, optionally with a dosing holiday between the third and fourth dose.
14. An anti-FcRn antibody or antigen binding fragment thereof or a use according to any one of claims 1 to 13, wherein at least 6 doses of antibody or antigen binding fragment are to be administered weekly and each dose is in the range of 4mg/kg to 30 mg/kg, for example 7mg/kg or 10mg/kg.
15. An anti-FcRn antibody or antigen binding fragment thereof or a use according to any one of claims 1 to 14 wherein the anti-FcRn antibody or antigen binding fragment thereof is to be administered subcutaneously or intravenously.
16. An anti-FcRn antibody or antigen binding fragment thereof or a use according to any one of claims 1 to 15 wherein the anti-FcRn antibody or antigen binding fragment thereof blocks binding of human IgG to human FcRn, optionally wherein the anti-FcRn antibody or antigen binding fragment thereof does not bind β 2 microglobulin.
17. An anti-FcRn antibody or antigen binding fragment thereof or a use according to any one of claims 1 to 16 wherein four, five or six weekly doses are to be administered, followed by one or more additional doses that are lower and/or less frequent than the initial four, five or six doses.
18. An anti-FcRn antibody or antigen binding fragment thereof or a use according to any one of claims 1-17 wherein the anti-FcRn antibody or antigen binding fragment thereof binds to an epitope of human FcRn which comprises at least one amino acid selected from the group consisting of residues V105, P106, T107, A108 and K109 of SEQ ID NO:94 and at least one residue, for example at least 2, 3, 4, 5, 6, 7, 8, 9 or 10 residues selected from the group consisting of P100, E115, E116, F117, M118, N119, F120, D121, L122, K123, Q124, G128, G129, D130, W131, P132 and E133 of SEQ ID NO:94.

19. An anti-FcRn antibody or antigen binding fragment thereof or a use according to any one of claims 1-18 wherein the human is suffering from generalised MG which is classified as moderate to severe.
- 5 20. An anti-FcRn antibody or antigen binding fragment thereof or a use according to any one of claims 1-19 wherein the human is anti-AChR and/or anti-MuSK autoantibody-positive and optionally is being considered for treatment with IVIg or plasma exchange.
21. An anti-FcRn antibody or antigen binding fragment thereof or a use according to any one of claims 1-20 wherein each dose is provided as a fixed unit dose selected from 280mg, 420mg, 560mg, 840mg and 1120mg.
- 10 22. Use of an anti-FcRn antibody or antigen-binding fragment thereof in the manufacture of a medicament for treating or preventing myasthenia gravis (MG) in a human in need thereof, wherein the medicament is to be administered to the human at least 3 doses, preferably at least 6 doses, wherein each dose is selected from 280mg, 315mg, 350mg, 385mg, 420mg, 455mg, 490mg, 525mg, 560mg, 595mg, 630mg, 665mg, 700mg, 735mg, 15 770mg, 805mg, 840mg, 875 mg, 910mg, 945mg, 980mg, 1015mg, 1050mg, 1085mg and 1120mg and wherein the anti-FcRn antibody or antigen binding fragment thereof comprises a heavy chain comprising the sequence given in SED ID NO:29 and a light chain comprising the sequence given in SEQ ID NO:15, optionally each dose is administered weekly.
- 20 23. Use of an anti-FcRn antibody or antigen-binding fragment thereof in the manufacture of a medicament for treating or preventing myasthenia gravis (MG) in a human in need thereof, wherein the medicament is to be administered to the human at least 6 doses, wherein for a body weight of less than 50kg the dose is 280mg, for a body weight of equal to or greater than 50kg but less than 70kg the dose is 420mg, for a body weight of 25 equal to or greater than 70kg but less than 100kg the dose is 560mg and for a body weight of equal to or greater than 100kg the dose is 840mg, optionally each dose is administered weekly.
- 30 24. Use of an anti-FcRn antibody or antigen-binding fragment thereof in the manufacture of a medicament for treating or preventing myasthenia gravis (MG) in a human in need thereof, wherein the medicament is to be administered to the human at least 6 doses and wherein for a body weight of less than 50kg the dose is 420mg, for a body weight of equal to or greater than 50kg but less than 70kg the dose is 560mg, for a body weight of equal to or greater than 70kg but less than 100kg the dose is 840mg and for a body weight of equal to or greater than 100kg the dose is 1120mg, optionally each dose is 35 administered weekly.