

CLAIMS

1. Use of an effective amount of a human neonatal Fc receptor (FcRn) antagonist in the manufacture of a medicament for treating pemphigus in a subject,
wherein the FcRn antagonist consists of a variant Fc region, wherein said variant Fc region consists of two Fc domains which form a homodimer, and wherein the amino acid sequence of each of the Fc domains is selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 2, and SEQ ID NO: 3.
2. The use according to claim 1, wherein disease control or complete remission is achieved in the subject.
3. The use according to claim 1 or claim 2, wherein disease control or complete remission is achieved and/or maintained in the subject at a corticosteroid dose of ≤ 0.5 mg prednisone/kg/day or equivalent.
4. The use according to any one of the preceding claims, wherein the pemphigus comprises pemphigus vulgaris (PV), pemphigus foliaceus (PF), or both PV and PF.
5. The use according to any one of the preceding claims, wherein the subject has mild, moderate, or severe pemphigus as classified by the Pemphigus Disease Area Index (PDAI).
6. The use according to any one of the preceding claims, wherein the FcRn antagonist is to be administered to the subject once weekly or biweekly until disease control or complete remission is achieved.
7. The use according to any one of the preceding claims, wherein the FcRn antagonist is to be administered to the subject intravenously at a dose of 10 mg/kg to 30 mg/kg once weekly or every two weeks, optionally wherein the FcRn antagonist is to be administered to the subject intravenously at a dose of 10 mg/kg once weekly or every two weeks.

8. The use according to any one of claims 1 to 6, wherein the FcRn antagonist is to be administered to the subject subcutaneously at a fixed dose of 750 mg to 3000 mg once weekly or every two weeks, optionally wherein the FcRn antagonist is to be administered to the subject subcutaneously at a fixed dose of 1000 mg or 2000 mg once weekly or every two weeks, optionally wherein the FcRn antagonist is to be administered to the subject subcutaneously at a fixed dose of about 1000 mg twice on the same day.

9. The use according to any one of the preceding claims, wherein the FcRn antagonist is to be administered to the subject with a tapering dose of corticosteroid after disease control or complete remission has been achieved, optionally wherein the tapering dose of corticosteroid begins at ≤ 0.5 mg prednisone/kg/day or equivalent, optionally wherein the tapering dose of corticosteroid begins at a dose of 10 mg prednisone/day or equivalent.

10. The use according to any one of the preceding claims, wherein the tapering of corticosteroids can comprise a reduction of about 0.5 mg prednisone/kg/day or equivalent, about 0.25 mg prednisone/kg/day or equivalent, or about 0.1 mg prednisone/kg/day or equivalent.

11. The use according to any one of the preceding claims, wherein the FcRn antagonist is to be administered to the subject in an induction phase and a consolidation phase, wherein

(i) during the induction phase the FcRn antagonist is to be administered to the subject once weekly or biweekly with a corticosteroid at a dose of ≤ 0.5 mg prednisone/kg/day or equivalent until disease control, and

(ii) during the consolidation phase the FcRn antagonist dose is reduced or the FcRn antagonist dosing interval is lengthened, and/or the corticosteroid dose is decreased or the corticosteroid dosing interval is lengthened, to an end-of-consolidation dose or dosing interval effective to prevent new lesions from appearing.

12. The use according to claim 11, further comprising a maintenance phase, wherein

(iii) during the maintenance phase the end-of-consolidation dose or dosing interval for the FcRn antagonist and/or the prednisone or equivalent is continued until complete clearance of lesions.

13. The use according to claim 11 or claim 12, wherein during the induction phase the FcRn antagonist is:
- (i) to be administered to the subject intravenously at a dose of 10 mg/kg to 30 mg/kg,
 - (ii) to be administered to the subject intravenously at a dose of 10 mg/kg,
 - (iii) to be administered to the subject subcutaneously at a fixed dose of 750 mg to 3000 mg, or
 - (iv) to be administered to the subject subcutaneously at a fixed dose of about 1000 mg twice on the same day.
14. The use according to any one of the previous claims, wherein the subject:
- (i) has refractory pemphigus,
 - (ii) has newly diagnosed pemphigus vulgaris, with a PDAI score of ≥ 15 ,
 - (iii) has relapsing pemphigus vulgaris,
 - (iv) has newly diagnosed pemphigus foliaceus, with a PDAI score of ≥ 15 ,
 - (v) has relapsing pemphigus foliaceus,
 - (vi) is rituximab-refractory, or
 - (vii) is corticosteroid intolerant.
15. The use according to any one of the previous claims, wherein the FcRn antagonist is to be administered to the subject with a B-cell depleting agent, optionally wherein the B-cell depleting agent is rituximab.