Claims

1. A unit dosage form for subcutaneous administration of a biologic, wherein:

(a) the biologic has an RD_{iv}, which results in a PK_{iv} and a PD_{iv} in a subject upon intravenous administration;

(b) the unit dosage form comprises an RD_{sc} of the biologic, which results in a PK_{sc} and a PD_{sc} in a subject upon subcutaneous administration; and

(c) the ratio PK_{sc}/PK_{iv} is less than 0.8 and the ratio PD_{sc}/PD_{iv} is from 0.9 to 1.1.

2. A unit dosage form for subcutaneous administration of a biologic, wherein:

(a) the biologic has an RD_{iv}, which results in a PK_{iv} and a BL_{iv} in a subject upon intravenous administration;

(b) the unit dosage form comprises an RD_{sc} of the biologic, which results in a PK_{sc} and a BL_{sc} in a subject upon subcutaneous administration; and

(c) the ratio PK_{sc}/PK_{iv} is less than about 0.8 and the ratio BL_{sc}/BL_{iv} is of about 0.9 to about 1.1.

3. A unit dosage form for subcutaneous administration of a biologic, wherein the amount subcutaneous dose of the biologic in the unit dosage form was determined by a method comprising the steps of:

(a) administration of a subcutaneous dose of the biologic to a subject, wherein the biologic has an RD_{iv}, which results in a PK_{iv} and a BL_{iv};

(b) determining the BL_{sc} of the biologic;

(c) determining the PK_{sc} of the biologic; and

(d) determining a subcutaneous dose that would result in a BL_{sc} / BL_{iv} ratio of about 0.9 to about 1.1 and a PK_{sc}/PK_{iv} ratio less than about 0.8.

4. Use of a biologic in the manufacture of a medicament for treating a subject with a subcutaneous dose of the biologic, wherein the subcutaneous dose of the biologic comprises a therapeutically effective dose of the biologic that was determined by a method comprising the steps of:

(a) administration of a subcutaneous dose of the biologic to a subject, wherein the biologic has an RD_{iv}, which results in a PK_{iv} and a BL_{iv};

(b) determining the BL_{sc} of the biologic;

(c) determining the PK_{sc} of the biologic; and

(d) determining a subcutaneous dose that would result in a BL_{sc} / BL_{iv} ratio of about 0.9 to about 1.1 and a PK_{sc}/PK_{iv} ratio less than about 0.8.

5. The use of claim 4, wherein the BL_{sc} and the BL_{iv} are levels of total IgG in a serum sample of the subject.

6. The use of claim 4 or claim 5, wherein the biologic comprises or consists of a variant Fc region, or FcRn binding fragment thereof, which binds to FcRn with a higher affinity at pH 5.5 as compared to a corresponding wild-type Fc region.

7. The use of any one of claims 4 to 6, wherein the biologic is efgartigimod.

8. The use of claim 7, wherein the RD_{iv} is 10 mg/kg or 25 mg/kg.

9. The use of any one of claims 4 to 8, wherein the therapeutically effective dose of the biologic is to be co-administered with a hyaluronidase enzyme, or is to be administered before or after a hyaluronidase enzyme.

10. The use of claim 9, wherein the hyaluronidase enzyme comprises an amino acid sequence selected from the group consisting of SEQ ID NO: 5-96.

11. The use of claim 9 or claim 10, wherein the hyaluronidase enzyme is rHuPH20.

12. The use of any one of claims 9 to 11, wherein the amount of hyaluronidase enzyme is from 1000 U/ml to 3000 U/ml, preferably 2000 U/mL.

13. Use of a variant Fc region, or FcRn binding fragment thereof, in the manufacture of a medicament for treating myasthenia gravis in a human patient, wherein the variant Fc region, or FcRn binding fragment thereof, is to be administered subcutaneously to the patient at a weekly dose of between 950 and 1050 mg, wherein the weekly dose is independent of the weight of the patient;

wherein the patient obtains a reduction in total serum IgG level of at least 60% compared to baseline IgG level, wherein at least one subtype of IgG is reduced; and

wherein the variant Fc region, or FcRn binding fragment thereof, comprises Fc domains having the amino acids Y, T, E, K, F, and Y at EU Kabat positions 252, 254, 256, 433, 434, and 436, respectively.

14. The use according to claim 13, wherein the weekly dose of the variant Fc region, or FcRn binding fragment thereof, is about 1000 mg.

15. Use of a variant Fc region, or FcRn binding fragment thereof, in the manufacture of a medicament for treating pemphigus vulgaris in a human patient, wherein the variant Fc region, or FcRn binding fragment thereof, is to be administered subcutaneously to the patient at a weekly dose of between 1950 and 2050 mg, wherein the weekly dose is independent of the weight of the patient;

wherein the patient obtains a reduction in total serum IgG level of at least 60% compared to baseline IgG level, wherein at least one subtype of IgG is reduced; and

wherein the variant Fc region, or FcRn binding fragment thereof, comprises Fc domains having the amino acids Y, T, E, K, F, and Y at EU Kabat positions 252, 254, 256, 433, 434, and 436, respectively.

16. The use according to claim 15, wherein the weekly dose of variant Fc region, or FcRn binding fragment thereof, is about 2000 mg.

17. The use according to any of claims 13 to 16, wherein at least 4 weekly doses are to be administered to the patient.

18. The use according to any of claims 13 to 17, wherein the variant Fc region, or FcRn binding fragment thereof, is to be co-administered with a hyaluronidase enzyme, or is to be administered before or after a hyaluronidase enzyme.

19. The use according to claim 18, wherein the hyaluronidase enzyme comprises an amino acid sequence selected from the group consisting of SEQ ID NO: 5-96.

20. The use according to claim 18 or claim 19, wherein the hyaluronidase enzyme is rHuPH20.

21. The use according to any one of claims 13 to 20, wherein the reduction in total serum IgG level is achieved within 1 month from the first weekly dose, or wherein the maximum percentage of total serum IgG reduction is achieved within 1 month from the first weekly dose.

22. The use according to any one of claims 13 to 21, wherein the total serum IgG in the patient is analyzed using a bioanalytical method, preferably ELISA or automated diagnostic analyzer (IVD).

23. The use according to any one of claims 13 to 22, wherein the variant Fc region is efgartigimod.