Claims

1. An antibody formulation comprising:

a humanized anti-APRIL antibody at a concentration of between 20 mg/mL to 190 mg/mL, the humanized anti-APRIL antibody comprising a heavy chain variable region comprising SEQ ID NO: 24 and a light chain variable region comprising SEQ ID NO: 26;

10 mM L-histidine or a salt thereof;

75 mM L-arginine or a salt thereof;

3% sorbitol;

0.01 % (w/v) polysorbate 20; and

a pH of 6.0 to 6.6;

wherein the formulation (i) has a viscosity of 16 cP or less, (ii) has an osmolality of between 250 mOsm/kg to 390 mOsm/kg, and (iii) has an OD330 of less than 1.0.

2. The antibody formulation according to claim 1, wherein the formulation is suitable for intravenous infusion or subcutaneous injection.

3. The antibody formulation according to claim 1 or 2, wherein the humanized anti-APRIL antibody is an IgG antibody.

4. The antibody formulation according to any one of claims 1-3, wherein the formulation maintains at least 96% purity of the anti-APRIL antibody following storage at 2-8ºC for 9 months following manufacture of the formulation.

5. The antibody formulation according to any one of claims 1-4, wherein the formulation maintains at least 95% purity of the anti-APRIL antibody following storage at 25ºC for 6 months following manufacture of the formulation.

6. The antibody formulation according to any one of claims 1-5, wherein the anti-APRIL antibody in the formulation is at a concentration of 150 mg/mL.

7. The antibody formulation according to claim 6, wherein the formulation has an osmolality of between 290 mOsm/kg to 390 mOsm/kg.

8. The antibody formulation according to any one of claims 6 or 7, wherein the formulation has an OD330 of 0.8 or less.

9. The antibody formulation according to any one of claims 1-5, wherein the anti-APRIL antibody is at a concentration of 20 mg/mL.

10. The antibody formulation according to claim 9, wherein the formulation has an osmolality of between 293 mOsm/kg to 333 mOsm/kg.

11. The antibody formulation according to any one of claims 1-10, wherein the formulation is free of glutamic acid or its salt, glycine, carbonate, HEPES, phosphate, citrate, and acetate.

12. The antibody formulation of any one of claims 1-11, wherein the formulation comprises a pH of 6.1 to 6.3.

13. The antibody formulation of any one of claims 1-12, wherein the formulation comprises 150 mg/mL of the humanized anti-APRIL antibody.

14. The antibody formulation of any one of claims 1-13, wherein the humanized anti-APRIL antibody comprises a heavy chain amino acid sequence of SEQ ID NO: 28 and a light chain amino acid sequence of SEQ ID NO: 30.

15. A single-use or multi-use vial comprising the antibody formulation of any one of claims 1-14.

16. The single-use or multi-use vial of claim 15, comprising a volume of between 0.5 mL and 50 mL of the formulation having an anti-APRIL antibody concentration of between 20 mg/mL to 190 mg/mL.

17. The single-use or multi-use vial of claim 16, wherein the formulation has an anti-APRIL antibody concentration of 20 mg/mL.

18. The single-use or multi-use vial of claim 16, wherein the formulation has an anti-APRIL antibody concentration of 150 mg/mL.

19. The single-use or multi-use vial of any one of claims 16-18 comprising a volume of 5 mL of the formulation.

20. A pre-filled syringe, autoinjector, or injector pen comprising the antibody formulation of any one of claims 1-14.

21. The pre-filled syringe, autoinjector, or injector pen of claim 20, comprising a volume of between 0.5 mL and 10 mL of the formulation having an anti-APRIL antibody concentration of between 20 mg/mL to 190 mg/mL.

22. The pre-filled syringe, autoinjector, or injector pen of claim 21, wherein the formulation has an anti-APRIL antibody concentration of 20 mg/mL.

23. The pre-filled syringe, autoinjector, or injector pen of claim 21, wherein the formulation has an anti-APRIL antibody concentration of 150 mg/mL.

24. The pre-filled syringe, autoinjector, or injector pen of one of claims 20-23 comprising a volume of 2 mL of the formulation.

25. A pharmaceutical formulation for use in the treatment of IgA nephropathy in an individual in need thereof, comprising the antibody formulation of any one of claims 1-14.

26. Use of the formulation of one of claims 1-14 in the manufacture of a medicament for treating IgA nephropathy, wherein the formulation is to be administered by subcutaneous injection into an individual in need thereof.

27. The use according to claim 26, wherein the administration is to be repeated on at least an every week (QW) schedule for at least 2 administration cycles.

28. The use according to claim 26, wherein the administration is to be repeated on at least an every two weeks (Q2W) schedule for at least 2 administration cycles.

29. The use according to claim 26, wherein the administration is to be repeated on at least an every 4 weeks (Q4W) or monthly (QMT) schedule for at least 2 administration cycles.

30. The use according to any one of claims 26-29, wherein a total dose of between 10 mg to 1350 mg of the anti-APRIL antibody is to be administered per dosing event.

31. The use according to claim 30, wherein 2 mL of the formulation at a concentration of 150 mg/mL of the anti-APRIL antibody is to be delivered per administration, and each dosing event comprises one or more of said administrations.

32. The use according to claim 30, wherein 4 mL of the formulation at a concentration of 150 mg/mL of the anti-APRIL antibody is to be delivered per administration, and each dosing event comprises one or more of said administrations.

33. The use according to any one of claims 26-32, wherein the formulation is to be subcutaneously administered into a site in the individual's thigh, abdomen, or upper arm.

34. Use of the formulation of one of claims 1-14 in the manufacture of a medicament for treating IgA nephropathy, wherein the formulation is to be administered by intravenous infusion into an individual in need thereof.

35. The use according to claim 34, wherein the administration is to be repeated on at least a QW schedule for at least 2 administration cycles.

36. The use according to claim 34, wherein the administration is to be repeated on at least a Q2W schedule for at least 2 administration cycles.

37. The use according to claim 34, wherein the administration is to be repeated on at least a Q4W or monthly schedule for at least 2 administration cycles.

38. The use according to any one of claims 34-37, wherein the intravenous infusion comprises:

the formulation of one of claims 1-14 diluted to a concentration of between 0.1 mg/mL to 10 mg/mL in 0.9% saline; and

a total dose of between 10 mg to 1350 mg of the anti-APRIL antibody is to be administered to the individual in a single intravenous dose of the diluted formulation over a period of 2 hours.

39. The use according to claim 38, wherein 15 mL of the formulation at a concentration of 20 mg/mL is to be added to 235 mL of 0.9% saline to provide the intravenous dose at a concentration of 1.2 mg/mL.

40. Use of the antibody formulation according to any one of claims 1-14 in the manufacture of a medicament for treating IgA nephropathy, wherein the anti-APRIL antibody is to be administered by a loading/maintenance administration protocol to an individual in need thereof.

41. The use according to claim 40, wherein the loading component of the loading/maintenance administration protocol comprises one or more administrations of the anti-APRIL antibody at a higher concentration than the anti-APRIL antibody concentration in the maintenance component of the loading/maintenance administration protocol.

42. The use according to claim 40, wherein the loading component of the loading/maintenance administration protocol comprises one or more administrations of the anti-APRIL antibody at a higher frequency than the frequency of administration of the anti-APRIL antibody in the maintenance component of the loading/maintenance administration protocol.

43. The use according to any one of claims 40-42, wherein the loading component of the loading/maintenance administration protocol comprises one or more administrations of the anti-APRIL antibody at a different route than the route of administration of the anti-APRIL antibody in the maintenance component of the loading/maintenance administration protocol.

44. The use according to claim 40, wherein the loading component of the loading/maintenance administration protocol comprises one or more intravenous administrations of the anti-APRIL antibody and the maintenance component of the loading/maintenance administration protocol comprises one or more subcutaneous administrations of the anti-APRIL antibody.

45. The use according to any one of claims 26-44, wherein the individual in need thereof has a serum IgA level greater than 4g/L.

46. The use according to any one of claims 26-44, wherein the individual in need thereof is an IgA nephropathy patient.

47. The use according to any one of claims 26-44, wherein the individual has a hyperimmunoglobulinemia.