CLAIMS

What is claimed is:

1. Use of a humanized antibody that specifically binds complement component C1s in the manufacture of a medicament for treating cold-agglutinin disease in a subject in need thereof,

wherein the antibody comprises a light chain (LC) complementarity determining region (CDR) 1 comprising the amino acid sequence of SEQ ID NO: 1, a LC CDR2 comprising the amino acid sequence of SEQ ID NO: 2, a LC CDR3 comprising the amino acid sequence of SEQ ID NO: 3, and a heavy chain (HC) CDR1 comprising the amino acid sequence of SEQ ID NO: 4, an HC CDR2 comprising the amino acid sequence of SEQ ID NO: 5, and an HC CDR3 comprising the amino acid sequence of SEQ ID NO: 6, and

wherein about 3.5 g of the humanized antibody is to be administered to the subject.

2. The use of claim 1, wherein the antibody is to be administered about every 10, 12, 14, or 16 weeks.

3. The use of claim 1, wherein the antibody is to be administered about every 12 weeks.

4. The use of any one of claims 1-3, wherein about 3.5 g of the antibody is to be administered about 4 weeks after the first dose.

5. The use of any one of claims 1-4, wherein the antibody is to be administered intravenously or subcutaneously.

6. The use of claim 1, wherein about 3.5 g of the antibody is to be administered intravenously on Day 1 and about every 10, 12, 14, or 16 weeks thereafter, and about 3.5 g of the antibody is to be additionally administered intravenously on or about Day 29.

7. The use of claim 1, wherein about 3.5 g of the antibody is to be administered intravenously on Day 1 and about every 12 weeks thereafter, and about 3.5 g of the antibody is to be additionally administered intravenously on or about Day 29.

8. The use of any one of claims 1-7, wherein administration of the antibody increases the level of hemoglobin in the subject.

9. The use of any one of claims 1-8, wherein administration of the antibody decreases the level of bilirubin in the subject.

10. The use of any one of claims 1-9, wherein administration of the antibody inhibits the classical complement pathway activity by about 90% or greater, as determined by measuring the amount of the terminal complement complex, C5b-9.

11. The use of any one of claims 1-10, wherein administration of the antibody decreases the 50% hemolytic complement activity (CH50) level to less than about 10 IU/mL.

12. The use of any one of claims 1-11, wherein following administration of the antibody, the subject has a plasma concentration of the antibody of at least about 100 μg/mL.

13. The use of any one of claims 1-12, wherein the antibody is contained in a syringe or a vial.

14. The use of any one of claims 1-13, wherein the antibody is to be administered using a syringe, a pre-filled syringe, or a large-volume drug delivery system.

15. The use of any one of claims 1-14, wherein the antibody is to be administered using an autoinjector.

16. The use of any one of claims 1-15, wherein the antibody comprises a light chain variable region (VL) comprising the amino acid sequence of SEQ ID NO: 7 and a heavy chain variable region (VH) comprising the amino acid sequence of SEQ ID NO: 8.

17. The use of any one of claims 1-16, wherein the antibody is a Fab fragment, a F(ab')2 fragment, a scFv, or a Fv.

18. The use of any one of claims 1-16, wherein the antibody comprises a heavy chain constant region of the isotype IgG4.

19. The use of claim 18, wherein the IgG4 constant region comprises a proline substitution, a glutamic acid substitution, a leucine substitution, and a serine substitution at amino acid residues 108, 115, 308, and 314, respectively, relative to the IgG4 constant region sequence of SEQ ID NO: 11.

20. The use of any one of claims 1-16 and 18-19, wherein the antibody comprises a light chain comprising the amino acid sequence of SEQ ID NO: 9 and a heavy chain comprising the amino acid sequence of SEQ ID NO: 10.

21. Use of a humanized antibody that specifically binds complement component C1s in the manufacture of a medicament for treating chronic inflammatory demyelinating polyneuropathy (CIDP) in a subject in need thereof,

wherein a loading dose of about 50 mg/kg of the subject's body weight of the humanized antibody, and one or more maintenance doses of about 300 mg, about 600 mg, about 1,200 mg, about 2,400 mg, about 3,600 mg, or about 7,200 mg of the antibody are to be administered to the subject,

wherein the antibody comprises: a light chain (LC) complementarity determining region (CDR) 1 comprising the amino acid sequence of SEQ ID NO: 1, a LC CDR2 comprising the amino acid sequence of SEQ ID NO: 2, and a LC CDR3 comprising the amino acid sequence of SEQ ID NO: 3; and a heavy chain (HC) CDR1 comprising the amino acid sequence of SEQ ID NO: 4, an HC CDR2 comprising the amino acid sequence of SEQ ID NO: 5, and an HC CDR3 comprising the amino acid sequence of SEQ ID NO: 6.

22. The use of claim 21, wherein the one or more maintenance doses are to be administered about every 1, 2, 4, or 12 weeks thereafter.

23. The use of claim 21 or 22, wherein the antibody is to be administered intravenously or subcutaneously.

24. The use of any one of claims 21-23, wherein the loading dose is to be administered intravenously on Day 1, followed by subcutaneous administration of the maintenance dose about every week starting on Day 8.

25. The use of any one of claims 21-24, wherein the subject is refractory to another CIDP treatment.

26. The use of any one of claims 21-24, wherein the subject has received another CIDP treatment within about one week of the loading dose or is concomitantly receiving another CIDP treatment.

27. The use of any one of claims 21-24, wherein the subject has not received another treatment for CIDP within about 6 months prior to the loading dose.

28. The use of any one of claims 25-27, wherein the other CIDP treatment is intravenous immunoglobulin (IVIg), subcutaneous immunoglobulin (SCIg), or corticosteroids.

29. The use of any one of claims 21-28, wherein administration of the antibody results in a one point or greater decrease in adjusted Inflammatory Neuropathy Cause and Treatment (INCAT) disability score relative to the INCAT score prior to treatment with the antibody.

30. The use of any one of claims 21-29, wherein following administration of the antibody, the subject has a plasma concentration of the antibody of at least about 100 μg/mL.

31. The use of any one of claims 21-30, wherein the antibody is contained in a syringe or a vial.

32. The use of any one of claims 21-31, wherein the antibody is to be administered using a syringe, a pre-filled syringe, or a large-volume drug delivery system.

33. The use of any one of claims 21-32, wherein the antibody is to be administered using an autoinjector.

34. The use of any one of claims 21-33, wherein the antibody comprises a light chain variable region (VL) comprising the amino acid sequence of SEQ ID NO: 7 and a heavy chain variable region (VH) comprising the amino acid sequence of SEQ ID NO: 8.

35. The use of any one of claims 21-34, wherein the antibody is a Fab fragment, a F(ab')2 fragment, a scFv, or a Fv.

36. The use of any one of claims 21-34, wherein the antibody comprises a heavy chain constant region of the isotype IgG4.

37. The use of claim 36, wherein the IgG4 constant region comprises a proline substitution, a glutamic acid substitution, a leucine substitution, and a serine substitution at amino acid residues 108, 115, 308, and 314, respectively, relative to the IgG4 constant region sequence of SEQ ID NO: 11.

38. The use of any one of claims 21-34 and 36-37, wherein the antibody comprises a light chain comprising the amino acid sequence of SEQ ID NO: 9 and a heavy chain comprising the amino acid sequence of SEQ ID NO: 10.