CLAIMS

1. Use of an effective dose of a humanized monoclonal anti-C1s antibody that comprises light chain complementarity determining regions (CDRs) of an antibody light chain variable region comprising the amino acid sequence of SEQ ID NO: 7 and heavy chain CDRs of an antibody heavy chain variable region comprising the amino acid sequence of SEQ ID NO: 8 in the manufacture of a medicament for treating a subject having a complement-mediated disorder, wherein the effective dose is 5 grams to 8 grams of the humanized anti-C1s antibody.

2. The use of claim 1, wherein the humanized monoclonal anti-C1s antibody comprises a light chain complementarity determining region 1 (CDR1) comprising the amino acid sequence of SEQ ID NO: 10, a light chain complementarity determining region 2 (CDR2) comprising the amino acid sequence of SEQ ID NO: 11, and a light chain complementarity determining region 3 (CDR3) comprising the amino acid sequence of SEQ ID NO: 3, a heavy chain CDR1 comprising the amino acid sequence of SEQ ID NO: 12, a heavy chain CDR2 comprising the amino acid sequence of SEQ ID NO: 13, a heavy chain CDR3 comprising the amino acid sequence of SEQ ID NO: 14.

3. The use of claim 1 or 2, wherein the humanized monoclonal anti-C1s antibody comprises a light chain variable region comprising the amino acid sequence of SEQ ID NO: 16 and a heavy chain variable region comprising the amino acid sequence of SEQ ID NO: 21.

4. The use of claim 3, wherein the humanized monoclonal anti-C1s antibody comprises a light chain that comprises the amino acid sequence of SEQ ID NO: 23 and a heavy chain that comprises the amino acid sequence of SEQ ID NO: 22.

5. The use of any one of claims 1-4, wherein the complement-mediated disorder is selected from the group consisting of: cold agglutinin disease, antibody-mediated kidney allograft rejection, immune thrombocytopenia, bullous pemphigoid, multifocal motor neuropathy, chronic inflammatory demyelinating polyneuropathy, myasthenia gravis, neuromyelitis optica, systemic lupus erythematosus, lupus nephritis, and membranoproliferative glomerulonephritis.

6. The use of claim 5, wherein the complement mediated disorder is cold agglutinin disease.

7. The use of claim 6, wherein the subject has not had a blood transfusion within 6 months of administration of the effective dose.

8. The use of claim 6, wherein the subject has had a blood transfusion within 6 months of administration of the effective dose.

9. The use of any one of claims 1-8, wherein the level of hemoglobin in the subject is increased by at least 1.6 g/dL within seven days of administration of the effective dose, relative to baseline levels of hemoglobin in the subject.

10. The use of any one of claims 1-9, wherein the level of bilirubin in the subject is lower than 1.2 g/dL within seven days of administration of the effective dose.

11. The use of any one of claims 1-10, wherein the level of haptoglobin, the level of lactate dehydrogenase, and/or the level of reticulocytes is/are normalized in the subject following repeat administration of the effective dose.

12. The use of claim 5, wherein the complement mediated disorder is immune thrombocytopenia.

13. The use of claim 12, wherein the complement mediated disorder is chronic immune thrombocytopenia.

14. The use of any one of claims 1-13, wherein following administration of the effective dose the subject has a serum concentration of the humanized monoclonal anti-C1s antibody of at least 100 μg/mL.

15. The use of any one of claims 1-14, wherein the effective dose is 6.5 grams to 7.5 grams.

16. The use of claim 15, wherein the effective dose is 6.5 grams.

17. The use of claim 16, wherein the subject weighs less than 75 kilograms.

18. The use of claim 15, wherein the effective dose is 7.5 grams.

19. The use of claim 18, wherein the subject weighs 75 kilograms or more.

20. The use of any one of claims 1-19, wherein the effective dose of the humanized monoclonal anti-C1s antibody is to be administered intravenously, subcutaneously, or intramuscularly.

21. Use of an effective dose of a humanized monoclonal anti-C1s antibody that comprises a light chain comprising the amino acid sequence of SEQ ID NO: 23 and a heavy chain comprising the amino acid sequence of SEQ ID NO: 22, in the manufacture of a medicament for treating a subject having cold agglutinin disease, wherein: (a) the subject weighs less than 75 kilograms, and the effective dose is 6.5 grams of the humanized anti-C1s antibody; or (b) the subject weighs 75 kilograms or more, and the effective dose is 7.5 grams of the humanized anti-C1s antibody, and the medicament is to be administered to the subject intravenously.

22. The use of any one of claims 1-21, wherein the effective dose is to be administered by intravenous infusion over 1 hour.

23. The use of claim 21 or 22, wherein the effective dose is to be administered on Day 0, Day 7, and every 14 days thereafter starting on Day 21.

24. A humanized monoclonal anti-C1s antibody comprising a light chain that comprises the amino acid sequence of SEQ ID NO: 23 and a heavy chain that comprises the amino acid sequence of SEQ ID NO: 22.

25. A pharmaceutical composition comprising the humanized monoclonal anti-C1s antibody of claim 24.

26. The pharmaceutical composition of claim 25, wherein the humanized monoclonal anti-C1s antibody is formulated as a solution at a concentration of 50 mg/mL.

27. A pharmaceutical composition comprising an effective dose of a humanized monoclonal anti-C1s antibody that comprises light chain complementarity determining regions (CDRs) of an antibody light chain variable region comprising the amino acid sequence of SEQ ID NO: 7 and heavy chain CDRs of an antibody heavy chain variable region comprising the amino acid sequence of SEQ ID NO: 8, wherein the effective dose is 5 grams to 8 grams of the humanized anti-C1s antibody.

28. The pharmaceutical composition of claim 27, wherein the humanized monoclonal anti-C1s antibody comprises a light chain complementarity determining region 1 (CDR1) comprising the amino acid sequence of SEQ ID NO: 10, a light chain complementarity determining region 2 (CDR2) comprising the amino acid sequence of SEQ ID NO: 11, and a light chain complementarity determining region 3 (CDR3) comprising the amino acid sequence of SEQ ID NO: 3, a heavy chain CDR1 comprising the amino acid sequence of SEQ ID NO: 12, a heavy chain CDR2 comprising the amino acid sequence of SEQ ID NO: 13, a heavy chain CDR3 comprising the amino acid sequence of SEQ ID NO: 14.

29. The pharmaceutical composition of claim 28, wherein the humanized monoclonal anti-C1s antibody comprises a light chain variable region comprising the amino acid sequence of SEQ ID NO: 16 and a heavy chain variable region comprising the amino acid sequence of SEQ ID NO: 21.

30. The pharmaceutical composition of claim 29, wherein the humanized monoclonal anti-C1s antibody comprises a light chain that comprises the amino acid sequence of SEQ ID NO: 23 and a heavy chain that comprises the amino acid sequence of SEQ ID NO: 22.

31. The pharmaceutical composition of any one of claims 27-30, wherein the effective dose is 6.5 grams to 7.5 grams.

32. The pharmaceutical composition of claim 31, wherein the effective dose is 6.5 grams.

33. The pharmaceutical composition of claim 32, wherein the subject weighs less than 75 kilograms.

34. The pharmaceutical composition of claim 31, wherein the effective dose is 7.5 grams.

35. The pharmaceutical composition of claim 34, wherein the subject weighs 75 kilograms or more.

36. The pharmaceutical composition of any one of claims 25-35, further comprising sterile saline.

37. The pharmaceutical composition of any one of claims 25-36, wherein the complement-mediated disorder is selected from the group consisting of: cold agglutinin disease, antibody-mediated kidney allograft rejection, immune thrombocytopenia, bullous pemphigoid, multifocal motor neuropathy, chronic inflammatory demyelinating polyneuropathy, myasthenia gravis, neuromyelitis optica, systemic lupus erythematosus, lupus nephritis, and membranoproliferative glomerulonephritis.

38. The pharmaceutical composition of claim 37, wherein the complement mediated disorder is cold agglutinin disease.

39. The pharmaceutical composition of claim 37, wherein the complement mediated disorder is immune thrombocytopenia.

40. The pharmaceutical composition of claim 39, wherein the complement mediated disorder is chronic immune thrombocytopenia.