CLAIMS

1. A formulation comprising at least 100 mg/mL of an anti-CD38 antibody, wherein the anti-CD38 antibody comprises a variable heavy region (VH) comprising three complementarity determining regions (CDRs) CDR-H1, CDR-H2, and CDR-H3 comprising the amino acid sequences set forth in SEQ ID NOs: 1-3, respectively, and a variable light region (VL) comprising three CDRs CDR-L1, CDR-L2, and CDR-L3 comprising the amino acid sequences set forth in SEQ ID NOs: 4-6, respectively,

the formulation comprises a viscosity reducing agent, a stabilizer, a buffering agent, and a surfactant, and

the formulation has a pH of 5.9-7.0 and a viscosity of at most 25 mPa·s at 20°C.

2. The formulation of claim 1, wherein the viscosity reducing agent is 90-150 mM Arg-Cl.

3. The formulation of claim 2, wherein the viscosity reducing agent is 90-125 mM Arg-Cl.

4. The formulation of claim 2, wherein the viscosity reducing agent is 110 mM Arg-Cl.

5. The formulation of any one of the preceding claims, wherein the surfactant is Poloxamer 188.

6. The formulation of any one of the preceding claims, wherein the surfactant is 0.4% (w/v) Poloxamer 188.

7. The formulation of any one of the preceding claims, wherein the buffering agent is histidine.

8. The formulation of any one of the preceding claims, wherein the buffering agent is 9 mM histidine.

9. The formulation of claim 1, wherein the viscosity reducing agent is 90-150 mM Lys-Ac.

10. The formulation of claim 9, wherein the viscosity reducing agent is 125 mM Lys-Ac.

11. The formulation of claim 9 or 10, wherein the surfactant is Polysorbate 80.

12. The formulation of claim 11, wherein the surfactant is 0.04% (w/v) Polysorbate 80.

13. The formulation of any one of the preceding claims, comprising 125-155 mg/mL of the anti-CD38 antibody.

14. The formulation of any one of the preceding claims, comprising 140 mg/mL of the anti-CD38 antibody.

15. The formulation of any one of the preceding claims, wherein the stabilizer is sucrose.

16. The formulation of any one of the preceding claims, wherein the stabilizer is 2% (w/v) sucrose.

17. The formulation of any one of the preceding claims, wherein the pH is 5.9-7.0.

18. The formulation of claim 17, wherein the pH is 6.2-6.3.

19. A formulation comprising 140 mg/mL of an anti-CD38 antibody, wherein

the anti-CD38 antibody comprises a variable heavy region (VH) comprising three complementarity determining regions (CDRs) CDR-H1, CDR-H2, and CDR-H3 comprising the amino acid sequences set forth in SEQ ID NOs: 1-3, respectively, and a variable light region (VL) comprising three CDRs CDR-L1, CDR-L2, and CDR-L3 comprising the amino acid sequences set forth in SEQ ID NOs: 4-6, respectively,

the formulation comprises 9 mM histidine, 110 mM Arg-Cl, 2% (w/v) sucrose, and 0.4% (w/v) Poloxamer 188, and wherein

the formulation has a pH of 6.2-6.3 and a viscosity of at most 14 mPa·s at 20°C.

20. A formulation comprising 140 mg/mL of an anti-CD38 antibody, wherein

the anti-CD38 antibody comprises a variable heavy region (VH) comprising three complementarity determining regions (CDRs) CDR-H1, CDR-H2, and CDR-H3 comprising the amino acid sequences set forth in SEQ ID NOs: 1-3, respectively, and a variable light region (VL) comprising three CDRs CDR-L1, CDR-L2, and CDR-L3 comprising the amino acid sequences set forth in SEQ ID NOs: 4-6, respectively,

the formulation comprises 125 mM Lys-Ac, 2% (w/v) sucrose, and 0.04% (w/v) Polysorbate 80, and

the formulation has a pH of 6.2 and a viscosity of at most 14 mPa·s at 20°C.

21. The formulation of any one of the preceding claims, wherein the formulation is suitable for subcutaneous administration.

22. The formulation of claim 21, wherein the subcutaneous administration is large-volume subcutaneous administration.

23. The formulation of any one of the preceding claims, wherein the VH of the anti-CD38 antibody comprises amino acid sequence set forth in SEQ ID NO: 7, and the VL of the anti-CD38 antibody comprises the amino acid sequence set forth in SEQ ID NO: 8.

24. The formulation of any one of the preceding claims, wherein the anti-CD38 antibody is isatuximab.

25. A packaged pharmaceutical product comprising a sterile container comprising a therapeutically effective amount of the formulation of any one of claims 1 to 24.

26. A device comprising a therapeutically effective amount of the formulation of any one of claims 1 to 24.

27. The device of claim 26, wherein the device is selected from the group consisting of a syringe, a syringe driver, and an infusion pump comprising the formulation.

28. The device of claim 27, wherein the syringe is a pre-filled syringe.

29. Use of an effective amount of the formulation of any one of claims 1 to 8 or 13 to 19 in the manufacture of a medicament for ~~A method of~~ treating a disease or condition characterized by presence or activity of $CD38^+$ cells~~, comprising administering to~~ in a subject ~~in need thereof an effective amount of the formulation of any one of claims 1 to 8 or 13 to 19~~, wherein the formulation is to be administered subcutaneously.

30. The ~~method~~ use of claim 29, wherein the disease or condition characterized by the presence or activity of $CD38^+$ cells is a $CD38^+$ hematological malignancy.

31. The ~~method~~ use of claim 29, wherein the disease or condition characterized by the presence or activity of $CD38^+$ cells is an autoimmune or inflammatory disease or condition.

32. Use of an effective amount of the formulation of any one of claims 1 to 8 or 13 to 19 in the manufacture of a medicament for ~~A method of~~ treating a $CD38^+$ hematological malignancy~~, comprising administering to~~ in a subject ~~in need thereof an effective amount of the formulation of any one of claims 1 to 8 or 13 to 19~~, wherein the formulation is to be administered subcutaneously.

33. The ~~method~~ use of claim 32, wherein the formulation comprises 140 mg/mL of an anti-CD38 antibody, wherein

the anti-CD38 antibody comprises a variable heavy region (VH) comprising three complementarity determining regions (CDRs) CDR-H1, CDR-H2, and CDR-H3 comprising the amino acid sequences set forth in SEQ ID NOs: 1-3, respectively, and a variable light region (VL) comprising three CDRs CDR-L1, CDR-L2, and CDR-L3 comprising the amino acid sequences set forth in SEQ ID NOs: 4-6, respectively,

the formulation comprises 9 mM histidine, 110 mM Arg-Cl, 2% (w/v) sucrose, and 0.4% (w/v) Poloxamer 188, and wherein

the formulation has a pH of 6.2 or 6.3, and a viscosity of at most 14 mPa·s at 20°C.

34. The ~~method~~ use of claim 32 or 33, wherein the formulation is to be administered by subcutaneous infusion.

35. The ~~method~~ use of claim 34, wherein the subcutaneous infusion is a large-volume subcutaneous infusion.

36. The ~~method~~ use of claim 34, wherein the subject is a human and the large-volume subcutaneous infusion is 5 to 10 mL.

37. The ~~method~~ use of any one of claims 32 to 34, wherein the $CD38^+$ hematological malignancy is multiple myeloma.

38. The ~~method~~ use of claim 37, wherein multiple myeloma is relapsed/refractory multiple myeloma.

39. The ~~method~~ use of claim 37 or 38, ~~further comprising administering to the subject~~ wherein one or more agents selected from the group consisting of a corticosteroid, a proteasome inhibitor, an immunomodulatory drug, a chemotherapy drug, and combinations thereof, is to be administered to the subject.

40. The ~~method~~ use of claim 39, wherein the chemotherapy drug is selected from the group consisting of cytarabine, daunorubicin, daunomycin, doxorubicin, liposomal doxorubicin, idarubicin, mitoxantrone, gemtuzumab, clofarabine, cladribine, hydroxyurea, etoposide, ~~,~~melphalan, cyclophosphamide, vincristine, and combinations thereof.

41. The ~~method~~ use of claim 39, wherein the proteasome inhibitor is selected from the group consisting of carfilzomib, bortezomib, and a combination thereof.

42. The ~~method~~ use of claim 39, wherein the immunomodulatory drug is selected from the group consisting of thalidomide, lenalidomide, pomalidomide, and combinations thereof.

43. The ~~method~~ use of claim 39, wherein the corticosteroid is dexamethasone.