CLAIMS

1. A formulation comprising 125-155 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 arginine (Arg), sucrose, histidine, and a Poloxamer 188 or Polysorbate 80, 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, 90-125 mM Arg, or 110 mM Arg.

3. The formulation of claim 1 or 2, wherein the surfactant is 0.4% (w/v) Poloxamer 188 or 0.04% (w/v) Polysorbate 80.

4. The formulation of any one of claims 1-3, wherein the buffering agent is 9 mM histidine.

5. The formulation of any one of claims 1-4, wherein the stabilizer is 2% (w/v) sucrose.

6. The formulation of any one of claims 1-5, wherein the pH is 6.2-6.3.

7. A formulation comprising 125-155 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 histidine, arginine (Arg), sucrose, and 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℃.

8. The formulation of claim 7, wherein the formulation comprises 9 mM histidine, 90-150 mM Arg, 2% (w/v) sucrose, and 0.5 (w/v) Poloxamer 188.

9. The formulation of any one of claims 1-8, wherein the formulation is suitable for subcutaneous administration or large-volume subcutaneous administration.

10 The formulation of any one of claims 1-9, 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.

11. The formulation of any one of claims 1-10, wherein the anti-CD38 antibody comprises a heavy chain comprising an amino acid sequence set forth in SEQ ID NO: 9, and a light chain comprising the amino acid sequence set forth in SEQ ID NO: 10.

12. The formulation of any one of claims 1-11, wherein the anti-CD38 antibody is isatuximab.

13. The formulation of any one of claims 1-12, wherein the formulation is free of hyaluronidase.

14. A packaged pharmaceutical product comprising a sterile container or a device comprising a therapeutically effective amount of the formulation of any one of claims 1 to 13.

15. The package of claim 14, wherein the sterile container or a device comprises an infusion volume of 10 mL to 12 mL.

16. The device of claim 14 or 15, wherein the device is selected from the group consisting of a syringe, a syringe driver, a pre-filled syringe, and an infusion pump comprising the formulation.

17. Use of a pharmaceutical composition comprising the formulation of any one of claims 1-16 for the manufacture of a medicament for the treatment in a subject of a $CD38^+$ hematological malignancy, a CD38+ autoimmune or inflammatory disease or condition.

18. The use of claim 17, wherein the $CD38^+$ hematological malignancy is multiple myeloma.

19. The use of claim 18, wherein multiple myeloma is relapsed/refractory multiple myeloma.

20. The use of any one of claims 17 to 19, further comprising the subject to be administered one or more agents selected from the group consisting of a corticosteroid, a proteasome inhibitor, an immunomodulatory drug, a chemotherapy drug, and combinations thereof.