stability than the individual antibody formulations. The formulations can be lyophilized for reconstitution or in liquid form.

In one aspect, the present disclosure provides a formulation comprising an anti-LAG3 antibody at a concentration of 10-250 mg/ml and comprises a variable light chain region comprising CDRL1 of SEQ ID NO: 39, CDRL2 of SEQ ID NO: 40, CDRL3 of SEQ ID NO: 41 and a variable heavy chain region comprising CDRH1 of SEQ ID NO: 42, CDRH2 of SEQ ID NO: 59, CDRH3 of SEQ ID NO: 44; one or more of an excipient selected from the group consisting of histidine, aspartate, glutamine, glycine, proline, methionine, arginine or pharmaceutically acceptable salt thereof, and NaCl at a total concentration of 40-250 mM; and 5-30 mM of a histidine, acetate or citrate buffer at pH 5.0-6.5.

In another aspect, the present disclosure provides a formulation comprising 20-30 mg/mL of an anti-LAG3 antibody; 50-90 mg/mL sucrose or trehalose; 0.05-1.0 mg/mL polysorbate 80 or 20; 5-30 mM L-histidine, acetate or citrate buffer at pH 5.3 - 6.4; and 40-150 mM L-arginine or a pharmaceutically acceptable salt thereof; wherein the anti-LAG3 antibody comprises a light chain sequence of SEQ ID NO: 35 and a heavy chain sequence of SEQ ID NO: 57.

In another aspect, the present disclosure provides a formulation comprising 20-30 mg/mL of an anti-LAG3 antibody; 20-50 mg/mL glycerol, sorbitol or PEG400; 0.05-1.0 mg/mL polysorbate 80 or 20; 5-30 mM L-histidine, acetate or citrate buffer at pH 5.3 – 6.4; and 40-150 mM L-arginine or a pharmaceutically acceptable salt thereof; wherein the anti-LAG3 antibody comprises a light chain sequence of SEQ ID NO: 35 and a heavy chain sequence of SEQ ID NO: 57.

In another aspect, the present disclosure provides a formulation comprising 20-30 mg/mL of an anti-LAG3 antibody; 20-50 mM L-glutamine, L-glycine, L-proline or L-methionine; 0.05-1.0 mg/mL polysorbate 80 or 20; 5-30 mM L-histidine, acetate or citrate buffer at pH 5.3 – 6.4; and 40-150 mM L-arginine or a pharmaceutically acceptable salt thereof ; wherein the anti-LAG3 antibody comprises a light chain sequence of SEQ ID NO: 35 and a heavy chain sequence of SEQ ID NO: 57.

In another aspect, the present disclosure provides a formulation comprising 20-30 mg/mL of an anti-LAG3 antibody; 0.05-1.0 mg/mL polysorbate 80 or 20; 5-30 mM L-histidine, acetate or citrate buffer at pH 5.3 - 6.4; and 40-150 mM NaCl; wherein the anti-LAG3 antibody comprises a light chain sequence of SEQ ID NO: 35 and a heavy chain sequence of SEQ ID NO: 57.

The present disclosure also provides a method of treating cancer or infection, comprising administering the reconstituted or liquid formulation (solution formulation) to a subject in need thereof. In further examples the formulation is used in treating chronic

CLAIMS

WHAT IS CLAIMED IS:

1. A formulation comprising an anti-LAG3 antibody at a concentration of 10-250 mg/ml and comprises a variable light chain region comprising CDRL1 of SEQ ID NO: 39, CDRL2 of SEQ ID NO: 40, CDRL3 of SEQ ID NO: 41 and a variable heavy chain region comprising CDRH1 of SEQ ID NO: 42, CDRH2 of SEQ ID NO: 59, CDRH3 of SEQ ID NO: 44; one or more of an excipient selected from the group consisting of histidine, aspartate, glutamine, glycine, proline, methionine, arginine or pharmaceutically acceptable salt thereof, and NaCl at a total concentration of 40-250 mM; and 5-30 mM of a histidine, acetate or citrate buffer at pH 5.0-6.5.

2. The formulation of claim 1, wherein the excipient is L-arginine or a pharmaceutically acceptable salt thereof at a concentration of 40-250 mM, or wherein the excipients are NaCl and L-arginine or a pharmaceutically acceptable salt thereof with total concentration of 40-250 mM, or wherein the excipient is L-histidine, L-aspartate, L-glutamine, or L-glycine at 40-250 mM.

3. The formulation of claim 1, wherein the excipient is L-arginine or a pharmaceutically acceptable salt thereof at a concentration of 40-150 mM.

4. The formulation of claim 1, wherein the excipient is a combination of NaCl and L-arginine or a pharmaceutically acceptable salt thereof with a total concentration of 70-100 mM.

5. The formulation of claim 1, wherein the excipient is NaCl at 40-150 mM.

6. The formulation of claim 1, wherein the excipient is L-histidine at 40-100 mM.

7. The formulation of any one of claims 1-4 further comprising a non-reducing disaccharide or polyol, or a non-ionic surfactant, or a combination thereof.

8. The formulation of claim 7, wherein the non-reducing disaccharide is trehalose or sucrose, or a combination thereof.

9. The formulation of claim 7, wherein the polyol is selected from the group consisting of mannitol, sorbitol, glycerol and polyethylene glycol.

10. The formulation of any one of claims 7 to 9, wherein the non-reducing disaccharide or polyol is at a concentration of 10-200 mg/ml.

11. The formulation of claim 7, wherein the non-ionic surfactant is a polysorbate.

12. The formulation of any one of claims 1 to 6, further comprising a surfactant selected from polysorbate 20 and polysorbate 80, and a sugar selected from sucrose and trehalose, or a combination thereof.

13. The formulation of any one of claims 1 to 6 further comprising 10-250 mg/mL sucrose, trehalose, mannitol, sorbitol, polyethylene glycol or glycerol; 0.005-2.0 mg/mL polysorbate 80 or 20.

14. The formulation of any one of claims 1 to 6 further comprising 30-120 mg/mL sucrose or trehalose; 0.05-1.5 mg/mL polysorbate 80 or 20; and wherein the buffer is 5-30 mM L-histidine, acetate or citrate buffer at pH 5.0 -6.5.

15. The formulation of any one of claims 1 to 6, further comprising 50-90 mg/mL sucrose or trehalose; 0.05-1.0 mg/mL polysorbate 80; and wherein the buffer is 5-30 mM L-histidine, acetate or citrate buffer at pH 5.0 -6.5.

16. The formulation of claim 1 comprising 20-220 mg/mL of the anti-LAG3 antibody; 50-90 mg/mL sucrose or trehalose; 0.05-1.0 mg/mL polysorbate 80 or 20; 5-20 mM L-histidine, acetate or citrate buffer at pH 5.0 - 6.5; and 40-150 mM L-arginine or a pharmaceutically acceptable salt thereof.

17. The formulation of claim 1 comprising 20-220 mg/mL of the anti-LAG3 antibody; 20-200 mg/mL glycerol, sorbitol or PEG400; 0.05-1.0 mg/mL polysorbate 80 or 20; 5-30 mM L-histidine, acetate or citrate buffer at pH 5.0 - 6.5; and 40-150 mM L-arginine or a pharmaceutically acceptable salt thereof.

18. The formulation of claim 1 comprising 20-220 mg/mL of the anti-LAG3 antibody; 20-150 mM L-glutamine, L-glycine, L-proline or L-methionine; 0.05-1.0 mg/mL polysorbate 80 or 20; 5-30 mM L-histidine, acetate or citrate buffer at pH 5.0 - 6.5; and 40-150 mM L-arginine or a pharmaceutically acceptable salt thereof.

19. The formulation of claim 1 comprising 20-220 mg/mL of the anti-LAG3 antibody; 0.05-1.0 mg/mL polysorbate 80 or 20; 5-30 mM L-histidine, acetate or citrate buffer at pH 5.0 - 6.5; and 40-150 mM NaCl.

20. The formulation of claim 1, comprising 25 mg/mL of the anti-LAG3 antibody; 50 mg/mL sucrose; 0.2 mg/mL polysorbate 80; 10 mM L-histidine buffer at pH 5.8; 70 mM L-arginine or a pharmaceutically acceptable salt thereof; and 10 mM L-methionine, or comprising 25 mg/mL of the anti-LAG3 antibody; 50 mg/mL sucrose; 0.2 mg/mL polysorbate 80; 10 mM L-histidine buffer at pH 5.8-6.0; and 70 mM L-arginine or L-arginine-HCl.

21. The formulation of any one of claims 1-20 that is a liquid formulation.

22. The formulation of any one of claims 1-20 that is a reconstituted solution from a lyophilized formulation.

23. The formulation of any one of claims 1-22, wherein the anti-LAG3 antibody comprises: a light chain variable region sequence of SEQ ID NO: 37 and a heavy chain variable region sequence of SEQ ID NO: 58.

24. The formulation of any one of claims 1-23, wherein the anti-LAG3 antibody comprises a light chain sequence of SEQ ID NO: 35 and a heavy chain sequence of SEQ ID NO: 57.

25. The formulation of any one of claims 1-24, further comprising an anti-PD-1 antibody that comprises a variable light chain region comprising CDRL1 of SEQ ID NO: 1, CDRL2 of SEQ ID NO: 2, and CDRL3 of SEQ ID NO: 3, and a variable heavy chain region comprising CDRH1 of SEQ ID NO: 6, CDRH2 of SEQ ID NO: 7, and CDRH3 of SEQ ID NO: 8.

26. The formulation of claim 25, wherein the anti-PD-1 antibody comprises a heavy chain variable region of SEQ ID NO: 9 and a light chain variable region of SEQ ID NO: 4.

27. The formulation of claim 25, wherein the anti-PD-1 antibody comprises a heavy chain sequence of SEQ ID NO: 10 and a light chain sequence of SEQ ID NO: 5.

28. The formulation of claim 27, wherein the molar ratio of anti-LAG3 antibody and anti-PD-1 antibody is 1:1, 2:1, 3:1 or 3.5:1.

29. The formulation of claim 27, comprising 10-120 mg/mL of the anti-LAG3 antibody and 10-120 mg/mL of the anti-PD-1 antibody.

30. The formulation of claim 25 comprising 10-120 mg/mL of an anti-LAG3 antibody; 10-120 mg/mL of an anti-PD-1 antibody; 30-120 mg/mL of a non-reducing disaccharide; 0.05-2.0 mg/mL polysorbate 80 or 20; 5-30 mM histidine or acetate buffer at pH 5.0 - 6.5; and 40-150 mM L-arginine or a pharmaceutically acceptable salt thereof; wherein the anti-LAG3 antibody comprises a light chain sequence of SEQ ID NO: 35 and a heavy chain sequence of SEQ ID NO: 57, and the anti-PD-1 antibody comprises a heavy chain sequence of SEQ ID NO: 10 and a light chain sequence of SEQ ID NO: 5.

31. The formulation of claim 27 comprising 20-30 mg/mL of the anti-LAG3 antibody; 20-30 mg/mL of the anti-PD-1 antibody; 50-90 mg/mL sucrose or trehalose; 0.05-1.0 mg/mL polysorbate 80 or 20; 5-30 mM histidine buffer at pH 5.0 - 6.5; and 40-100 mM L-arginine or a pharmaceutically acceptable salt thereof.

32. The formulation of any one of claims 1-31, further comprising 3-100 mM L-methionine.

33. The formulation of any one of claims 1-31, further comprising 5-15 mM L-methionine.

34. The formulation of any one of claims 1-33, wherein at 5 °C, the % monomer of the anti-LAG3 antibody is ≥ 95% after 3 months as measured by size exclusion chromatography.

35. The formulation of any one of claims 1-34, wherein at 5 °C, the % acidic variant of the anti-LAG3 antibody is less than 15% after 3 months as measured by ion exchange chromatography.

36. A formulation comprising 20-30 mg/mL of an anti-LAG3 antibody; 50-90 mg/mL sucrose or trehalose; 0.05-1.0 mg/mL polysorbate 80 or 20; 5-30 mM L-histidine, acetate or citrate buffer at pH 5.3 - 6.4; and 40-150 mM L-arginine or a pharmaceutically acceptable salt thereof; wherein the anti-LAG3 antibody comprises a light chain sequence of SEQ ID NO: 35 and a heavy chain sequence of SEQ ID NO: 57.

37. A formulation comprising 20-30 mg/mL of an anti-LAG3 antibody; 20-50 mg/mL glycerol, sorbitol or PEG400; 0.05-1.0 mg/mL polysorbate 80 or 20; 5-30 mM L-histidine, acetate or citrate buffer at pH 5.3 - 6.4; and 40-150 mM L-arginine or a pharmaceutically acceptable salt thereof; wherein the anti-LAG3 antibody comprises a light chain sequence of SEQ ID NO: 35 and a heavy chain sequence of SEQ ID NO: 57.

38. A formulation comprising 20-30 mg/mL of an anti-LAG3 antibody; 20-50 mM L-glutamine, L-glycine, L-proline or L-methionine; 0.05-1.0 mg/mL polysorbate 80 or 20; 5-30 mM L-histidine, acetate or citrate buffer at pH 5.3 - 6.4; and 40-150 mM L-arginine or a pharmaceutically acceptable salt thereof ; wherein the anti-LAG3 antibody comprises a light chain sequence of SEQ ID NO: 35 and a heavy chain sequence of SEQ ID NO: 57.

39. A formulation comprising 20-30 mg/mL of an anti-LAG3 antibody; 0.05-1.0 mg/mL polysorbate 80 or 20; 5-30 mM L-histidine, acetate or citrate buffer at pH 5.3 - 6.4; and 40-150 mM NaCl; wherein the anti-LAG3 antibody comprises a light chain sequence of SEQ ID NO: 35 and a heavy chain sequence of SEQ ID NO: 57.