

CLAIMS

WHAT IS CLAIMED IS:

1. A formulation comprising: about 5-300 mg/mL of an anti-LAG3
5 antibody or antigen-binding fragment thereof, one or more of an excipient selected from the group consisting of histidine, aspartate, glutamine, glycine, proline, methionine, arginine or pharmaceutically acceptable salt thereof, NaCl, KCl, LiCl, CaCl₂, MgCl₂, ZnCl₂, and FeCl₂, at a total concentration of 10-1000 mM, and a buffer at pH about 5-8.
2. The formulation of claim 1 that comprises the anti-LAG3 antibody or
10 antigen-binding fragment thereof 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,
15 arginine or pharmaceutically acceptable salt thereof, NaCl, KCl, LiCl at a total concentration of 15-300 mM, and a buffer at pH about 5.0-6.5.
3. The formulation of claim 1 or 2, wherein the excipient is L-arginine or a pharmaceutically acceptable salt thereof at a concentration of 15-250 mM.
4. The formulation of claim 1 or 2, wherein the excipient is
20 L-arginine or pharmaceutically acceptable salt thereof at a concentration of 40-100 mM.
5. The formulation of claim 1 or 2, wherein the excipients are NaCl and L-arginine or a pharmaceutically acceptable salt thereof with total concentration of 20-250 mM.
6. The formulation of claim 1 or 2, wherein the excipient is NaCl, KCl or
25 LiCl at about 40-150 mM.
7. The formulation of claim 1 or 2, wherein the excipient is L-histidine, L-aspartate, L-glutamine, or L-glycine at about 15-200 mM.
8. The formulation of claim 1 or 2, wherein the excipient is L-histidine at about 40-100 mM.
- 30 9. The formulation of any one of claims 1 to 8 wherein the buffer is a histidine buffer, an acetate buffer or a citrate buffer.
10. The formulation of claim 9 wherein the buffer has a concentration of about 1-300 mM.

antigen binding fragment comprises: a light chain variable region sequence of SEQ ID NO: 37 and a heavy chain variable region sequence of SEQ ID NO: 58, and the anti-PD-1 antibody or antigen binding fragment thereof comprises a heavy chain variable region of SEQ ID NO: 9 and a light chain variable region of SEQ ID NO: 4.

5 45. The formulation of claim 43, 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.

10 46. The formulation of any one of claims 43-45 comprising about 10-120 mg/mL of the anti-LAG3 antibody; about 10-120 mg/mL of the anti-PD-1 antibody; about 30-120 mg/mL of a non-reducing disaccharide; about 0.05-2.0 mg/mL polysorbate 80 or 20; a buffer at pH about 5.0 - 6.5; and about 40-150 mM L-arginine or a pharmaceutically acceptable salt thereof.

15 47. The formulation of any one of claims 43-45 comprising about 10-30 mg/mL of the anti-LAG3 antibody; about 10-30 mg/mL of the anti-PD-1 antibody; about 50-90 mg/mL sucrose or trehalose; about 0.05-1.0 mg/mL polysorbate 80 or 20; about 3-30 mM histidine buffer at pH about 5.0 - 6.5; and about 40-100 mM L-arginine or a pharmaceutically acceptable salt thereof.

20 48. The formulation of any one of claims 43-47, further comprising about 3-100 mM L-methionine.

 49. The formulation of any one of claims 43-47, further comprising about 5-15 mM L-methionine.

25 50. The formulation of any one of claims 43-45 comprising about 10 mg/mL of the anti-LAG3 antibody; about 10 mg/mL of the anti-PD-1 antibody; about 50 mg/mL sucrose; about 0.2 mg/mL polysorbate 80; about 10 mM histidine buffer at pH about 5.8; about 70 mM L-arginine or a pharmaceutically acceptable salt thereof; and about 10 mM L-methionine.

30 51. The formulation of any one of claims 43-45 comprising about 10-30 mg/mL of the anti-LAG3 antibody; about 10-30 mg/mL of the anti-PD-1 antibody; about 50 mg/mL sucrose; about 0.2 mg/mL polysorbate 80; about 10 mM histidine buffer at pH about 5.8; about 70 mM L-arginine or a pharmaceutically acceptable salt thereof; and about 10 mM L-methionine.

 52. The formulation of any one of claims 43-51, wherein at 5 °C, the %

monomer of the anti-LAG3 antibody is $\geq 95\%$ after 3 months as measured by size exclusion chromatography.

53. The formulation of any one of claims 43-52, wherein at 5 °C, the % acidic variant of the anti-LAG3 antibody is less than 15% after 3 months as measured by ion
- 5 exchange chromatography.
54. A vessel or injection device comprising the formulation of any one of claims 1-53.