

Table 16: % Peak Area of Basic Variants

	40	34.5		32.5	23.4
	-60			34.4	-
	RT/RL		34.8	33.2	-
F5.5N	25	34.3		34.0	33.2
	40			32.5	20.5
	-60			34.4	-
F5.75	25	34.2		33.8	32.6
	40			31.6	21.2
	-60			34.9	-
F6.0	25	34.2		34.2	32.1
	40			30.2	19.4
	-60			35.0	-
F6.25	25	34.6		33.3	31.8
	40			29.0	17.9
	-60			34.5	-

Overall stability profile

[0224] There was not much change in appearance, pH, protein concentration, purity, charge and size variant distribution for the drug product between pH 4.80 to 6.25 during 3-month exposure at -60 °C and 25 °C, indicating that the product is relatively stable under the current specification of pH 5.5±0.5 and at intended storage temperature of 2-8 °C. High temperature exposure at 40 °C did not significantly change appearance, pH, protein concentration, and purity, but provided a strong signal of formation of size and charge-related degradants in the formulations at the stressed condition. The signal of size and charge-related change can be used to establish an overall pH stability profile and to select an optimal formulation pH value. ~~Error! Reference source not found.~~ **FIG. 1** shows the percent degradants of these two major groups in the samples with different pH values at 40°C. From the figure, an X-shaped profile is

identified with the curves intersecting at ~pH 5.5. The profile curves clearly show that the size-related degradants (HMWs and LMWs) increased with decreasing pH whereas charge-related degradants (iCIEF acidic species) increased with increasing pH. The pH value of ~5.5 is the cross point and will minimize the possibility for the drug product to be out of specifications established either by iCIEF or SEC.

[0225] At lower temperature of 25°C, the differences were not as strong between pH values for these two types of degradants although there appears a similar trend as that at 40°C (**FIG. 2**). As no or very little degradation occurred over 3 months at 25°C, significantly longer period of exposure at 25°C is likely required to show the similar pH-stability profile observed at 40°C.

[0226] Furthermore, varying the concentration of anti-LAG-3 antibody (4 mg/ml versus 12 mg/ml) did not change the percentage of acidic charge variants during storage at 5°C, 25°C, or 40°C for 1-6 months (**FIGs. 3A and 3B**).

Light impact on drug product stability

[0227] The effect of room temperature/room lighting (RT/RL) is shown in ~~Error! Reference source not found.~~ **FIG. 4**. There is essentially no difference between light-exposed and light-protected samples in appearance, pH, protein concentration, purity, HMWs and LMWs for the exposure period (up to 1 month). The particulate count for both samples is also very low and all within the limits established by USP. There is no increase of iCIEF acidic peak area after 2-week exposure to room light, and a very slight increase (~2%) is shown at 1-month time point. This increase could be due to either analytical method variation or a real trend of light-induced reaction. However, there should be no significant impact on the drug product quality as the change in acidic species is relatively minor (<3%). Based on the above comparison between light-exposed and light-protected samples, it is concluded that there will be sufficient stability for the drug product under room light for up to 4 weeks.

Impact of DTPA on drug product stability

[0228] The effect of DTPA on the DP stability is shown in **FIG. 5**. The appearance, pH, protein concentration, and purity of samples containing DTPA were similar to samples without DTPA following storage for up to 3 months at 40 °C. The particulate counts for all samples were also low and within USP limits. However, there was a more significant difference in HMW and LMW species levels between DTPA and non-DTPA samples with

WHAT IS CLAIMED IS:

1. A pharmaceutical composition comprising:

~~(a)i) from about 1 mg/ml to about 300 mg/ml of an anti-LAG-3 antibody or antigen binding fragment thereof;~~

~~(ii) from about 5 mM to about 50 mM of a buffering agent;~~

~~(iii) from about 50 mM to about 300 mM of a stabilizing agent or bulking agent; and~~

~~(iv) from about 0.001% to about 1% (w/v) of a surfactant.~~

~~2. The pharmaceutical composition of claim 1, comprising from ____ about 80 mg of to about 240 mg of the an anti-LAG-3 antibody or antigen binding fragment thereof.~~

~~3. The pharmaceutical composition of claim 2, comprising about 80 mg, about 120 mg, about 160 mg, or about 240 mg of the anti-LAG-3 antibody or antigen binding fragment thereof.~~

~~4. The pharmaceutical composition of claim 1, comprising from about 4 mg/ml to about 12 mg/ml of the anti-LAG-3 antibody or antigen binding fragment thereof.~~

~~5. The pharmaceutical composition of claim 4, comprising about 4 mg/ml, about 8 mg/ml, about 10 mg/ml, or about 12 mg/ml of the anti-LAG-3 antibody or antigen binding fragment thereof.~~

~~6. The pharmaceutical composition of any one of claims 1-5, wherein the anti-LAG-3 antibody or antigen binding fragment thereof comprises CDR1, CDR2, and CDR3 domains of the heavy chain variable region having the sequence set forth in SEQ ID NO:3, and CDR1, CDR2, and CDR3 domains of the light chain variable region having the sequence set forth in SEQ ID NO:5;~~

~~7. The pharmaceutical composition of any one of claims 1-5, wherein the anti-LAG-3 antibody or antigen binding fragment thereof comprises (a) a heavy chain variable region CDR1 comprising the sequence set forth in SEQ ID NO:7; (b) a heavy chain variable region CDR2 comprising the sequence set forth in SEQ ID NO:8; (c) a heavy chain variable region CDR3~~

~~comprising the sequence set forth in SEQ ID NO:9; (d) a light chain variable region CDR1 comprising the sequence set forth in SEQ ID NO:10; (e) a light chain variable region CDR2 comprising the sequence set forth in SEQ ID NO:11; and (f) a light chain variable region CDR3 comprising the sequence set forth in SEQ ID NO:12.~~

~~8. The pharmaceutical composition of any one of claims 1-5, wherein the anti-LAG-3 antibody or antigen binding fragment thereof comprises heavy and light chain variable regions comprising the sequences set forth in SEQ ID NOs:3 and 5, respectively.~~

~~9. The pharmaceutical composition of any one of claims 1-5, wherein the anti-LAG-3 antibody or antigen binding fragment thereof comprises heavy and light chains comprising the sequences set forth in SEQ ID NOs:1 and 2, respectively.~~

~~10. The pharmaceutical composition of any one of claims 1-5, wherein the anti-LAG-3 antibody is BMS-986016, IMP731 (H5L7BW), MK-4280 (28G-10), REGN3767, GSK2831781, humanized BAP050, IMP-701 (LAG-5250), or FS-118.~~

~~11. The pharmaceutical composition of any one of claims 1-10, wherein the buffering agent is histidine, Tris-Cl, citrate, Tris-citrate, phosphate, or any combination thereof.~~

~~12. The pharmaceutical composition of any one of claims 1-11, comprising about 10 mM or about 20 mM of the buffering agent.~~

~~13. The pharmaceutical composition of any one of claims 1-12, wherein the stabilizing agent is sucrose, trehalose, raffinose, arginine, or any combination thereof.~~

~~14. The pharmaceutical composition of any one of claims 1-12, wherein the bulking agent is sodium chloride, mannitol, glycine, alanine, or any combination thereof.~~

~~15. The pharmaceutical composition of any one of claims 1-14, comprising about 150 mM or about 250 mM of the stabilizing agent or bulking agent.~~

~~16. The pharmaceutical composition of any one of claims 1-15, wherein the surfactant is polysorbate-80 (PS80), polysorbate-20 (PS20), poloxamer-188 (PX188), or any combination thereof.~~

17. ~~The pharmaceutical composition of any one of claims 1-16, comprising from about 0.05% to about 1% of the surfactant.~~

18. ~~The pharmaceutical composition of any one of claims 1-17, further comprising (v) from about 5 μ M to about 1 mM of a chelating agent.~~

19. ~~The pharmaceutical composition of claim 18, wherein the chelating agent is diethylenetriaminepentaacetic acid (DTPA), ethylenediaminetetraacetic acid (EDTA), nitrilotriacetic acid, or any combination thereof.~~

20. ~~The pharmaceutical composition of claim 18 or 19, comprising about 20 μ M of the chelating agent.~~

21. ~~A pharmaceutical composition comprising:~~

(i) ~~from about 1 mg/ml to about 100 mg/ml of an anti-LAG-3 antibody or antigen binding fragment thereof;~~

(ii) ~~from about 5 mM to about 50 mM of citrate;~~

(iii) ~~from about 50 mM to about 300 mM of sodium chloride; and~~

(iv) ~~from about 0.001% to about 1% (w/v) of polysorbate or poloxamer.~~

22. ~~A pharmaceutical composition comprising:~~

(i) ~~about 11 mg/ml of an anti-LAG-3 antibody or antigen binding fragment thereof;~~

(ii) ~~about 10 mM of sodium citrate and about 10 mM sodium phosphate;~~

(iii) ~~about 150 mM of sodium chloride; and~~

(iv) ~~about 0.05% (w/v) of polysorbate 80.~~

23. ~~A pharmaceutical composition comprising:~~

(i) ~~from about 1 mg/ml to about 100 mg/ml of an anti-LAG-3 antibody or antigen binding fragment thereof;~~

(ii) ~~from about 5 mM to about 50 mM of histidine;~~

(iii) ~~from about 50 mM to about 300 mM of sucrose; and~~

(iv) ~~from about 0.001% to about 1% (w/v) of polysorbate or poloxamer.~~

~~24. A pharmaceutical composition comprising:~~

(i) ~~about 10 mg/ml of an anti-LAG-3 antibody or antigen binding fragment thereof;~~

(ii) ~~about 20 mM of histidine;~~

(iii) ~~about 250 mM of sucrose; and~~

(iv) ~~about 0.05% (w/v) of polysorbate 80.~~

~~25. A pharmaceutical composition comprising:~~

(i) ~~from about 1 mg/ml to about 100 mg/ml of an anti-LAG-3 antibody or antigen binding fragment thereof;~~

(ii) ~~from about 5 mM to about 50 mM of histidine;~~

(iii) ~~from about 50 mM to about 300 mM of sucrose;~~

(iv) ~~from about 5 μ M to about 1 mM of one or more chelating agents; and~~

(v) ~~from about 0.001% to about 1% (w/v) of polysorbate or poloxamer.~~

~~26. A pharmaceutical composition comprising:~~

(i) ~~about 10 mg/ml of an anti-LAG-3 antibody or antigen binding fragment thereof;~~

(ii) ~~about 20 mM of histidine;~~

(iii) ~~about 250 mM of sucrose;~~

(iv) ~~about 20 μ M to about 50 μ M of DTPA or EDTA; and~~

(v) ~~about 0.05% (w/v) of polysorbate 80.~~

~~27. A pharmaceutical composition comprising:~~

- (i) ~~11 mg/ml of an anti-LAG-3 antibody or antigen binding fragment thereof;~~
- (ii) ~~10 mM of sodium citrate and 10 mM sodium phosphate;~~
- (iii) ~~150 mM of sodium chloride; and~~
- (iv) ~~0.05% (w/v) of polysorbate 80.~~

28. ~~A pharmaceutical composition comprising:~~

- (i) ~~110 mg of an anti-LAG-3 antibody or antigen binding fragment thereof;~~
- (ii) ~~10 mM of sodium citrate and 10 mM sodium phosphate;~~
- (iii) ~~150 mM of sodium chloride; and~~
- (iv) ~~0.05% (w/v) of polysorbate 80.~~

29. ~~A pharmaceutical composition comprising:~~

- (i) ~~10 mg/ml of an anti-LAG-3 antibody or antigen binding fragment thereof;~~
- (ii) ~~20 mM of histidine;~~
- (iii) ~~250 mM of sucrose; and~~
- (iv) ~~0.05% (w/v) of polysorbate 80.~~

30. ~~A pharmaceutical composition comprising:~~

- (i) ~~100 mg of an anti-LAG-3 antibody or antigen binding fragment thereof;~~
- (ii) ~~20 mM of histidine;~~
- (iii) ~~250 mM of sucrose; and~~
- (iv) ~~0.05% (w/v) of polysorbate 80.~~

31. ~~A pharmaceutical composition comprising:~~

- (i) ~~80 mg of an anti-LAG-3 antibody or antigen binding fragment thereof;~~

- ~~(ii) — 20 mM of histidine;~~
- ~~(iii) — 250 mM of sucrose; and~~
- ~~(iv) — 0.05% (w/v) of polysorbate 80.~~

~~32. — A pharmaceutical composition comprising:~~

- ~~(i) — 10 mg/ml of an anti LAG-3 antibody or antigen binding fragment thereof;~~
- ~~(ii) — 20 mM of histidine;~~
- ~~(iii) — 250 mM of sucrose;~~
- ~~(iv) — from 20 μ M to 50 μ M of DTPA or EDTA; and~~
- ~~(v) — 0.05% (w/v) of polysorbate 80.~~

~~33. — A pharmaceutical composition comprising:~~

- ~~(i) — 100 mg of an anti LAG-3 antibody or antigen binding fragment thereof;~~
- ~~(ii) — 20 mM of histidine;~~
- ~~(iii) — 250 mM of sucrose;~~
- ~~(iv) — from 20 μ M to 50 μ M of DTPA or EDTA; and~~
- ~~(v) — 0.05% (w/v) of polysorbate 80.~~

~~34. — A pharmaceutical composition comprising:~~

- ~~(i) — 80 mg of an anti LAG-3 antibody or antigen binding fragment thereof;~~
- ~~(ii) — 20 mM of histidine;~~
- ~~(iii) — 250 mM of sucrose;~~
- ~~(iv) — from 20 μ M to 50 μ M of DTPA or EDTA; and~~
- ~~(v) — 0.05% (w/v) of polysorbate 80.~~

35. — ~~The pharmaceutical composition of any one of claims 1-34, wherein the pH of the composition is from about 5 to about 6.~~

36. — ~~The pharmaceutical composition of claim 35, wherein the pH is about 5.5 or about 5.6.~~

37. — ~~A pharmaceutical composition comprising:~~

(i) — ~~from about 1 mg/ml to about 100 mg/ml of an anti-LAG-3 antibody or antigen binding fragment thereof;~~

(ii) — ~~from about 1 mg/ml to about 100 mg/ml of an anti-PD-1 antibody, or an anti-PD-L1 antibody, or antigen binding fragments thereof;~~

(iii) — ~~from about 5 mM to about 50 mM of a buffering agent;~~

(iv) — ~~from about 50 mM to about 300 mM of a stabilizing agent;~~

(v) — ~~from about 5 μ M to about 1 mM of a chelating agent; and~~

(vi) — ~~from about 0.001% to about 1% (w/v) of a surfactant.~~

38. — ~~The pharmaceutical composition of claim 37, comprising from about 4 mg/ml to about 12 mg/ml of the anti-LAG-3 antibody or antigen binding fragment thereof. —~~

39. — ~~The pharmaceutical composition of claim 38, comprising about 4 mg/ml, about 8 mg/ml, about 10 mg/ml, or about 12 mg/ml of the anti-LAG-3 antibody or antigen binding fragment thereof.~~

40. — ~~The pharmaceutical composition of claim 37, comprising from about 80 mg to about 240 mg of the anti-LAG-3 antibody or antigen binding fragment thereof.~~

41. — ~~The pharmaceutical composition of claim 40, comprising about 80 mg, about 120 mg, about 160 mg, or about 240 mg of the anti-LAG-3 antibody or antigen binding fragment thereof.~~

42. — ~~The pharmaceutical composition of any one of claims 37-41, wherein the anti-LAG-3 antibody or antigen binding fragment thereof comprises CDR1, CDR2, and CDR3 domains of the heavy chain variable region having the sequence set forth in SEQ ID NO:3, and CDR1,~~

~~CDR2, and CDR3 domains of the light chain variable region having the sequence set forth in SEQ ID NO:5.~~

~~43. The pharmaceutical composition of any one of claims 37-41, wherein the anti LAG-3 antibody or antigen binding fragment thereof comprises (a) a heavy chain variable region CDR1 comprising the sequence set forth in SEQ ID NO:7; (b) a heavy chain variable region CDR2 comprising the sequence set forth in SEQ ID NO:8; (c) a heavy chain variable region CDR3 comprising the sequence set forth in SEQ ID NO:9; (d) a light chain variable region CDR1 comprising the sequence set forth in SEQ ID NO:10; (e) a light chain variable region CDR2 comprising the sequence set forth in SEQ ID NO:11; and (f) a light chain variable region CDR3 comprising the sequence set forth in SEQ ID NO:12.~~

~~44. The pharmaceutical composition of any one of claims 37-41, wherein the anti LAG-3 antibody is BMS 986016, IMP731 (H5L7BW), MK 4280 (28G 10), REGN3767, GSK2831781, humanized BAP050, IMP 701 (LAG 5250), or FS 118.~~

~~45. The pharmaceutical composition of any one of claims 37-41, wherein the anti LAG-3 antibody or antigen binding fragment thereof comprises heavy and light chain variable regions comprising the sequences set forth in SEQ ID NOs:3 and 5, respectively.~~

~~46. The pharmaceutical composition of any one of claims 37-41, wherein the anti LAG-3 antibody or antigen binding fragment thereof comprises heavy and light chains comprising the sequences set forth in SEQ ID NOs:1 and 2, respectively.~~

~~47. The pharmaceutical composition of any one of claims 37-46, comprising from (b) _____ about 240 60 mg to about 300 mg of an the anti-PD-1 antibody, anti-PD-L1 antibody, or antigen binding fragment thereof.~~

~~48. The pharmaceutical composition of any one of claims 37-47, wherein the anti PD-1 antibody, anti PD-L1 antibody, or antigen binding fragment thereof comprises comprising CDR1, CDR2, and CDR3 domains of the heavy chain variable region having the sequence set forth in SEQ ID NO:19, and CDR1, CDR2, and CDR3 domains of the light chain variable region having the sequence set forth in SEQ ID NO:21;.~~

49. — ~~The pharmaceutical composition of any one of claims 37-47, wherein the anti-PD-1 antibody, anti-PD-L1 antibody, or antigen-binding fragment thereof comprises (a) a heavy chain variable region CDR1 comprising the sequence set forth in SEQ ID NO:23; (b) a heavy chain variable region CDR2 comprising the sequence set forth in SEQ ID NO:24; (c) a heavy chain variable region CDR3 comprising the sequence set forth in SEQ ID NO:25; (d) a light chain variable region CDR1 comprising the sequence set forth in SEQ ID NO:26; (e) a light chain variable region CDR2 comprising the sequence set forth in SEQ ID NO:27; and (f) a light chain variable region CDR3 comprising the sequence set forth in SEQ ID NO:28.~~

50. — ~~The pharmaceutical composition of any one of claims 37-47, wherein the anti-PD-1 antibody, anti-PD-L1 antibody, or antigen-binding fragment thereof comprises heavy and light chain variable regions comprising the sequences set forth in SEQ ID NOs:19 and 21, respectively.~~

51. — ~~The pharmaceutical composition of any one of claims 37-47, wherein the anti-PD-1 antibody, anti-PD-L1 antibody, or antigen-binding fragment thereof comprises heavy and light chains comprising the sequences as set forth in SEQ ID NOs:17 and 18, respectively.~~

52. — ~~The pharmaceutical composition of any one of claims 37-47, wherein the anti-PD-1 antibody is pembrolizumab (KEYTRUDA; MK-3475), pidilizumab (CT-011), or nivolumab (OPDIVO; BMS-936558).~~

53. — ~~The pharmaceutical composition of any one claims 37-47, wherein the anti-PD-L1 antibody is atezolizumab (TECENTRIQ; RG7446), durvalumab (IMFINZI; MEDI4736), or BMS-936559.~~

54. — ~~The pharmaceutical composition of any one of claims 37-47, wherein the anti-LAG-3 antibody is BMS-986016 and the anti-PD-1 antibody is nivolumab, the anti-LAG-3 antibody is MK-4280 and the anti-PD-1 antibody is pembrolizumab, the anti-LAG-3 antibody is REGN3767 and the anti-PD-1 antibody is REGN2810, the anti-LAG-3 antibody is LAG525 and the anti-PD-1 is REGN2810, or the anti-LAG-3 antibody is LAG525 and the anti-PD-1 antibody is PDR001.~~

55. — ~~The pharmaceutical composition of any one of claims 37-54, wherein the ratio of the amount of the anti-LAG-3 antibody or antigen binding fragment thereof to the anti-PD-1 antibody, anti-PD-L1 antibody, or antigen binding fragment thereof to the amount of is about 1:3, about 1:2, about 1:1, or about 2:3.~~

56. — ~~The pharmaceutical composition of any one of claims 37-54, comprising about 240 mg of the anti-PD-1 antibody, anti-PD-L1 antibody, or antigen binding fragment thereof and about 80 mg of the anti-LAG-3 antibody or antigen binding fragment thereof.~~

57. — ~~The pharmaceutical composition of any one of claims 37-54, comprising about 240 mg of the anti-PD-1 antibody, anti-PD-L1 antibody, or antigen binding fragment thereof and about 160 mg of the anti-LAG-3 antibody or antigen binding fragment thereof.~~

58. — ~~The pharmaceutical composition of any one of claims 37-54, comprising about 240 mg of the anti-PD-1 antibody, anti-PD-L1 antibody, or antigen binding fragment thereof and about 240 mg of the anti-LAG-3 antibody or antigen binding fragment thereof.~~

59. — ~~The pharmaceutical composition of any one of claims 37-54, comprising about 12 mg/ml of the anti-PD-1 antibody, anti-PD-L1 antibody, or antigen binding fragment thereof and about 4 mg/ml of the anti-LAG-3 antibody or antigen binding fragment thereof.~~

60. — ~~The pharmaceutical composition of any one of claims 37-54, comprising about 12 mg/ml of the anti-PD-1 antibody, anti-PD-L1 antibody, or antigen binding fragment thereof and about 8 mg/ml of the anti-LAG-3 antibody or antigen binding fragment thereof.~~

61. — ~~The pharmaceutical composition of any one of claims 37-54, comprising about 12 mg/ml of the anti-PD-1 antibody, anti-PD-L1 antibody, or antigen binding fragment thereof and about 12 mg/ml of the anti-LAG-3 antibody or antigen binding fragment thereof.~~

62. — ~~The pharmaceutical composition of any one of claims 37-61, wherein the buffering agent is histidine, Tris-Cl, citrate, Tris-citrate, phosphate, or any combination thereof.~~

63. — ~~The pharmaceutical composition of any one of claims 37-62, comprising about 20 mM of the buffering agent.~~

64. — ~~The pharmaceutical composition of any one of claims 37-63, wherein the stabilizing agent is sucrose, trehalose, raffinose, arginine, sodium chloride, or any combination thereof.~~

65. — ~~The pharmaceutical composition of any one of claims 37-64, comprising about 250 mM of the stabilizing agent.~~

66. — ~~The pharmaceutical composition of any one of claims 37-65, wherein the chelating agent is DTPA, EDTA, nitrilotriacetic acid, or any combination thereof.~~

67. — ~~The pharmaceutical composition of any one of claims 37-66, comprising from about 20 μ M to about 50 μ M of the chelating agent.~~

68. — ~~The pharmaceutical composition of any one of claims 37-67, wherein the surfactant is PS80, PS20, PX188, or any combination thereof.~~

69. — ~~The pharmaceutical composition of any one of claims 37-68, comprising about 0.05% (w/v) of the surfactant.~~

70. — ~~A pharmaceutical composition comprising:~~

(i) — ~~from about 1 mg/ml to about 100 mg/ml of an anti-LAG-3 antibody or antigen binding fragment thereof;~~

(ii) — ~~from about 1 mg/ml to about 100 mg/ml of an anti-PD-1 antibody, anti-PD-L1 antibody, or antigen binding fragment thereof;~~

(iii) — ~~from about 5 mM to about 50 mM of histidine;~~

(iv) — ~~from about 50 mM to about 300 mM of sucrose;~~

(v) — ~~from about 5 μ M to about 1 mM of DTPA or EDTA; and~~

(vi) — ~~from about 0.001% to about 1% (w/v) of polysorbate or poloxamer.~~

71. — ~~A pharmaceutical composition comprising:~~

(i) — ~~from about 80 mg to about 240 mg of an anti-LAG-3 antibody or antigen binding fragment thereof;~~

(ii) — ~~from about 60 mg to about 300 mg of an anti-PD-1 antibody, anti-PD-L1 antibody, or antigen binding fragment thereof;~~

- (iii) ~~from about 5 mM to about 50 mM of histidine;~~
- (iv) ~~from about 50 mM to about 300 mM of sucrose;~~
- (v) ~~from about 5 μ M to about 1 mM of DTPA or EDTA; and~~
- (vi) ~~from about 0.001% to about 1% (w/v) of polysorbate or poloxamer.~~

72. ~~A pharmaceutical composition comprising:~~

- (i) ~~about 4 mg/ml, about 8 mg/ml, or about 12 mg/ml of an anti-LAG-3 antibody or antigen-binding fragment thereof;~~
- (ii) ~~about 12 mg/ml of an anti-PD-1 antibody, anti-PD-L1 antibody, or antigen binding fragment thereof;~~
- (iii) ~~about 20 mM of histidine;~~
- (iv) ~~about 250 mM of sucrose;~~
- (v) ~~from about 20 μ M to about 50 μ M of DTPA or EDTA; and~~
- (vi) ~~about 0.05% (w/v) of polysorbate 80.~~

73. ~~A pharmaceutical composition comprising:~~

- (i) ~~about 80 mg, about 160 mg, or about 240 mg of an anti-LAG-3 antibody or antigen-binding fragment thereof;~~
- (ii) ~~about 240 mg of an anti-PD-1 antibody, anti-PD-L1 antibody, or antigen binding fragment thereof;~~
- (iii) ~~about 20 mM of histidine;~~
- (iv) ~~about 250 mM of sucrose;~~
- (v) ~~from about 20 μ M to about 50 μ M of DTPA or EDTA; and~~
- (vi) ~~about 0.05% (w/v) of polysorbate 80.~~

74. ~~A pharmaceutical composition comprising:~~

- ~~(i) 4 mg/ml, 8 mg/ml, or 12 mg/ml of an anti LAG-3 antibody or antigen binding fragment thereof;~~
- ~~(ii) 12 mg/ml of an anti PD-1 antibody, anti PD-L1 antibody, or antigen binding fragment thereof;~~
- ~~(iii) 20 mM of histidine;~~
- ~~(iv) 250 mM of sucrose;~~
- ~~(v) from 20 μ M to 50 μ M of DTPA or EDTA; and~~
- ~~(vi) 0.05% (w/v) of polysorbate 80.~~

75. ~~A pharmaceutical composition comprising:~~

- ~~(i) 80 mg, 160 mg, or 240 mg of an anti LAG-3 antibody, or antigen binding fragment thereof;~~
- ~~(ii) 240 mg of an anti PD-1 antibody, anti PD-L1 antibody, or antigen binding fragment thereof;~~
- ~~(iii) 20 mM of histidine;~~
- ~~(iv) 250 mM of sucrose;~~
- ~~(v) from 20 μ M to 50 μ M of DTPA or EDTA; and~~
- ~~(vi) 0.05% (w/v) of polysorbate 80.~~

76. ~~The pharmaceutical composition of any one of claims 37-74, wherein the pH of the composition is from about 5 to about 6.5.~~

77. ~~The pharmaceutical composition of claim 76, wherein the pH is about 5.3 to about 6.3.~~

78. ~~The pharmaceutical composition of claim 77, wherein the pH is 5.8.~~

79. — ~~The pharmaceutical composition of any one of claims 35, 36 and 76-78, wherein the pH is determined using a pH meter.~~

80. — ~~The pharmaceutical composition of any one of claims 1-79, wherein the composition is for intravenous administration.~~

81. — ~~The pharmaceutical composition of any one of claims 1-80, which is diluted prior to use.~~

82. — ~~The pharmaceutical composition of claim 81, which is diluted with 0.9% Sodium Chloride Injection, USP or 5% Dextrose Injection, USP prior to use.~~

83. — ~~The pharmaceutical composition of claim 81 or 82, wherein the composition is diluted to obtain a desired antibody concentration.~~

84. — ~~A vial comprising the pharmaceutical composition of any one of claims 1-83.~~

85. — ~~The vial of claim 84, further comprising a stopper and a seal.~~

86. — ~~The vial of claim 84 or 85, wherein the total volume in the vial is 8 mls or 10 mls.~~

87. — ~~The vial of any one of claims 84-86, wherein the pharmaceutical composition further comprises a third therapeutic agent.~~

88. — ~~The vial of claim 87, wherein the third therapeutic agent is an antibody.~~

89. — ~~The vial of claim 88, wherein the third therapeutic agent is an immune oncology agent.~~

90. — ~~A syringe comprising the pharmaceutical composition of any one of claims 1-83.~~

91. — ~~An intravenous bag comprising the pharmaceutical composition of any one claims 1-83.~~

92. — ~~A kit comprising the pharmaceutical composition of any one of claims 1-83.~~

93. — ~~The pharmaceutical composition of any one of claims 1-83, wherein the composition is stable at about -60 °C for at least about 1 month, at least about 2 months, at least about 3 months, at least about 6 months, at least about 9 months, at least about 1 year, at least about 2 years, at least about 3 years, at least about 4 years, or at least about 5 years.~~

94. — ~~The pharmaceutical composition of any one of claims 1-83 and 93, wherein the composition is stable at about 5 °C for at least about 1 month, at least about 2 months, at least about 3 months, at least about 6 months, at least about 9 months, at least about 1 year, at least about 2 years, at least about 3 years, at least about 4 years, or at least about 5 years.~~

95. — ~~The pharmaceutical composition of any one of claims 1-83, 93 and 94, wherein the composition is stable at about 25 °C for at least about 1 month, at least about 2 months, at least about 3 months, at least about 6 months, at least about 9 months, at least about 1 year, at least about 2 years, at least about 3 years, at least about 4 years, or at least about 5 years.~~

96. — ~~The pharmaceutical composition of any one of claims 1-83 and 93-95, wherein the composition is stable at about 40 °C for at least about 1 month, at least about 2 months, at least about 3 months, at least about 6 months, at least about 9 months, at least about 1 year, at least about 2 years, at least about 3 years, at least about 4 years, or at least about 5 years.~~

97. — ~~The pharmaceutical composition of any one of claims 1-83 and 93-96, wherein the composition has no significant change in pH for at least about 1 month, at least about 2 months, at least about 3 months, at least about 6 months, at least about 9 months, at least about 1 year, at least about 2 years, at least about 3 years, at least about 4 years, or at least about 5 years.~~

98. — ~~The pharmaceutical composition of claim 97, wherein the pH of the composition changes by no more than 0.2 for at least about 1 month, at least about 2 months, at least about 3 months, at least about 6 months, at least about 9 months, at least about 1 year, at least about 2 years, at least about 3 years, at least about 4 years, or at least about 5 years.~~

99. — ~~The pharmaceutical composition of any one of claims 1-83 and 93-98, wherein the composition has no significant change in protein concentration for at least about 1 month, at least about 2 months, at least about 3 months, at least about 6 months, at least about 9 months, at least about 1 year, at least about 2 years, at least about 3 years, at least about 4 years, or at least about 5 years.~~

100. — ~~The pharmaceutical composition of claim 99, wherein the protein concentration of the composition increases by no more than about 0.7 mg/ml for at least about 1 month, at least about 2 months, at least about 3 months, at least about 6 months, at least about 9 months, at least about~~

1 year, at least about 2 years, at least about 3 years, at least about 4 years, or at least about 5 years.

101. — The pharmaceutical composition of any one of claims 1-83 and 93-100, wherein the composition has a low particulate count for at least about 1 month, at least about 2 months, at least about 3 months, at least about 6 months, at least about 9 months, at least about 1 year, at least about 2 years, at least about 3 years, at least about 4 years, or at least about 5 years.

102. — The pharmaceutical composition of any one of claims 1-83 and 93-101, wherein the composition has no significant decrease in the concentration of antibody monomer species for at least about 1 month, at least about 2 months, at least about 3 months, at least about 6 months, at least about 9 months, at least about 1 year, at least about 2 years, at least about 3 years, at least about 4 years, or at least about 5 years.

103. — The pharmaceutical composition of claim 102, wherein the concentration of antibody monomer species decreases by no more than about 10% for at least about 1 month, at least about 2 months, at least about 3 months, at least about 6 months, at least about 9 months, at least about 1 year, at least about 2 years, at least about 3 years, at least about 4 years, or at least about 5 years.

104. — The pharmaceutical composition of any one of claims 1-83 and 93-103, wherein the composition has no significant increase in the concentration of high molecular weight (HMW) antibody species for at least about 1 month, at least about 2 months, at least about 3 months, at least about 6 months, at least about 9 months, at least about 1 year, at least about 2 years, at least about 3 years, at least about 4 years, or at least about 5 years.

105. — The pharmaceutical composition of claim 104, wherein the concentration of HMW antibody species increases by no more than about 10% for at least about 1 month, at least about 2 months, at least about 3 months, at least about 6 months, at least about 9 months, at least about 1 year, at least about 2 years, at least about 3 years, at least about 4 years, or at least about 5 years.

106. — The pharmaceutical composition of any one of claims 1-83 and 93-105, wherein the composition has no significant increase in the concentration of low molecular weight (LMW) antibody species for at least about 1 month, at least about 2 months, at least about 3 months, at

least about 6 months, at least about 9 months, at least about 1 year, at least about 2 years, at least about 3 years, at least about 4 years, or at least about 5 years.

~~107. The pharmaceutical composition of claim 106, wherein the concentration of LMW antibody increases by no more than about 3% for at least about 1 month, at least about 2 months, at least about 3 months, at least about 6 months, at least about 9 months, at least about 1 year, at least about 2 years, at least about 3 years, at least about 4 years, or at least about 5 years.~~

~~108. The pharmaceutical composition of any one of claims 1-83 and 93-107, wherein the composition has no significant change in purity for at least about 1 month, at least about 2 months, at least about 3 months, at least about 6 months, at least about 9 months, at least about 1 year, at least about 2 years, at least about 3 years, at least about 4 years, or at least about 5 years.~~

~~109. The pharmaceutical composition of claim 108, wherein the purity of the antibody decreases by no more than about 5%, about 4%, about 3%, about 2%, or about 1% for at least about 1 month, at least about 2 months, at least about 3 months, at least about 6 months, at least about 9 months, at least about 1 year, at least about 2 years, at least about 3 years, at least about 4 years, or at least about 5 years.~~

~~110. The pharmaceutical composition of any one of claims 1-83 and 93-109, which exhibits a change of an acidic peak that is less than about 15%, about 14%, about 13%, about 12%, about 11%, about 10%, about 9%, about 8%, about 7%, about 6%, about 5%, about 4%, about 3%, about 2%, or about 1%, for at least about 1 month, at least about 2 months, at least about 3 months, at least about 6 months, at least about 9 months, at least about 1 year, at least about 2 years, at least about 3 years, at least about 4 years, or at least about 5 years.~~

~~111. The pharmaceutical composition of any one of claims 1-83 and 93-110, which exhibits no significant change in charge distribution for at least about 1 month, at least about 2 months, at least about 3 months, at least about 6 months, at least about 9 months, at least about 1 year, at least about 2 years, at least about 3 years, at least about 4 years, or at least about 5 years.~~

~~112. The pharmaceutical composition of claim 111, wherein the change in charge distribution is no more than about 5%, about 4%, about 3%, about 2%, or about 1%.~~

~~113. A method of making the pharmaceutical composition of any one of claims 1-83 and 93-112.~~

~~114.— A method of modulating an immune response to a patient in need thereof comprising administering the pharmaceutical composition of any one of claims 1-83 and 93-112 to the patient.~~

~~115.— A method of treating a disease or condition comprising administering the pharmaceutical composition of any one of claims 1-83 and 93-112 to a patient.~~

~~116.— The method of claim 115, wherein the disease or condition is an infectious disease.~~

~~117.— The method of claim 115, wherein the disease is cancer.~~

~~118.— The method of claim 117, wherein the cancer is melanoma cancer, renal cancer, prostate cancer, breast cancer, colon cancer, oral cancer, lung cancer, bone cancer, pancreatic cancer, skin cancer, cancer of the head or neck, cutaneous or intraocular malignant melanoma, uterine cancer, ovarian cancer, rectal cancer, cancer of the anal region, stomach cancer, testicular cancer, uterine cancer, carcinoma of the fallopian tubes, carcinoma of the endometrium, carcinoma of the cervix, carcinoma of the vagina, carcinoma of the vulva, Hodgkin's Disease, non-Hodgkin's lymphoma, cancer of the esophagus, cancer of the small intestine, cancer of the endocrine system, cancer of the thyroid gland, cancer of the parathyroid gland, cancer of the adrenal gland, sarcoma of soft tissue, cancer of the urethra, cancer of the penis, chronic or acute leukemias including acute myeloid leukemia, chronic myeloid leukemia, acute lymphoblastic leukemia, chronic lymphocytic leukemia, solid tumors of childhood, lymphocytic lymphoma, cancer of the bladder, cancer of the kidney or ureter, carcinoma of the renal pelvis, neoplasm of the central nervous system (CNS), primary CNS lymphoma, tumor angiogenesis, spinal axis tumor, brain stem glioma, pituitary adenoma, Kaposi's sarcoma, epidermoid cancer, squamous cell cancer, T-cell lymphoma, environmentally induced cancers including those induced by asbestos, and any combination thereof.~~

~~119.— The method of claim 117, wherein the lung cancer is small cell lung cancer or non-small cell lung cancer.~~

~~120.— The method of any one of claims 117-119, wherein the cancer is refractory to treatment.~~

~~121.— The method of claim 120, wherein the cancer is refractory to treatment with an anti-PD1 antibody.~~

~~122. The method of claim 120, wherein the cancer is refractory to treatment with an anti PD-L1 antibody.~~

~~123. The method of claim 120, wherein cancer is refractory to treatment with an immune-oncology agent.~~

~~124. The method of any one of claims 114-123, wherein the method further comprises administering a pharmaceutical composition comprising an anti PD-1 antibody, anti PD-L1 antibody, or antigen binding fragment thereof.~~

~~125. The method of claim 124, wherein the pharmaceutical composition comprising the anti-LAG-3 antibody or antigen binding fragment thereof and the pharmaceutical composition comprising the anti PD-1 antibody, anti PD-L1 antibody, or antigen binding fragment thereof are co-administered.~~

~~126. The method of claim 124, wherein the pharmaceutical composition comprising the anti-LAG-3 antibody or antigen binding fragment thereof and the pharmaceutical composition comprising the anti PD-1 antibody, anti PD-L1 antibody, or antigen binding fragment thereof are sequentially administered.~~

~~127. The method of claim 124, wherein the pharmaceutical composition comprising the anti-LAG-3 antibody or antigen binding fragment thereof is administered prior to the pharmaceutical composition comprising the anti PD-1 antibody, anti PD-L1 antibody, or antigen binding fragment thereof.~~

~~128. The method of any one of claims 124-127, wherein the anti LAG-3 antibody or antigen binding fragment thereof and the anti PD-1 antibody, anti PD-L1 antibody, or antigen binding fragment thereof are administered as a first line of treatment.~~

~~129. The method of any one of claims 124-127, wherein the anti LAG-3 antibody or antigen binding fragment thereof and the anti PD-1 antibody, anti PD-L1 antibody, or antigen binding fragment thereof are administered as a second line of treatment.~~

~~130. A pharmaceutical composition comprising:~~

~~(i) from about 5 mM to about 50 mM of a buffering agent;~~

(ii) ~~from about 50 mM to about 300 mM of a stabilizing agent or bulking agent; and~~

(iii) ~~from about 0.001% to about 1% (w/v) of a surfactant.~~

131. ~~A pharmaceutical composition comprising:~~

(i) ~~from about 5 mM to about 50 mM of a buffering agent;~~

(ii) ~~from about 50 mM to about 300 mM of a stabilizing agent;~~

(iii) ~~from about 5 μ M to about 1 mM of a chelating agent; and~~

(iv) ~~from about 0.001% to about 1% (w/v) of a surfactant.~~

132. ~~The pharmaceutical composition of any claim 130 or 131, wherein the buffering agent is histidine, Tris-Cl, citrate, Tris-citrate, phosphate, or any combination thereof.~~

133. ~~The pharmaceutical composition of any one of claims 130-132, comprising about 10 mM or about 20 mM of the buffering agent.~~

134. ~~The pharmaceutical composition of any one of claims 130-133, wherein the stabilizing agent is sucrose, trehalose, raffinose, arginine, or any combination thereof.~~

135. ~~The pharmaceutical composition of any one of claims 130-134, wherein the bulking agent is sodium chloride, mannitol, glycine, alanine, or any combination thereof.~~

136. ~~The pharmaceutical composition of any one of claims 130-135, comprising about 150 mM or about 250 mM of the stabilizing agent or bulking agent.~~

137. ~~The pharmaceutical composition of any one of claims 130-136, wherein the surfactant is PS80, PS20, PX188, or any combination thereof.~~

138. ~~The pharmaceutical composition of any one of claims 130-137, comprising from about 0.05% to about 1% of the surfactant.~~

139. ~~The pharmaceutical composition of claim 131, wherein the chelating agent is DTPA, EDTA, nitrilotriacetic acid, or any combination thereof.~~

140. ~~The pharmaceutical composition of claim 131 or 139, comprising about 20 μ M of the chelating agent.~~

141. ~~A pharmaceutical composition comprising:~~

- ~~(i) — from about 5 mM to about 50 mM of citrate;~~
- ~~(ii) — from about 50 mM to about 300 mM of sodium chloride; and~~
- ~~(iii) — from about 0.001% to about 1% (w/v) of polysorbate or poloxamer.~~

142. ~~A pharmaceutical composition comprising:~~

- ~~(i) — about 10 mM of citrate and about 10 mM of phosphate;~~
- ~~(ii) — about 150 mM of sodium chloride; and~~
- ~~(iii) — about 0.05% (w/v) of polysorbate 80.~~

143. ~~A pharmaceutical composition comprising:~~

- ~~(i) — about 20 mM of histidine;~~
- ~~(ii) — about 250 mM of sucrose; and~~
- ~~(iii) — about 0.05% (w/v) of polysorbate 80.~~

144. ~~A pharmaceutical composition comprising:~~

- ~~(i) — from about 5 mM to about 50 mM of histidine;~~
- ~~(ii) — from about 50 mM to about 300 mM of sucrose;~~
- ~~(iii) — from about 5 μ M to about 1 mM of one or more chelating agents; and~~
- ~~(iv) — from about 0.001% to about 1% (w/v) of polysorbate or poloxamer.~~

145. ~~A pharmaceutical composition comprising:~~

- ~~(i) — about 20 mM of histidine;~~

- ~~(ii) — about 250 mM of sucrose;~~
- ~~(iii) — about 20 μ M to about 50 μ M of DTPA or EDTA; and~~
- ~~(iv) — about 0.05% (w/v) of polysorbate 80.~~

~~146. — A pharmaceutical composition comprising:~~

- ~~(i) — 10 mM of citrate and 10 mM phosphate;~~
- ~~(ii) — 150 mM of sodium chloride; and~~
- ~~(iii) — 0.05% (w/v) of polysorbate 80.~~

~~147. — A pharmaceutical composition comprising:~~

- ~~(i) — 20 mM of histidine;~~
- ~~(ii) — 250 mM of sucrose; and~~
- ~~(iii) — 0.05% (w/v) of polysorbate 80.~~

~~148. — A pharmaceutical composition comprising:~~

- ~~(i) — 20 mM of histidine;~~
- ~~(ii) — 250 mM of sucrose;~~
- ~~(iii) — from 20 μ M to 50 μ M of DTPA or EDTA; and~~
- ~~(iv) — 0.05% (w/v) of polysorbate 80.~~

~~149. — The pharmaceutical composition of any one of claims 130-148, further comprising an antibody or antigen binding fragment thereof.~~

- (c) — about 20 mM of histidine buffer;
- (d) — about 250 mM of sucrose;
- (e) — about 20 μ M of DTPA; and
- (f) — about 0.05% (w/v) of polysorbate 80;

wherein the pharmaceutical composition has a pH of about 5.8.

2. The pharmaceutical composition of claim 1, wherein the anti-LAG-3 antibody or antigen binding fragment thereof comprises heavy chain variable region CDR1, CDR2, and CDR3 domains comprising the sequences set forth in SEQ ID NOs:7, 8, and 9, respectively, and light chain variable region CDR1, CDR2, and CDR3 domains comprising the sequences set forth in SEQ ID NOs:10, 11, and 12, respectively.

3. The pharmaceutical composition of claim 1, wherein the anti-PD-1 antibody or antigen binding fragment thereof comprises heavy chain variable region CDR1, CDR2, and CDR3 domains comprising the sequences set forth in SEQ ID NOs:23, 24, and 25, respectively, and light chain variable region CDR1, CDR2, and CDR3 domains comprising the sequences set forth in SEQ ID NOs:26, 27, and 28, respectively.

4. The pharmaceutical composition of claim 1, wherein the anti-LAG-3 antibody or antigen binding fragment thereof comprises heavy chain variable region CDR1, CDR2, and CDR3 domains comprising the sequences set forth in SEQ ID NOs:7, 8, and 9, respectively, and light chain variable region CDR1, CDR2, and CDR3 domains comprising the sequences set forth in SEQ ID NOs:10, 11, and 12, respectively, and the anti-PD-1 antibody or antigen binding fragment thereof comprises heavy chain variable region CDR1, CDR2, and CDR3 domains comprising the sequences set forth in SEQ ID NOs:23, 24, and 25, respectively, and light chain variable region CDR1, CDR2, and CDR3 domains comprising the sequences set forth in SEQ ID NOs:26, 27, and 28, respectively.

5. The pharmaceutical composition of claim 1, wherein the anti-LAG-3 antibody or antigen binding fragment thereof comprises heavy and light chain variable regions comprising the sequences set forth in SEQ ID NOs:3 and 5, respectively.

6. The pharmaceutical composition of claim 1, wherein the anti-PD-1 antibody or antigen binding fragment thereof comprises heavy and light chain variable regions comprising the sequences set forth in SEQ ID NOs:19 and 21, respectively.

7. The pharmaceutical composition of claim 1, wherein the anti-LAG-3 antibody or antigen binding fragment thereof comprises heavy and light chain variable regions comprising the sequences set forth in SEQ ID NOs:3 and 5, respectively, and the anti-PD-1 antibody or antigen binding fragment thereof comprises heavy and light chain variable regions comprising the sequences set forth in SEQ ID NOs:19 and 21, respectively.

8. The pharmaceutical composition of claim 1, wherein the anti-LAG-3 antibody comprises heavy and light chains comprising the sequences set forth in SEQ ID NOs:1 and 2, respectively.

9. The pharmaceutical composition of claim 1, wherein the anti-PD-1 antibody comprises heavy and light chains comprising the sequences as set forth in SEQ ID NOs:17 and 18, respectively.

10. The pharmaceutical composition of claim 1, wherein the anti-LAG-3 antibody comprises heavy and light chains comprising the sequences set forth in SEQ ID NOs:1 and 2, respectively, and the anti-PD-1 antibody comprises heavy and light chains comprising the sequences as set forth in SEQ ID NOs:17 and 18, respectively.

11. The pharmaceutical composition of claim 1, wherein the concentrations of the anti-LAG-3 antibody or antigen binding fragment thereof and the anti-PD-1 antibody or antigen binding fragment thereof are 4 mg/mL and 12 mg/mL, respectively.

12. The pharmaceutical composition of claim 1, wherein the composition is for intravenous administration.

13. A vial comprising 20 mL of a pharmaceutical composition comprising:

(a) about 80 mg of an anti-LAG-3 antibody or antigen binding fragment thereof comprising CDR1, CDR2, and CDR3 domains of the heavy chain variable region having the sequence set forth in SEQ ID NO:3, and CDR1, CDR2, and CDR3 domains of the light chain variable region having the sequence set forth in SEQ ID NO:5;

(b) about 240 mg of an anti-PD-1 antibody or antigen binding fragment thereof comprising CDR1, CDR2, and CDR3 domains of the heavy chain variable region having the sequence set forth in SEQ ID NO:19, and CDR1, CDR2, and CDR3 domains of the light chain variable region having the sequence set forth in SEQ ID NO:21;

(c) about 20 mM of histidine buffer;

(d) about 250 mM of sucrose;

(e) about 20 μ M of DTPA; and

(f) about 0.05% (w/v) of polysorbate 80;

wherein the pharmaceutical composition has a pH of about 5.8.

14. The vial of claim 13, wherein the anti-LAG-3 antibody or antigen binding fragment thereof comprises heavy chain variable region CDR1, CDR2, and CDR3 domains comprising the sequences set forth in SEQ ID NOs:7, 8, and 9, respectively, and light chain variable region CDR1, CDR2, and CDR3 domains comprising the sequences set forth in SEQ ID NOs:10, 11, and 12, respectively, and the anti-PD-1 antibody or antigen binding fragment thereof comprises heavy chain variable region CDR1, CDR2, and CDR3 domains comprising the sequences set forth in SEQ ID NOs:23, 24, and 25, respectively, and light chain variable region

CDR1, CDR2, and CDR3 domains comprising the sequences set forth in SEQ ID NOs:26, 27, and 28, respectively.

15. The vial of claim 13, wherein the anti-LAG-3 antibody or antigen binding fragment thereof comprises heavy and light chain variable regions comprising the sequences set forth in SEQ ID NOs:3 and 5, respectively, and the anti-PD-1 antibody or antigen binding fragment thereof comprises heavy and light chain variable regions comprising the sequences set forth in SEQ ID NOs:19 and 21, respectively.

16. The vial of claim 13, wherein the anti-LAG-3 antibody comprises heavy and light chains comprising the sequences set forth in SEQ ID NOs:1 and 2, respectively, and the anti-PD-1 antibody comprises heavy and light chains comprising the sequences as set forth in SEQ ID NOs:17 and 18, respectively.

17. An infusion solution comprising:

(a) about 160 mg of an anti-LAG-3 antibody or antigen binding fragment thereof comprising CDR1, CDR2, and CDR3 domains of the heavy chain variable region having the sequence set forth in SEQ ID NO:3, and CDR1, CDR2, and CDR3 domains of the light chain variable region having the sequence set forth in SEQ ID NO:5;

(b) about 480 mg of an anti-PD-1 antibody or antigen binding fragment thereof comprising CDR1, CDR2, and CDR3 domains of the heavy chain variable region having the sequence set forth in SEQ ID NO:19, and CDR1, CDR2, and CDR3 domains of the light chain variable region having the sequence set forth in SEQ ID NO:21;

(c) about 20 mM of histidine buffer;

(d) about 250 mM of sucrose;

(e) about 20 μ M of DTPA; and

(f) about 0.05% (w/v) of polysorbate 80;

wherein the infusion solution has a pH of about 5.8.

18. The infusion solution of claim 17, wherein the anti-LAG-3 antibody or antigen binding fragment thereof comprises heavy chain variable region CDR1, CDR2, and CDR3 domains comprising the sequences set forth in SEQ ID NOs:7, 8, and 9, respectively, and light chain variable region CDR1, CDR2, and CDR3 domains comprising the sequences set forth in SEQ ID NOs:10, 11, and 12, respectively, and the anti-PD-1 antibody or antigen binding fragment thereof comprises heavy chain variable region CDR1, CDR2, and CDR3 domains comprising the sequences set forth in SEQ ID NOs:23, 24, and 25, respectively, and light chain variable region CDR1, CDR2, and CDR3 domains comprising the sequences set forth in SEQ ID NOs:26, 27, and 28, respectively.

19. The infusion solution of claim 17, wherein the anti-LAG-3 antibody or antigen binding fragment thereof comprises heavy and light chain variable regions comprising the sequences set forth in SEQ ID NOs:3 and 5, respectively, and the anti-PD-1 antibody or antigen binding fragment thereof comprises heavy and light chain variable regions comprising the sequences set forth in SEQ ID NOs:19 and 21, respectively.

20. The infusion solution of claim 17, wherein the anti-LAG-3 antibody comprises heavy and light chains comprising the sequences set forth in SEQ ID NOs:1 and 2, respectively, and the anti-PD-1 antibody comprises heavy and light chains comprising the sequences as set forth in SEQ ID NOs:17 and 18, respectively.

21. An intravenous bag comprising the infusion solution of claim 17.

22. An intravenous bag comprising a dilution of the infusion solution of claim 17.

23. The intravenous bag of claim 22, wherein the diluent is 0.9% Sodium Chloride Injection, USP.

24. The intravenous bag of claim 22, wherein the diluent is 5% Dextrose Injection, USP.