

WHAT IS CLAIMED IS:

1. A pharmaceutical formulation comprising
 - (a) an antibody or antigen-binding fragment thereof that ~~(a)~~ binds to an epitope of human PD-1, wherein the antibody or antigen-binding fragment comprises:
 - a light chain variable region (VL) comprising:
 - a VL complementarity determining region 1 (CDR1) comprising SEQ ID NO:1 or SEQ ID NO:7,
 - a VL CDR2 comprising SEQ ID NO:2, and
 - a VL CDR3 comprising SEQ ID NO:3; and
 - a heavy chain variable region (VH) comprising:
 - a VH CDR1 comprising SEQ ID NO:4,
 - a VH CDR2 comprising SEQ ID NO:5, and
 - a VH CDR3 comprising SEQ ID NO:6;
 - (b) a buffer system selected from the group consisting of an acetate buffer, succinate buffer, histidine buffer, and citrate buffer,
 - wherein the concentration of the buffer system is within the range of 0.1 mM to 1 M, and
 - wherein the pH of the buffer system is within the range of pH 4-6.5;
 - (c) a polyol selected from the group consisting of a sugar, sugar alcohol, and sugar acid; and
 - (d) a surfactant.
2. The pharmaceutical formulation of claim 1, wherein the antibody or antigen-binding fragment thereof comprises (i) a VL comprising an amino acid sequence of SEQ ID NO:8, SEQ ID NO:9, or SEQ ID NO:10; or (ii) a VH comprising an amino acid sequence of SEQ ID NO:11 or SEQ ID NO:12, or SEQ ID NO:13.

3. The pharmaceutical formulation of claim 1, wherein the antibody or antigen-binding fragment thereof comprises:
 - (a) a VL comprising an amino acid sequence of SEQ ID NO:8; and a VH comprising an amino acid sequence of SEQ ID NO:11;
 - (b) a VL comprising an amino acid sequence of SEQ ID NO:9; and a VH comprising an amino acid sequence of SEQ ID NO:11;
 - (c) a VL comprising an amino acid sequence of SEQ ID NO:10; and a VH comprising an amino acid sequence of SEQ ID NO:11;
 - (d) a VL comprising an amino acid sequence of SEQ ID NO:8; and a VH comprising an amino acid sequence of SEQ ID NO:12;
 - (e) a VL comprising an amino acid sequence of SEQ ID NO:9; and a VH comprising an amino acid sequence of SEQ ID NO:12;
 - (f) a VL comprising an amino acid sequence of SEQ ID NO:10; and a VH comprising an amino acid sequence of SEQ ID NO:12;
 - (g) a VL comprising an amino acid sequence of SEQ ID NO:8; and a VH comprising an amino acid sequence of SEQ ID NO:13;
 - (h) a VL comprising an amino acid sequence of SEQ ID NO:9; and a VH comprising an amino acid sequence of SEQ ID NO:13; or
 - (i) a VL comprising an amino acid sequence of SEQ ID NO:10; and a VH comprising an amino acid sequence of SEQ ID NO:13.
4. The pharmaceutical formulation of any one of claims 1 to 3, wherein the antibody or antigen-binding fragment thereof comprises a human IgG1 Fc region, a human IgG4 Fc region, a human IgG4P Fc region, a human IgG4PE Fc region, or a mutant thereof.
5. The pharmaceutical formulation of any one of claims 1 to 3, wherein the antibody or antigen-binding fragment thereof comprises a human IgG1-K322A Fc region.
6. The pharmaceutical formulation of any one of claims 1 to 5, wherein the antibody or antigen-binding fragment thereof comprises a heavy chain Fc region comprising an

amino acid sequence selected from the group consisting of SEQ ID NO:36, SEQ ID NO:37, SEQ ID NO:38, SEQ ID NO:39 and SEQ ID NO:40.

7. The pharmaceutical formulation of any one of claims 1 to 6, wherein the antibody or antigen-binding fragment thereof further comprises a light chain constant region comprising an amino acid sequence of SEQ ID NO:41.
8. The pharmaceutical formulation of any one of claims 1 to 7, wherein the antibody or antigen-binding fragment thereof comprises a light chain comprising an amino acid sequence of SEQ ID NO:31.
9. The pharmaceutical formulation of any one of claims 1 to 7, wherein the antibody or antigen-binding fragment thereof comprises a heavy chain comprising an amino acid sequence of SEQ ID NO:32, SEQ ID NO:33, SEQ ID NO:34 or SEQ ID NO:35.
10. The pharmaceutical formulation of any one of claims 1 to 7, wherein the antibody or antigen-binding fragment thereof comprises:
 - (a) a light chain comprising an amino acid sequence of SEQ ID NO:31; and a heavy chain comprising an amino acid sequence of SEQ ID NO:32;
 - (b) a light chain comprising an amino acid sequence of SEQ ID NO:31; and a heavy chain comprising an amino acid sequence of SEQ ID NO:33;
 - (c) a light chain comprising an amino acid sequence of SEQ ID NO:31; and a heavy chain comprising an amino acid sequence of SEQ ID NO:34; or
 - (d) a light chain comprising an amino acid sequence of SEQ ID NO:31; and a heavy chain comprising an amino acid sequence of SEQ ID NO:35.
11. The pharmaceutical formulation of any one of claims 1 to 10, wherein
 - (a) the antibody is a monoclonal antibody;
 - (b) the antibody is a humanized, human, or chimeric antibody; wherein optionally the humanized antibody is a deimmunized antibody or a composite human antibody;

- (c) the antibody or antigen-binding fragment thereof is a Fab, a Fab', a F(ab')₂, a Fv, a scFv, a dsFv, a diabody, a triabody, a tetrabody, or a multispecific antibody formed from antibody fragments; and/or
 - (d) the antibody or antigen-binding fragment thereof is conjugated to an agent, wherein optionally the agent selected from the group consisting of a radioisotope, a metal chelator, an enzyme, a fluorescent compound, a bioluminescent compound, and a chemiluminescent compound.
- 12. The pharmaceutical formulation of any one of claims 1 to 11, wherein the concentration of the buffer system is within the range of 1 mM to 100 mM; wherein optionally the concentration of the buffer system is 10 mM.
- 13. The pharmaceutical formulation of any one of claims 1 to 12, wherein the pH of the buffer system is within the range pH 4.7-5.7; wherein optionally the pH of the buffer system is pH 5.2.
- 14. The pharmaceutical formulation of any one of claims 1 to 13, wherein the sugar is sucrose; wherein optionally the concentration of the sucrose is within the range of 5-10% (w/v); and wherein optionally the concentration of the sucrose is 8.5% (w/v).
- 15. The pharmaceutical formulation of any one of claims 1 to 14, wherein the surfactant is polysorbate-20 or polysorbate-80; wherein optionally the concentration of the polysorbate-80 is within the range of 0.001-0.1% (w/v); and wherein optionally the concentration of the polysorbate-80 is 0.005% (w/v).
- 16. The pharmaceutical formulation of any one of claims 1 to 15, comprising
 - (a) 1 mM to 100 mM sodium acetate buffer, wherein the pH is within the range of 4.7-5.7,
 - (c) 5-10% (w/v) sucrose, and
 - (d) 0.001-0.1% (w/v) polysorbate-80.
- 17. The pharmaceutical formulation of any one of claims 1 to 16, comprising 10 mM sodium acetate buffer (pH 5.2), 8.5% (w/v) sucrose, and 0.005% (w/v) polysorbate-80.

18. The pharmaceutical formulation of any one of claims 1 to 17, wherein the pharmaceutical formulation is stable for at least 12 months when stored at $-70\text{ }^{\circ}\text{C} \pm 10\text{ }^{\circ}\text{C}$ or stable for at least 6 months when stored at $5\text{ }^{\circ}\text{C} \pm 3\text{ }^{\circ}\text{C}$.
19. A method of making the pharmaceutical formulation of any one of claims 1 to 18, comprising:
- (a) culturing a cell in a medium, wherein the cell comprises one or more polynucleotides comprising nucleotide sequences encoding a heavy chain, a light chain, or both a heavy chain and a light chain of the antibody or antigen-binding fragment thereof;
 - (b) harvesting the medium;
 - (c) subjecting the medium to a series of purification steps; wherein optionally the purification steps comprise:
 - (i) an affinity chromatography; wherein optionally the affinity chromatography is a protein A affinity chromatography;
 - (ii) a viral inactivation;
 - (i) an ion exchange chromatography; wherein optionally the ion exchange chromatography is an anion exchange chromatography
 - (iv) a viral filtration; wherein optionally the viral inactivation step is a low-pH viral inactivation step; and
 - (v) an ultrafiltration/diafiltration; and

wherein optionally the method further comprises a formulation step.