WHAT IS CLAIMED IS:

1. A pharmaceutical formulation, comprising a monoclonal anti-OX40 antibody or antigen-binding fragment thereof, a buffer, a stabilizer, and a surfactant.

2. The pharmaceutical formulation of claim 1, wherein the monoclonal anti-OX40 antibody comprises a heavy chain and a light chain, wherein the heavy chain comprises a heavy chain variable region V_H which comprises:

HCDR1 comprising the amino acid sequence as set forth in SEQ ID NO: 1;

HCDR2 comprising the amino acid sequence as set forth in SEQ ID NO: 2,

HCDR3 comprising the amino acid sequence as set forth in SEQ ID NO: 3;

wherein the light chain comprises a light chain variable region V_L which comprises:

LCDR1 comprising the amino acid sequence as set forth in SEQ ID NO: 4,

LCDR2 comprising the amino acid sequence as set forth in SEQ ID NO: 5,

LCDR3 comprising the amino acid sequence as set forth in SEQ ID NO: 6;

and

wherein the heavy chain further comprises Fc region variant, and the Fc region variant is human IgG1 N297A.

3. The pharmaceutical formulation of any one of claims 1 to 2, wherein the heavy chain variable region V_H comprises the amino acid sequence selected from the group consisting of: SEQ ID NO: 7, SEQ ID NO: 9, and SEQ ID NO: 10.

4. The pharmaceutical formulation of any one of claims 1 to 3, wherein the light chain variable region V_L comprises the amino acid sequence selected from the group consisting of: SEQ ID NO: 8, SEQ ID NO: 11, and SEQ ID NO: 12.

5. The pharmaceutical formulation of any one of claims 1 to 4, wherein the concentration of the monoclonal anti-OX40 antibody in the pharmaceutical formulation is about 0.5-200 mg/ml, preferably about 40-60 mg/ml.

6. The pharmaceutical formulation of any one of claims 1 to 5, wherein the pharmaceutical formulation has a pH of about 5.0-8.0.

7. The pharmaceutical formulation of any one of claims 1 to 6, wherein the buffer is selected from the group consisting of acetate buffer, histidine buffer, citrate buffer,

glutamic acid buffer, arginine buffer, citrate & arginine buffer, and glutamic acid & histidine buffer, aspartic acid & histidine buffer, wherein the concentration of the buffer in the pharmaceutical formulation is about 1-100 mmol/L.

8. The pharmaceutical formulation of any one of claims 1 to 7, wherein the stabilizer is selected from the group consisting of sucrose, sorbitol, trehalose, xylitol and mannose, wherein the concentration of the stabilizer in the pharmaceutical formulation is about 0.5%-50% w/v.

9. The pharmaceutical formulation of any one of claims 1 to 8, wherein the surfactant is selected from the group consisting of polysorbate 80 and polysorbate 20, wherein the concentration of the surfactant in the pharmaceutical formulation is about 0.001-0.1 %w/v.

10. The pharmaceutical formulation of any one of claims 1 to 9, wherein the concentration of the monoclonal anti-OX40 antibody in the pharmaceutical formulation is about 40-60 mg/ml, the concentration of the buffer in the pharmaceutical formulation is about 10-30 mmol/L, the concentration of the stabilizer in the pharmaceutical formulation is about 4-12% w/v, the concentration of the surfactant in the pharmaceutical formulation is about 0.01-0.05% w/v, and/or the pharmaceutical formulation has a pH of about 5.0-6.0.

11. The pharmaceutical formulation of any one of claims 1 to 10, wherein the concentration of the monoclonal anti-OX40 antibody in the pharmaceutical formulation is about 50 mg/ml, the concentration of the buffer in the pharmaceutical formulation is about 20 mmol/L, the concentration of the stabilizer in the pharmaceutical formulation is about 4.5-8.8% w/v, the concentration of the surfactant in the pharmaceutical formulation is about 0.02 - 0.04% w/v, and/or wherein the pharmaceutical formulation has a pH of about 5.0-5.5.

12. The pharmaceutical formulation of claim 11, wherein the concentration of the stabilizer in the pharmaceutical formulation is about 8% w/v, the concentration of the surfactant in the pharmaceutical formulation is about 0.02% w/v, and/or the pharmaceutical formulation has a pH of about 5.0.

13. The pharmaceutical formulation of any one of claims 1 to 12, wherein the buffer is

glutamic acid & histidine buffer, aspartic acid & histidine buffer or combination thereof; and/or

wherein the stabilizer is sucrose, sorbitol, trehalose, or combination thereof; and/or

wherein the surfactant is polysorbate 80.

14. The pharmaceutical formulation of any one of claims 1 to 12, comprising:

a monoclonal anti-OX40 antibody or antigen-binding fragment thereof, at a concentration of about 40-60 mg/ml,

glutamic acid & histidine buffer or aspartic acid & histidine buffer at a concentration of about 10-30 mmol/L,

sucrose at a concentration of about 4-12 % w/v, and

polysorbate 80 at a concentration of about 0.01-0.05% w/v,

and the pharmaceutical formulation has a pH of about 5.0-5.5.

15. The pharmaceutical formulation of any one of claims 1 to 12, comprising:

a monoclonal anti-OX40 antibody or antigen-binding fragment thereof, at a concentration of about 50 mg/ml,

glutamic acid & histidine buffer or aspartic acid & histidine buffer at a concentration of about 20 mmol/L,

sucrose at a concentration of about 8 % w/v, and

polysorbate 80 at a concentration of about 0.02 % w/v,

and wherein the pharmaceutical formulation has a pH of about 5.0.

16. The pharmaceutical formulation of any one of claims 1 to 15, wherein the pharmaceutical formulation is suitable for subcutaneous administration or for intravenous administration.

17. Use of the pharmaceutical formulation of any one of claims 1 to 16 in the manufacture of a medicament for the treatment or prevention of OX40-associated disease.

18. The use of claim 17, wherein the OX40-associated disease is inflammation and/or autoimmune diseases, such as graft-versus-host disease.

19. The use of claim 17, wherein the medicament is to be administered via

subcutaneous injection or intravenous injection.

20. A method of preparing the pharmaceutical formulation of any one of claims 1 to 16, comprising combining the buffer, the stabilizer, the surfactant, and a pharmaceutically effective amount of the monoclonal anti-OX40 antibody or antigen-binding fragment thereof.

21. A kit comprising the pharmaceutical formulation of any one of claims 1 to 16 in one or more containers.

22. The kit of claim 21, further comprises instructions for use of the kit.