

CLAIMS

1. A pharmaceutical composition, comprising: (a) an anti-TSLP antibody, (b) a buffering agent, (c) a surfactant, and one or more (d) stabilizers, wherein the anti-TSLP antibody comprises a heavy chain variable region comprising a VH-CDR1 region, a VH-CDR2 region and a VH-CDR3 region, and a light chain variable region comprising a VL-CDR1 region, a VL-CDR2 region and a VL-CDR3 region, wherein the VH-CDR1 region, the VH-CDR2 region, the VH-CDR3 region, the VL-CDR1 region, the VL-CDR2 region, and the VL-CDR3 region comprise: amino acid sequences set forth in SEQ ID NOs: 1, 2, 3, 4, 5 and 6, respectively.
2. The pharmaceutical composition according to claim 1, wherein the anti-TSLP antibody comprises a heavy chain variable region and a light chain variable region, and the heavy chain variable region and the light chain variable region can comprise an amino acid sequence selected from the following amino acid sequences: (1) respectively as set forth in SEQ ID NOs: 7 and 10; (2) respectively as set forth in SEQ ID NOs: 8 and 11 (X1 = S, X2 = V); (3) respectively as set forth in SEQ ID NOs: 9 (X1 = R, X2 = V, X3 = R) and 11 (X1 = S, X2 = V); (4) respectively as set forth in SEQ ID NOs: 9 (X1 = R, X2 = V, X3 = V) and 11 (X1 = S, X2 = V); (5) respectively as set forth in SEQ ID NOs: 9 (X1 = R, X2 = A, X3 = R) and 11 (X1 = S, X2 = V); (6) respectively as set forth in SEQ ID NOs: 9 (X1 = K, X2 = A, X3 = R) and 11 (X1 = S, X2 = V); (7) respectively as set forth in SEQ ID NOs: 9 (X1 = K, X2 = A, X3 = V) and 11 (X1 = S, X2 = V); (8) respectively as set forth in SEQ ID NOs: 8 and 11 (X1 = A, X2 = I); (9) respectively as set forth in SEQ ID NOs: 9 (X1 = R, X2 = V, X3 = R) and 11 (X1 = A, X2 = I); (10) respectively as set forth in SEQ ID NOs: 9 (X1 = R, X2 = V, X3 = V) and 11 (X1 = A, X2 = I); (11) respectively as set forth in SEQ ID NOs: 9 (X1 = R, X2 = A, X3 = R) and 11 (X1 = A, X2 = I); (12) respectively as set forth in SEQ ID NOs: 9 (X1 = K, X2 = A, X3 = R) and 11 (X1 = A, X2 = I); (13) respectively as set forth in SEQ ID NOs: 9 (X1 = K, X2 = A, X3 = V) and 11 (X1 = A, X2 = I); (14) respectively as set forth in SEQ ID NOs: 8 and 11 (X1 = S, X2 = I); (15) respectively as set forth in SEQ ID NOs: 9 (X1 = R, X2 = V, X3 = R) and 11 (X1 = S, X2 = I); (16) respectively as set forth in SEQ ID NOs: 9 (X1 = R, X2 = V, X3 = V) and 11 (X1 = S, X2 = I); (17) respectively as set forth in SEQ ID NOs: 9 (X1 = R, X2 = A, X3 = R) and 11 (X1 = S, X2 = I); (18) respectively as set forth in SEQ ID NOs: 9 (X1 = K, X2 = A, X3 = R) and 11 (X1 = S, X2 = I); or (19) respectively as set forth in SEQ ID NOs: 9 (X1 = K, X2 = A, X3 = V) and 11 (X1 = S, X2 = I).
3. The pharmaceutical composition according to any one of claims 1-2, wherein the anti-TSLP antibody has a concentration of 30 mg/mL to 300 mg/mL, preferably 50 mg/mL to 250 mg/mL, preferably 70 mg/mL to 200 mg/mL, more preferably 90 mg/mL to 150 mg/mL, most preferably

120 mg/mL to 150 mg/mL.

4. The pharmaceutical composition according to any one of claims 1-3, wherein the buffering agent comprises a phosphate buffering agent, a histidine buffering agent, an acetate buffering agent, or a citrate buffering agent.

5. The pharmaceutical composition according to claim 4, wherein the phosphate buffering agent is a sodium phosphate buffering agent, the acetate buffering agent is a sodium acetate buffering agent, and the citrate buffering agent is a sodium citrate buffering agent.

6. The pharmaceutical composition according to any one of claims 1-5, wherein the buffering agent has a concentration of 1 mM to 100 mM, preferably 2 mM to 80 mM, more preferably 5 mM to 60 mM, most preferably 10 mM to 40 mM.

7. The pharmaceutical composition according to any one of claims 1-6, wherein the surfactant comprises polysorbate 80 or polysorbate 20.

8. The pharmaceutical composition according to any one of claims 1-7, wherein the surfactant has a concentration of 0.001% (w/v) to 0.1% (w/v), preferably 0.004% (w/v) to 0.08% (w/v), more preferably 0.006% (w/v) to 0.06% (w/v), most preferably 0.008% (w/v) to 0.04% (w/v).

9. The pharmaceutical composition according to any one of claims 1-8, wherein the stabilizer comprises trehalose, mannitol, sucrose, arginine or a pharmaceutically acceptable salt thereof, glycine, or proline.

10. The pharmaceutical composition according to any one of claims 1-9, wherein the stabilizer has a concentration of 100 mM to 1000 mM, preferably 120 mM to 800 mM, more preferably 150 mM to 700 mM, most preferably 150 mM to 600 mM.

11. The pharmaceutical composition according to any one of claims 1-10, wherein the pharmaceutical composition has a pH of 5 to 7, preferably 5.5 to 7, more preferably 5.5 to 6.5.

12. A lyophilized formulation comprising an anti-TSLP antibody, the lyophilized formulation being obtained by lyophilizing the pharmaceutical composition according to any one of claims 1-11.

13. A lyophilized formulation comprising an anti-TSLP antibody, the lyophilized formulation being capable of forming the pharmaceutical composition according to any one of claims 1-11 upon reconstitution.

14. An article of manufacture, comprising a container comprising the pharmaceutical composition according to any one of claims 1-11, or the lyophilized formulation according to any one of claims 12-13.

15. Use of the pharmaceutical composition according to any one of claims 1-11 or the lyophilized formulation according to any one of claims 12-13 or the article of manufacture according to claim

14 in the preparation of a medicament ~~A method for treating and preventing TSLP-related diseases, comprising administering to a patient in need thereof a therapeutically effective amount of the pharmaceutical composition according to any one of claims 1-11 or the lyophilized formulation according to any one of claims 12-13 or the article of manufacture according to claim 14.~~