

CLAIMS:

1. A pharmaceutical composition, comprising an anti-ANGPTL3 antibody or an antigen-binding fragment thereof, and a buffer, wherein the buffer is selected from any of acetic acid-sodium acetate, succinic acid-sodium succinate, histidine-hydrochloride, and citric acid-sodium citrate buffers, and is preferably an acetic acid-sodium acetate or succinic acid-sodium succinate buffer; wherein the anti-ANGPTL3 antibody or the antigen-binding fragment thereof comprises an antibody heavy chain variable region and an antibody light chain variable region, wherein the heavy chain variable region comprises a HCDR1, a HCDR2 and a HCDR3, the amino acid sequences of which are set forth in SEQ ID NO: 14, SEQ ID NO: 15 and SEQ ID NO: 16, respectively; and the light chain variable region comprises a LCDR1, a LCDR2 and a LCDR3, the amino acid sequences of which are set forth in SEQ ID NO: 11, SEQ ID NO: 12 and SEQ ID NO: 13, respectively.
2. The pharmaceutical composition according to claim 1, wherein the buffer has a pH of 4.0 to 7.0, preferably 5.0 to 5.4, and most preferably about 5.2.
3. The pharmaceutical composition according to claim 1 or 2, wherein the concentration of the buffer is 5 mM to 40 mM, preferably 5 mM to 20 mM, and most preferably about 10 mM.
4. The pharmaceutical composition according to any of claims 1 to 3, wherein the concentration of the anti-ANGPTL3 antibody or the antigen-binding fragment thereof is 10 mg/mL to 200 mg/mL, preferably 80 mg/mL to 120 mg, and most preferably about 100 mg/mL.
5. The pharmaceutical composition according to any of claims 1 to 4, further comprising a surfactant, wherein the surfactant is preferably polysorbate 80 or polysorbate 20, more preferably polysorbate 80.
6. The pharmaceutical composition according to claim 5, wherein the concentration of the surfactant is 0.05 mg/mL to 0.6 mg/mL, preferably 0.1 mg/mL to 0.4 mg/mL, and more preferably about 0.2 mg/mL.
7. The pharmaceutical composition according to any of claims 1 to 6, further comprising a stabilizer, wherein the stabilizer is a sugar; preferably, the sugar is selected from the group consisting of sucrose, trehalose, mannitol and sorbitol; more preferably, the sugar is sucrose.
8. The pharmaceutical composition according to claim 7, wherein the concentration of

the sugar is 60 mg/mL to 90 mg/mL, preferably 70 mg/mL to 80 mg/mL, and most preferably about 75 mg/mL.

9. The pharmaceutical composition according to any of claims 1 to 8, comprising:

- 5 (a) 10 mg/mL to 200 mg/mL anti-ANGPTL3 antibody or antigen-binding fragment thereof,
- (b) 5 mM to 30 mM acetate buffer,
- (c) 60 mg/mL to 90 mg/mL sucrose, and
- (d) 0.05 mg/mL to 0.6 mg/mL polysorbate 80,
- 10 wherein the pharmaceutical composition preferably has a pH of 4.5 to 6.5, and more preferably has a pH of 5.0 to 5.4.

10. The pharmaceutical composition according to any of claims 1 to 9, comprising:

- (a) about 100 mg/mL anti-ANGPTL3 antibody or antigen-binding fragment thereof,
- 15 (b) 5 mM to 15 mM acetic acid-sodium acetate buffer,
- (c) 60 mg/mL to 90 mg/mL sucrose, and
- (d) 0.1 mg/mL to 0.4 mg/mL polysorbate 80,
- wherein the pharmaceutical composition preferably has a pH of 5.0 to 5.4, and more preferably has a pH of about 5.2.

11. The pharmaceutical composition according to any of claims 1 to 10, wherein the anti-ANGPTL3 antibody or the antigen-binding fragment thereof is a murine, chimeric or humanized antibody; preferably, the light and heavy chain FR sequences of the humanized antibody are derived from human germline light and heavy chain FRs,
25 respectively.

12. The pharmaceutical composition according to any of claims 1 to 11, wherein the amino acid sequence of the heavy chain variable region is set forth in SEQ ID NO: 17 or has at least 90% sequence identity thereto, and the amino acid sequence of the light chain
30 variable region is set forth in SEQ ID NO: 18 or has at least 90% sequence identity thereto.

13. The pharmaceutical composition according to any of claims 1 to 12, wherein the anti-ANGPTL3 antibody or the antigen-binding fragment thereof comprises an antibody heavy chain and an antibody light chain, wherein: the amino acid sequence of the heavy
35 chain is set forth in SEQ ID NO: 21 or has at least 90% sequence identity thereto, and the amino acid sequence of the light chain is set forth in SEQ ID NO: 22 or has at least 90% sequence identity thereto.

14. A method for preparing the pharmaceutical composition according to any of claims 1
40 to 13, comprising the step of subjecting a stock solution of the anti-ANGPTL3 antibody or the antigen-binding fragment thereof to a buffer exchange, wherein the buffer is

preferably an acetic acid-sodium acetate buffer.

15. A lyophilized formulation comprising an anti-ANGPTL3 antibody or an antigen-binding fragment thereof, wherein the lyophilized formulation is obtained by lyophilizing the pharmaceutical composition according to any of claims 1 to 13; preferably, the lyophilizing comprises the steps of pre-freezing, primary drying and secondary drying in sequence.

16. A reconstituted solution comprising an anti-ANGPTL3 antibody or an antigen-binding fragment thereof, wherein the reconstituted solution is obtained by reconstituting the lyophilized formulation according to claim 15.

17. An article of manufacture, comprising a container, wherein the container contains the pharmaceutical composition according to any of claims 1 to 13, or the lyophilized formulation according to claim 15, or the reconstituted solution according to claim 16.

18. Use of the pharmaceutical composition according to any of claims 1 to 13, or the lyophilized formulation according to claim 15, or the reconstituted solution according to claim 16, in the preparation of a medicament for treating and/or preventing a disease or disorder;

wherein preferably, the disease or disorder is selected from one or more of hyperlipidemia, hyperlipoproteinemia, dyslipidemia, cardiovascular diseases or disorders, cancer or tumors, non-neoplastic angiogenesis-related diseases or disorders, and inflammatory diseases or disorders;

more preferably, the disease or disorder is selected from one or more of atherosclerotic dyslipidemia, diabetic dyslipidemia, hypertriglyceridemia, hypercholesterolemia, chylomicronemia, mixed dyslipidemia, lipodystrophy, lipoatrophy, atherosclerosis, aneurysm, hypertension, angina pectoris, strokes, cerebrovascular diseases, congestive heart failure, coronary artery disease, myocardial infarction, peripheral vascular disease, acute pancreatitis, nonalcoholic steatohepatitis (NASH), blood glucose abnormality, age-related macular degeneration, central or branch retinal vein occlusion, diabetic retinopathy, retinopathy of prematurity, arthritis, rheumatoid arthritis (RA), and psoriasis.