

CLAIMS

1. An aqueous liquid pharmaceutical formulation of TACI-Fc fusion protein, comprising TACI-Fc fusion protein, 85-125 mmol/L mannitol, 35-45 mmol/L sucrose, 50-100 mmol/L arginine hydrochloride, and 8-12 mmol/L histidine hydrochloride, wherein the TACI-Fc fusion protein has an amino acid sequence set forth in SEQ ID NO: 1.

2. The aqueous liquid pharmaceutical formulation according to claim 1, wherein the formulation comprises histidine hydrochloride at a concentration of about 10 mmol/L; and arginine hydrochloride at a concentration of 70-95 mmol/L, 75-90 mmol/L, about 90 mmol/L, or about 75 mmol/L.

3. The aqueous liquid pharmaceutical formulation according to claim 1 or 2, wherein the formulation comprises sucrose at a concentration of about 40 mmol/L.

4. The aqueous liquid pharmaceutical formulation according to any one of claims 1-3, wherein the formulation comprises mannitol at a concentration of 90-120mmol/L, about 120 mmol/L, or about 90 mmol/L.

5. The aqueous liquid pharmaceutical formulation according to any one of claims 1-4, wherein the formulation comprises the TACI-Fc fusion protein at a concentration of 5-240 mg/mL, 50-100 mg/mL, or 80-100 mg/mL.

6. The aqueous liquid pharmaceutical formulation according to claim 5, wherein the formulation comprises 90-120 mmol/L mannitol, 75-125 mmol/L arginine hydrochloride, and 80-100 mg/mL TACI-Fc fusion protein.

7. The aqueous liquid pharmaceutical formulation according to any one of claims 1-6, comprising 1-10% (w/v, g/100 mL) of the TACI-Fc fusion protein, preferably 6-10% (w/v, g/100 mL) of the TACI-Fc fusion protein.

8. The aqueous liquid pharmaceutical formulation according to claim 6 or 7, wherein the formulation comprises about 90 mmol/L mannitol, about 40 mmol/L sucrose, about 90 mmol/L arginine hydrochloride, about 10 mmol/L histidine hydrochloride, and about 80 mg/mL TACI-Fc fusion protein.

9. The aqueous liquid pharmaceutical formulation according to claim 6 or 7, wherein the formulation comprises about 120 mmol/L mannitol, about 40 mmol/L sucrose, about 75 mmol/L arginine hydrochloride, about 10 mmol/L histidine hydrochloride, and about 80 mg/mL TACI-Fc fusion protein.

10. The aqueous liquid pharmaceutical formulation according to any one of claims 1-9, wherein the formulation has a pH of 4.0 to 8.0, preferably 4.5 to 7.0, 5.0 to 6.0, or about 5.5.

11. A lyophilized pharmaceutical formulation obtained by lyophilization of the aqueous liquid pharmaceutical formulation according to any one of claims 1-10.

12. The lyophilized pharmaceutical formulation according to claim 11, wherein the aqueous liquid pharmaceutical formulation comprises about 90 mmol/L mannitol, about 40 mmol/L sucrose, about 90 mmol/L arginine hydrochloride, about 10 mmol/L histidine hydrochloride, and about 80 mg/mL TACI-Fc fusion protein, and has a pH of 5.0 to 6.0.

13. The lyophilized pharmaceutical formulation according to claim 11, wherein the aqueous liquid pharmaceutical formulation comprises about 120 mmol/L mannitol, about 40 mmol/L

sucrose, about 75 mmol/L arginine hydrochloride, about 10 mmol/L histidine hydrochloride, and about 80 mg/mL TACI-Fc fusion protein, and has a pH of 5.0 to 6.0.

14. The lyophilized pharmaceutical formulation according to claim 11, wherein the aqueous liquid pharmaceutical formulation comprises about 16.4 mg/mL mannitol, about 13.7 mg/mL sucrose, about 19.0 mg/mL arginine hydrochloride, and about 2.1 mg/mL histidine hydrochloride.

15. The lyophilized pharmaceutical formulation according to claim 11, wherein the aqueous liquid pharmaceutical formulation comprises about 21.9 mg/mL mannitol, about 13.7 mg/mL sucrose, about 15.8 mg/mL arginine hydrochloride, and about 2.1 mg/mL histidine hydrochloride.

16. The pharmaceutical formulation according to any one of claims 1-15 for use as a medicament.

17. The pharmaceutical formulation according to claim 16, wherein the autoimmune disease is selected from the group consisting of systemic lupus erythematosus, rheumatoid arthritis, neuromyelitis optica spectrum disorder (NMOSD), multiple sclerosis (MS), and Sjogren's syndrome.

18. The pharmaceutical formulation according to claim 17, wherein the NMOSD comprises neuromyelitis optica, recurrent optic neuritis, longitudinally extending transverse myelitis, optic-spinal form of multiple sclerosis, long-term transverse myelitis, unilateral or bilateral optic neuritis, optic neuritis or myelitis accompanying with autoimmune disease, optic neuritis or myelitis accompanying with symptomatic or asymptomatic intracranial lesions.

19. The pharmaceutical formulation according to any one of claims 1-15 for use as a medicament in the treatment of lymphoma.

20. The pharmaceutical formulation according to claim 19, wherein the lymphoma is selected from the group consisting of chronic lymphocytic leukemia, multiple myeloma, and B lymphocyte lymphoma.

21. A method for preparing a TACI-Fc fusion protein pharmaceutical formulation, comprising: (1) preparing the formulation according to any one of claims 1-15; and (2) evaluating the stability of the TACI-Fc fusion protein in the formulation.