

CLAIMS

1. A pharmaceutical composition that comprises:
 - (a) 10 mg/mL of Inebilizumab;
 - (b) 20 mM histidine/histidine hydrochloride;
 - (c) 70 mM NaCl;
 - (d) 106 mM trehalose dihydrate; and
 - (e) 0.01% (w/v) polysorbate 80.
2. A pharmaceutical composition that comprises from 250 mg to 350 mg of an antibody that comprises a variable heavy chain and variable light chain that comprise SEQ ID NO: 1 and SEQ ID NO: 2, respectively.
3. The pharmaceutical composition of claim 2, wherein the antibody is Inebilizumab.
4. The pharmaceutical composition of any one of claims 1-3, wherein the pharmaceutical composition comprises a pH of 6.
5. A vial comprising the pharmaceutical composition of any one of claims 1-4.
6. The vial of claim 5, wherein the vial is 10-mL.
7. A pharmaceutical composition according to any one of claims 1-6 for use in the treatment of an autoimmune disease.
8. The pharmaceutical composition for use of claim 7, wherein the use is selected from:
 - (a) treating neuromyelitis optica spectrum disorder (NMOSD);
 - (b) reducing active MRI lesions in a subject diagnosed with NMOSD;
 - (c) reducing Aquaporin-4 (AQP4)-IgG titers in a AQP4-IgG positive subject in need of treatment for NMOSD;
 - (d) reducing NMOSD-related disability in a subject diagnosed with NMOSD; or
 - (e) reducing NMOSD-related attacks in a subject in need of treatment for NMOSD.
9. Use of a composition comprising: (a) 10 mg/mL of Inebilizumab; (b) 20 mM histidine/histidine hydrochloride; (c) 70 mM NaCl; (d) 106 mM trehalose dihydrate; and (e) 0.01% (w/v) polysorbate 80 in the manufacture of a medicament for treating neuromyelitis optica spectrum disorder (NMOSD) in a subject.
10. The use of claim 9, wherein the medicament comprises a pH of 6.
11. The use of claim 9, wherein the medicament is to be administered at a dose of 300 mg.
12. The use of claim 9, wherein the medicament is to be administered every 6 months.

13. The use of claim 9, wherein the medicament is effective in reducing worsening of Expanded Disability Status Scale (EDSS) in the subject, as determined by: a worsening of fewer than 2 points in EDSS score if the subject has a baseline score of 0; a worsening of fewer than 1 point if the subject has a baseline score of 1 to 5; or a worsening of less than 0.5 point if the subject has a baseline score of 5.5 or more, when the medicament is to be administered to the subject.
14. The use of claim 9, wherein the medicament is effective in reducing a number of lesions, as determined by magnetic resonance imaging (MRI), when the medicament is to be administered to the subject.
15. The use of claim 14, wherein the lesions are T2 MRI lesions.
16. The use of claim 14, wherein the lesions are new MRI lesions.
17. The use of claim 9, wherein the medicament is effective in reducing worsening of a modified Ranking score when the medicament is to be administered to the subject.
18. The use of claim 9, wherein the medicament is effective in reducing frequency of in-patient hospitalizations related to the NMOSD when the medicament is to be administered to the subject.
19. The use of claim 9, wherein the medicament is effective in reducing risk of an NMOSD-related attack, as determined by appearance of a new symptom of the NMOSD or worsening of an existing symptom of the NMOSD, when the medicament is to be administered to the subject.
20. A pharmaceutical composition that comprises from 250 mg to 350 mg of an antibody that comprises a variable heavy chain and variable light chain that comprise SEQ ID NO: 1 and SEQ ID NO: 2, respectively for use in therapy.
21. A pharmaceutical composition that comprises from 250 mg to 350 mg of an antibody that comprises a variable heavy chain and variable light chain that comprise SEQ ID NO: 1 and SEQ ID NO: 2, respectively for use in the treatment of neuromyelitis optica spectrum disorder (NMOSD).
22. The pharmaceutical composition for use of claims 20-21, wherein the pharmaceutical composition further comprises: histidine/histidine hydrochloride; NaCl; trehalose dihydrate; and polysorbate 80.

23. The pharmaceutical composition for use of claim 22, wherein the pharmaceutical composition comprises: 20 mM histidine/histidine hydrochloride; 70 mM NaCl; 106 mM trehalose dihydrate; and 0.01% (w/v) polysorbate 80.
24. The pharmaceutical composition for use of any one of claims 20-23, wherein the pharmaceutical composition comprises 300 mg of the antibody.
25. The pharmaceutical composition for use of claim 24, wherein the antibody is Inebilizumab.
26. The pharmaceutical composition for use of any one of claims 20-25, wherein a corticosteroid is to be co-administered to a subject in need in an amount sufficient to provide prophylaxis against a neuromyelitis optica spectrum disorder (NMOSD) attack with the pharmaceutical composition.
27. The pharmaceutical composition for use of claim 26, wherein the corticosteroid is prednisone.
28. The pharmaceutical composition for use of claim 26, wherein the amount sufficient to provide prophylaxis against the NMOSD attack is 20 mg/day.
29. The pharmaceutical composition for use of claim 26, wherein the amount is tapered after a two week period.