

CLAIMS

1. A formulation comprising:
 - an anti-Respiratory Syncytial Virus (RSV) F protein monoclonal antibody;
 - an ionic excipient comprising lysine hydrochloride or arginine hydrochloride; and
 - one or more buffers comprising histidine,wherein the monoclonal antibody comprises light chain CDR sequences:
 - CDR-L1 of SEQ ID NO: 3
 - CDR-L2 of SEQ ID NO: 4
 - CDR-L3 of SEQ ID NO: 5and heavy chain CDR sequences:
 - CDR-H1 of SEQ ID NO: 6
 - CDR-H2 of SEQ ID NO: 7
 - CDR-H3 of SEQ ID NO: 8,wherein the monoclonal antibody is present at a concentration of about 50mg/ml or greater, wherein the ionic excipient is present at a concentration of about 75 mM to about 120 mM, wherein the one or more buffers is present at a concentration of about 10 mM to about 50 mM, and wherein the formulation has a pH of about 5.5 to about 7.5.
2. A formulation according to claim 1, wherein the monoclonal antibody comprises a light chain variable region comprising a sequence with at least 90% identity to SEQ ID NO: 9 and a heavy chain variable region comprising a sequence with at least 90% identity to SEQ ID NO: 10.
3. A formulation according to claim 1, wherein the monoclonal antibody comprises a light chain variable region comprising a sequence with at least 95% identity to SEQ ID NO: 9 and a heavy chain variable region comprising a sequence with at least 95% identity to SEQ ID NO: 10.

4. A formulation according to claim 1, wherein the monoclonal antibody comprises a light chain variable region sequence of SEQ ID NO: 9 and a heavy chain variable region sequence of SEQ ID NO: 10.
5. A formulation according to any one of the preceding claims, wherein the monoclonal antibody comprises an IgG1 heavy chain constant region comprising an Fc domain comprising a modified CH2 region.
6. A formulation according to claim 5, wherein the modified CH2 region comprises amino acid substitutions M252Y, S254T, and T256E.
7. A formulation according to any one of the preceding claims, wherein the monoclonal antibody comprises a light chain sequence of SEQ ID NO: 1 and a heavy chain sequence of SEQ ID NO: 2.
8. A formulation according to any one of the preceding claims, wherein the ionic excipient comprises arginine hydrochloride.
9. A formulation according to claim 8, wherein the arginine hydrochloride is present at a concentration of about 80 mM.
10. A formulation according to any one of the preceding claims, further comprising sucrose.
11. A formulation according to claim 10, wherein the sucrose is present at a concentration of about 100 mM to about 140 mM.
12. A formulation according to claim 10 or claim 11, wherein the sucrose is present at a concentration of about 120 mM.
13. A formulation according to any one of the preceding claims, wherein the one or more buffers is histidine, histidine hydrochloride, or a combination thereof.

14. A formulation according to claim 13, wherein the one or more buffers is L-histidine, L-histidine hydrochloride, or a combination thereof.
15. A formulation according to claim 13 or claim 14, wherein the one or more buffers is present at a concentration of about 30 mM
16. A formulation according to any one of the preceding claims, further comprising polysorbate-80.
17. A formulation according to claim 16, wherein the polysorbate-80 is present at a concentration of about 0.001% (w/v) to about 0.07% (w/v).
18. A formulation according to claim 16 or claim 17, wherein the polysorbate-80 is present in the formulation at a concentration of about 0.02% (w/v) to about 0.07% (w/v).
19. A formulation according to any one of claims 16 to 18, wherein the polysorbate-80 is present at a concentration of about 0.02% (w/v) or about 0.04% (w/v).
20. A formulation according to any one of the preceding claims, wherein the monoclonal antibody is present at a concentration of about 75 mg/ml to about 200 mg/ml.
21. A formulation according to any one of the preceding claims, wherein the monoclonal antibody is present at a concentration of about 100 mg/ml to about 165 mg/ml.
22. A formulation according to any one of the preceding claims, wherein the monoclonal antibody is present at a concentration of about 100 mg/ml.
23. A formulation according to any one of the preceding claims, further comprising one or more additional excipients.

24. A formulation according to claim 23, wherein the one or more additional excipients is selected from one or more sugars, salts, amino acids, polyols, chelating agents, emulsifiers and/or preservatives.
25. A formulation according to any one of the preceding claims, wherein the formulation has a pH of about 5.7 to about 6.3.
26. A formulation according to claim 25, wherein the formulation has a pH of about 6.0.
27. A formulation comprising:
an anti-Respiratory Syncytial Virus (RSV) F protein monoclonal antibody comprising a CDR-L1 sequence of QASQDIVNYLN (SEQ ID NO: 3), a light chain CDR-L2 sequence of VASNLET (SEQ ID NO: 4), and a light chain CDR-L3 sequence of QQYDNLPLT (SEQ ID NO: 5) and a heavy chain comprising a CDR-H1 sequence of DYIIN (SEQ ID NO: 6), a CDR-H2 sequence of GIIPVLGTVHYGPKFQG (SEQ ID NO: 7), and a CDR-H3 sequence of ETALVVSETYLPHYFDN (SEQ ID NO: 8), wherein the monoclonal antibody is present at a concentration of about 75 mg/ml to about 200 mg/ml;
about 75 mM to about 100 mM arginine hydrochloride;
about 10 mM to about 50 mM histidine, histidine hydrochloride, or a combination thereof;
about 100 mM to about 140 mM sucrose; and
about 0.02% (w/v) to about 0.07% (w/v) polysorbate-80,
wherein the formulation has a pH of about 5.5 to 6.5.
28. A formulation according to claim 27, wherein the monoclonal antibody comprises a light chain variable region comprising a sequence with at least 90% identity to SEQ ID NO: 9 and a heavy chain variable region comprising a sequence with at least 90% identity to SEQ ID NO: 10.
29. A formulation according to claim 27, wherein the monoclonal antibody comprises a light chain variable region comprising a sequence with at least 95% identity to SEQ ID NO: 9

- and a heavy chain variable region comprising a sequence with at least 95% identity to SEQ ID NO: 10.
30. A formulation according to claim 27, wherein the monoclonal antibody comprises a light chain variable region sequence of SEQ ID NO: 9 and a heavy chain variable region sequence of SEQ ID NO: 10.
 31. A formulation according to claim 27, wherein the monoclonal antibody comprises a light chain sequence of SEQ ID NO: 1 and a heavy chain sequence of SEQ ID NO: 2.
 32. A formulation comprising:
an anti-Respiratory Syncytial Virus (RSV) F protein monoclonal antibody comprising a light chain sequence of SEQ ID NO: 1 and a heavy chain sequence of SEQ ID NO: 2,
wherein the monoclonal antibody is present at a concentration of about 75 mg/ml to about 200 mg/ml;
about 80 mM arginine hydrochloride;
about 30 mM histidine, histidine hydrochloride, or a combination thereof;
about 120 mM sucrose; and
about 0.02% (w/v) to about 0.07% (w/v) polysorbate-80,
wherein the formulation has a pH of about 5.5 to about 6.5.
 33. A formulation according to any one of the preceding claims, wherein the formulation is a pharmaceutical formulation.
 34. A pharmaceutical formulation according to claim 33 for use as a medicament.
 35. A formulation according to any one of claims 1 to 34, wherein the formulation is liquid.
 36. A formulation according to any one of claims 1 to 34, wherein the formulation is lyophilized.

37. Use of a pharmaceutical formulation according to claim 33 in the manufacture of a medicament for the prevention of RSV lower respiratory tract disease in a subject.