

What is claimed is:

1. Use of a pharmaceutical composition in the manufacture of a medicament for the prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract infection (LRTI) in a subject, wherein the pharmaceutical composition comprises an anti-RSV monoclonal antibody or an antigen-binding fragment thereof and wherein:

(a) if the subject weighs < 5 kg and is in the first year of life and/or is entering or experiencing their first RSV season, then the anti-RSV monoclonal antibody or antigen-binding fragment thereof is present in the pharmaceutical composition at a single fixed dose of 50 mg,

(b) if the subject weighs ≥ 5 kg and is in the first year of life and/or is entering or experiencing their first RSV season, then the anti-RSV monoclonal antibody or antigen-binding fragment thereof is present in the pharmaceutical formulation at a single fixed dose of 100 mg, and

(c) if the subject is in the second year of life and/or is entering or experiencing their second RSV season, and the subject is at a high risk of severe RSV infection, then the anti-RSV monoclonal antibody or antigen-binding fragment thereof is present in the pharmaceutical formulation at a single fixed dose of 200 mg;

wherein the anti-RSV monoclonal antibody or antigen-binding fragment thereof comprises a light chain variable region comprising a CDR-L1 of SEQ ID NO: 3, a CDR-L2 of SEQ ID NO: 4, and a CDR-L3 of SEQ ID NO: 5, and a heavy chain variable region comprising a CDR-H1 of SEQ ID NO: 6, a CDR-H2 of SEQ ID NO: 7, and a CDR-H3 of SEQ ID NO: 8.

2. The use of claim 1, wherein the subject at high risk of severe RSV infection has chronic lung disease, congenital heart disease, Down's Syndrome, primary immunodeficiency, and/or acquired immunodeficiency.

3. The use of claim 1 or claim 2, wherein the subject in the first year of life and/or entering or experiencing their first RSV season has chronic lung disease, congenital heart disease, Down's Syndrome, primary immunodeficiency, and/or acquired immunodeficiency.

4. The use of any one of claims 1 to 3, wherein the subject in the second year of life and/or entering or experiencing their second RSV season weighs ≥ 5 kg.

5. The use of any one of claims 1 to 4, wherein the subject weighs ≥ 5 kg and is in the first year of life and the anti-RSV monoclonal antibody or antigen-binding fragment thereof is present in the pharmaceutical composition at a single fixed dose of 100 mg; or the subject is in the second year of life and the anti-RSV monoclonal antibody or antigen-binding fragment thereof is present in the pharmaceutical composition at a single fixed dose of 200 mg.

6. The use of any one of claims 1 to 5, wherein the subject weighs ≥ 5 kg and is entering or experiencing their first RSV season and the anti-RSV monoclonal antibody or antigen-binding fragment thereof is present in the pharmaceutical composition at a single fixed dose of 100 mg; or the subject is entering or experiencing their second RSV season and the anti-RSV monoclonal antibody or antigen-binding fragment thereof is present in the pharmaceutical composition at a single fixed dose of 200 mg.

7. The use of any one of claims 1 to 3, wherein the subject weighs < 5 kg, is in the first year of life, and is entering their first RSV season, and the anti-RSV monoclonal antibody or antigen-binding fragment thereof is present in the pharmaceutical composition at a single fixed dose of 50 mg; or the subject weighs ≥ 5 kg, is in the first year of life, and is entering their first RSV season, and the anti-RSV monoclonal antibody or antigen-binding fragment thereof is present in the pharmaceutical composition at a single fixed dose of 100 mg.

8. The use of any one of claims 1 to 7, wherein the light chain variable region comprises SEQ ID NO: 9 and the heavy chain variable region comprises SEQ ID NO: 10.

9. The use of any one of claims 1 to 7, wherein the anti-RSV monoclonal antibody or antigen-binding fragment thereof comprises a light chain comprising SEQ ID NO: 1 and a heavy chain comprising SEQ ID NO: 2.

10. The use of any one of claims 1 to 7, wherein the anti-RSV monoclonal antibody is nirsevimab.

11. The use of any one of claims 1 to 10, wherein the anti-RSV monoclonal antibody or antigen-binding fragment thereof is present at a concentration of 100 mg/mL.

12. The use of any one of claims 1 to 11, wherein the medicament further comprises an ionic excipient, a buffer, a sugar, and a surfactant, wherein

the ionic excipient comprises 50 mM to 150 mM arginine or lysine,

the buffer comprises 20 mM to 50 mM histidine,

the sugar comprises 100 mM to 140 mM sucrose, and

the surfactant comprises 0.01% (w/v) to 0.05% (w/v) polysorbate-80,

wherein the pharmaceutical composition has a pH of 5.5 to 6.5.

13. The use of claim 12, wherein:

the ionic excipient comprises 80 mM L-arginine hydrochloride,

the buffer comprises 30 mM L-histidine, L-histidine hydrochloride, or a combination thereof,

the sugar comprises 120 mM sucrose,

the surfactant comprises 0.02% (w/v) or 0.04% (w/v) polysorbate-80, and

the pharmaceutical composition has a pH of 5.5 to 6.5.

14. The use of any one of claims 1 to 13, wherein the medicament is capable of preventing medically attended RSV-confirmed LRTI or preventing RSV LRTI hospitalization.

15. The use of any one of claims 1 to 14, wherein the amount of the single fixed dose is selected to maintain serum concentrations of the anti-RSV monoclonal antibody or antigen-binding fragment thereof in the subject above an $AUC_{0-\infty}$ of 12 day·mg/mL.

16. The use of any one of claims 1 to 15, wherein the medicament is formulated for intramuscular administration.

17. The use of any one of claims 1 to 16, wherein the medicament is to be administered at the beginning of the RSV season.

18. The use of any one of claims 1 to 17, wherein the medicament is to be administered in combination with at least one other agent.

19. The use of claim 18, wherein the at least one other agent comprises an anti-viral agent.

20. A pharmaceutical unit dose comprising 50 mg, 100 mg, or 200 mg of

an anti-Respiratory Syncytial Virus (RSV) monoclonal antibody or antigen-binding fragment thereof, wherein the anti-RSV monoclonal antibody or antigen-binding fragment thereof is present in the pharmaceutical unit dose at a concentration of 100 mg/ml and comprises

a light chain variable region comprising a CDR-L1 of SEQ ID NO: 3, a CDR-L2 of SEQ ID NO: 4, and a CDR-L3 of SEQ ID NO: 5, and

a heavy chain variable region comprising a CDR-H1 of SEQ ID NO: 6, a CDR-H2 of SEQ ID NO: 7, and a CDR-H3 of SEQ ID NO: 8.

21. A pharmaceutical unit dose comprising 100 mg or 200 mg of an anti-Respiratory Syncytial Virus (RSV) monoclonal antibody or antigen-binding fragment thereof, wherein the anti-RSV

monoclonal antibody or antigen-binding fragment thereof is present in the pharmaceutical unit dose at a concentration of 100 mg/ml and comprises

a light chain variable region comprising a CDR-L1 of SEQ ID NO: 3, a CDR-L2 of SEQ ID NO: 4, and a CDR-L3 of SEQ ID NO: 5, and

a heavy chain variable region comprising a CDR-H1 of SEQ ID NO: 6, a CDR-H2 of SEQ ID NO: 7, and a CDR-H3 of SEQ ID NO: 8.

22. The pharmaceutical unit dose of claim 20 or claim 21, wherein the anti-RSV monoclonal antibody or antigen-binding fragment thereof comprises a light chain variable region comprising SEQ ID NO: 9 and a heavy chain variable region comprising SEQ ID NO: 10.

23. The pharmaceutical unit dose of claim 20 or claim 21, wherein the anti-RSV monoclonal antibody or antigen-binding fragment thereof comprises a light chain comprising SEQ ID NO: 1 and a heavy chain comprising SEQ ID NO: 2.

24. The pharmaceutical unit dose of claim 20 or claim 21, wherein the anti-RSV monoclonal antibody is nirsevimab.

25. The pharmaceutical unit dose of any one of claims 20 to 24, wherein the pharmaceutical unit dose is formulated for intramuscular administration.

26. The pharmaceutical unit dose of any one of claims 20 to 25, wherein the pharmaceutical unit dose is 100 mg.

27. The pharmaceutical unit dose of any one of claims 20 to 25, wherein the pharmaceutical unit dose is 200 mg.

28. The pharmaceutical unit dose of any one of claims 20 to 27, further comprising an ionic excipient, a buffer, a sugar, and a surfactant, wherein

the ionic excipient comprises 50 mM to 150 mM arginine or lysine,

the buffer comprises 20 mM to 50 mM histidine,

the sugar comprises 100 mM to 140 mM sucrose, and

the surfactant comprises 0.01% (w/v) to 0.05% (w/v) polysorbate-80,

wherein the pharmaceutical unit dose has a pH of 5.5 to 6.5.

29. The pharmaceutical unit dose of claim 28, wherein

the ionic excipient comprises 80 mM L-arginine hydrochloride,

the buffer comprises 30 mM L-histidine, L-histidine hydrochloride, or a combination thereof,

the sugar comprises 120 mM sucrose,

the surfactant comprises 0.02% (w/v) to 0.04% (w/v) polysorbate-80, and

the pharmaceutical unit dose has a pH of 5.5 to 6.5.

30. The pharmaceutical unit dose of claim 28 or claim 29, wherein the anti-RSV monoclonal antibody or antigen-binding fragment thereof in the pharmaceutical unit dose is stable at 2°C to 8°C for at least 3 months as determined by high performance size exclusion chromatography (HPSEC).