

What is claimed is:

1. ~~A method~~ Use of treating or preventing RSV infection a pharmaceutical composition in a patient in need thereof, the method comprising:

~~determining the age~~manufacture of the patient;

~~in response to the patient being in the second year of life, administering a composition comprising a fixed dose of 200 milligrams (mg) of 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:

~~in response to~~(a) if the patient being~~subject weighs < 5 kg and is in the first year of life;~~
~~determining the patient's weight; and~~

~~in response to the patient having a weight of at least 5 kilograms (kg), administering a composition comprising a fixed dose of 100 mg of an anti-~~or is entering or experiencing their first
~~RSV monoclonal antibody or an antigen binding fragment thereof,~~

~~wherein~~season, then ~~the anti-RSV monoclonal antibody or an antigen-binding fragment thereof has an IC₅₀ of 5.0 ng/ml or less is present in a neutralization assay of RSV A, or has an IC₅₀ of 3.0 ng/ml or less in a neutralization assay of RSV B9320, or both.~~

2. ~~A method of treating or preventing RSV infection in a patient in need thereof, the method comprising administering to a patient having a weight of at least 5 kilograms (kg) a fixed dose of 200 milligrams (mg) of an anti-RSV monoclonal antibody or an antigen binding fragment thereof, wherein the anti-RSV monoclonal antibody or an antigen binding fragment thereof has an IC₅₀ of 5.0 ng/ml or less in a neutralization assay of RSV A, or has an IC₅₀ of 3.0 ng/ml or less in a neutralization assay of RSV B9320, or both.~~

3. ~~A method of treating or preventing RSV infection in a patient in need thereof, the method comprising:~~

~~determining the weight of a patient~~

~~administering to a patient having a weight of at least 5 kilograms (kg) a fixed dose of 200 milligrams (mg) of an anti-RSV monoclonal antibody or an antigen binding fragment thereof, wherein the anti-RSV monoclonal antibody or an antigen binding fragment thereof has an IC₅₀ of~~

5.0 ng/ml or less in a neutralization assay of RSV A, or has an IC₅₀ of 3.0 ng/ml or less in a neutralization assay of RSV B9320, or both;

administering to a patient having a weight of up to 5 kg a fixed dose of 100 mg of an anti-RSV monoclonal antibody or an antigen binding fragment thereof, wherein the anti-RSV monoclonal antibody or an antigen binding fragment thereof has an IC₅₀ of 5.0 ng/ml or less in a neutralization assay of RSV A, or has an IC₅₀ of 3.0 ng/ml or less in a neutralization assay of RSV B9320, or both.

4. A method of treating or preventing RSV infection in a patient in need thereof, the method comprising

determining the age of the patient; and

administering a fixed dose of 200 milligrams (mg) of an anti-RSV monoclonal antibody or an antigen binding fragment thereof to a patient aged 3 months or older, wherein the anti-RSV monoclonal antibody or an antigen binding fragment thereof has an IC₅₀ of 5.0 ng/ml or less in a neutralization assay of RSV A, or has an IC₅₀ of 3.0 ng/ml or less in a neutralization assay of RSV B9320 or both.

5. A method of treating or preventing RSV infection in a patient in need thereof, the method comprising:

determining the age of a patient;

administering a fixed dose of 200 milligrams (mg) of an anti-RSV monoclonal antibody or an antigen binding fragment thereof to a patient aged 3 months or older;

administering a fixed dose of 100 mg of an anti-RSV monoclonal antibody or an antigen binding fragment thereof to a patient aged up to 3 months,

wherein the anti-RSV monoclonal antibody or an antigen binding fragment thereof has an IC₅₀ of 5.0 ng/ml or less in a neutralization assay of RSV A, or has an IC₅₀ of 3.0 ng/ml or less in a neutralization assay of RSV B9320, or both.

6. A method of treating or preventing RSV infection in a patient in need thereof, the method comprising:

determining the age of a patient;

administering a fixed dose of 200 milligrams (mg) of an anti-RSV monoclonal antibody or an antigen binding fragment thereof to a patient aged 6 months or older;

administering a fixed dose of 100 mg of an anti-RSV monoclonal antibody or an antigen binding fragment thereof to a patient aged up to 6 months;

wherein the anti-RSV monoclonal antibody or an antigen binding fragment thereof has an IC₅₀ of 5.0 ng/ml or less in a neutralization assay of RSV A, or has an IC₅₀ of 3.0 ng/ml or less in a neutralization assay of RSV B9320, or both.

7. A method of treating or preventing RSV infection in a patient in need thereof, the method comprising:

determining whether the patient is experiencing their first or second RSV season;

in response to the patient experiencing their second RSV season, administering a composition comprising a fixed dose of 200 milligrams (mg) of an anti-RSV monoclonal antibody or an antigen binding fragment thereof;

in response to the patient experiencing their first RSV season, determining the patient's weight; and

in response to the patient having a weight of at least 5 kilograms (kg), administering a composition comprising a fixed dose of 100 mg of an anti-RSV monoclonal antibody or an antigen binding fragment thereof;

wherein the anti-RSV monoclonal antibody or an antigen binding fragment thereof has an IC₅₀ of 5.0 ng/ml or less in a neutralization assay of RSV A, or has an IC₅₀ of 3.0 ng/ml or less in a neutralization assay of RSV B9320, or both.

8. A method of treating or preventing RSV infection in a patient in need thereof, the method comprising

determining whether the patient is experiencing their first or second RSV season; and

administering a fixed dose of 200 milligrams (mg) of an anti-RSV monoclonal antibody or an antigen binding fragment thereof to a patient experiencing their second RSV season, wherein the anti-RSV monoclonal antibody or an antigen binding fragment thereof has an IC₅₀ of 5.0 ng/ml or less in a neutralization assay of RSV A, or has an IC₅₀ of 3.0 ng/ml or less in a neutralization assay of RSV B9320 or both.

9. A method of treating or preventing RSV infection in a patient in need thereof, the method comprising:

determining whether the patient is experiencing their first or second RSV season;

administering a fixed dose of 200 milligrams (mg) of an anti RSV monoclonal antibody or an antigen binding fragment thereof to a patient, wherein the patient is experiencing their second RSV season;

administering a fixed dose of 100 mg of an anti RSV monoclonal antibody or an antigen binding fragment thereof to a patient, wherein the patient is experiencing their first RSV season;

wherein the anti RSV monoclonal antibody or an antigen binding fragment thereof has an IC₅₀ of 5.0 ng/ml or less in a neutralization assay of RSV A, or has an IC₅₀ of 3.0 ng/ml or less in a neutralization assay of RSV B9320, or both.

10. The method of any one of claims 1 to 9, wherein the anti RSV monoclonal antibody comprises nirsevimab or wherein the antigen binding fragment of the anti RSV monoclonal antibody comprises an antigen binding fragment of nirsevimab.

11. The method of any one of claims 1 to 10, the method comprising administering the anti RSV monoclonal antibody or an antigen binding fragment thereof in a composition, the composition comprising an ionic excipient, a buffer, a sugar, and a surfactant,

wherein the ionic excipient comprises L-arginine hydrochloride at a concentration of 80 mM,

wherein the buffer comprises 30 mM L-histidine/L-histidine hydrochloride,

wherein the sugar comprises 120 mM sucrose,

wherein the surfactant comprises polysorbate 80 in a range of 0.01% (w/v) to 0.05% (w/v),

and

wherein the composition has a pH in a range of from 5.5 to 6.5.

12. A pharmaceutical composition for the treatment or prevention of RSV infection, the composition comprising 100 mg of nirsevimab, wherein the composition is administered to a patient in the first year of life or a patient experiencing their first RSV season, the patient having a weight of at least 5 kg.

13. ~~A pharmaceutical composition for the treatment or prevention of RSV infection, the composition comprising 200 mg of nirsevimab, wherein the composition is administered to a patient in the second year of life or a patient experiencing their second RSV season.~~

5 ~~14. The pharmaceutical composition of claim 12 or 13, wherein the patient exhibits $AUC_{0-\infty}$ of greater than 13.4 day·mg/mL, 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

10 ~~15. The pharmaceutical composition formulation at a single fixed dose of any one 100 mg, and~~

(c) if the subject is in the second year of claims 12 to 14, 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;

15 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.

20 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.

25 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.

30 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. composition~~ The use of any one of claims 1 to 11, wherein the medicament further
~~comprising~~ comprises an ionic excipient, a buffer, a sugar, and a surfactant, wherein
5 ~~wherein the ionic excipient comprises L-50 mM to 150 mM arginine hydrochloride at a~~
~~concentration of 80~~ or lysine,
the buffer comprises 20 mM to 50 mM, histidine,
~~wherein the buffer~~ sugar comprises 30 100 mM L-histidine/L-histidine hydrochloride, to 140
mM sucrose, and
10 ~~wherein the sugar comprises 120 mM sucrose,~~
~~wherein the surfactant comprises polysorbate-80 in a range of 0.01% (w/v) to 0.05% (w/v),~~
and) polysorbate-80,
wherein the pharmaceutical composition has a pH in a range of from 5.5 to 6.5.

~~16. A pharmaceutical unit dose comprising 100 mg~~ 13. The use of nirsevimab claim 12,
15 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,
20 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. said unit dose~~ 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.

25 ~~15. suitable~~ 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.

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

17. ~~A pharmaceutical unit dose comprising 200 mg~~ The use of nirsevimab ~~any one of claims 1 to 16, wherein said unit dose~~ the medicament is suitable for intramuscular administration to be administered at the beginning of the RSV season.

18.- ~~The pharmaceutical unit dose~~ use of claim 16 or 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 comprising the nirsevimab is present in a composition, the composition 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

wherein the ionic excipient comprises L-50 mM to 150 mM arginine hydrochloride at a concentration of 80 mM or lysine,

wherein the buffer comprises 30 to 50 mM histidine/L-histidine hydrochloride,

wherein the sugar comprises 120 to 140 mM sucrose, and

wherein the surfactant comprises polysorbate-80 in a range of 0.01% (w/v) to 0.05% (w/v), and) polysorbate-80,

wherein the composition pharmaceutical unit dose has a pH in a range of from 5.5 to 6.5.

29. The pharmaceutical unit dose of any one of claims 16 to 18 claim 28, wherein

the nirsevimab in 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,

composition 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
5 for at least 3 months as determined by high performance size exclusion chromatography (HPSEC).

~~20. The pharmaceutical unit dose of any one of claims 16 to 19, wherein the nirsevimab is present at a concentration of 100 mg/mL.~~

10