## CLAIMS

~~1. A method for treating nasal polyposis, the method comprising administering to a subject in need thereof a pharmaceutical composition comprising~~

**What is claimed is:**

1. Use of an antibody, or antigen binding fragment thereof, that specifically binds an interleukin-4 receptor (IL-4R~~),~~ ) for the preparation of a pharmaceutical composition for treating chronic rhinosinusitis with nasal polyposis (CRSwNP) in a subject, and wherein the antibody, or antigen ~~-~~binding fragment thereof, comprises:

   three HCDRs (HCDR1, HCDR2 and HCDR3) and three LCDRs (LCDR1, LCDR2 and LCDR3), wherein the HCDR1 comprises the amino acid sequence of SEQ ID NO:3, the HCDR2 comprises the amino acid sequence of SEQ ID NO:4, the HCDR3 comprises the amino acid sequence of SEQ ID NO:5, the LCDR1 comprises the amino acid sequence of SEQ ID NO:6, the LCDR2 comprises the amino acid sequence of SEQ ID NO:7, and the LCDR3 comprises the amino acid sequence of SEQ ID NO:8.

2. The use of claim 1, wherein the subject has chronic rhinosinusitis with bilateral nasal polyposis.

3. The use of claims 1 or 2, wherein the antibody or antigen-binding fragment thereof comprises: a heavy chain ~~and light chain CDR sequences from the heavy chain variably region (~~variable region (HCVR) ~~and~~ having the amino acid sequence of SEQ ID NO: 1; and
   a light chain variable region (LCVR) having the amino acid sequence ~~pair~~ of SEQ ID ~~NOs:1 and~~NO: 2~~, wherein the method optionally treats bilateral nasal polyposis.~~ .

   ~~2. The method of claim 1, wherein the antibody or antigen binding fragment thereof comprises light chain CDR sequences of SEQ ID NOs:6, 7, and 8, and heavy chain CDR sequences of SEQ ID NOs:3, 4 and 5.~~

4. The use of any one of claims 1-3~~. The method of claim 1~~, wherein the subject has one or more of ~~sinusitis, rhinitis,~~ asthma, aspirin hypersensitivity, or hypersensitivity to a non-steroidal anti-inflammatory drug (NSAID~~) hypersensitivity, has undergone surgery for nasal polyps, or has chronic rhinosinusitis.~~).

   ~~4.~~

5. The ~~method~~use of ~~claim~~any one of claims 1-4, wherein the ~~antibody or antigen binding fragment thereof is administered at a dose of 0.1 mg to 600 mg, 100 mg to 400 mg, or 300 mg~~subject has severe nasal polyposis.

   ~~5. The method of claim 1, wherein the antibody or antigen binding fragment thereof comprises an HCVR having the amino acid sequence of SEQ ID NO:1 and an LCVR having the amino acid sequence of SEQ ID NO:2.~~

   ~~6.~~

6. The ~~method~~use of ~~claim~~any one of claims 1-5, wherein the composition is formulated for administration as a single initial dose and one or more ~~of the following conditions are met:~~secondary doses.

   ~~(a) the pharmaceutical composition is administered to the subject systemically;~~

~~(b) the pharmaceutical composition is administered to the subject locally;~~

~~(c)~~

7. The use of claim 6, wherein the initial dose and one or more secondary doses are each about 300 mg.

8. The use of claim 6 or 7, wherein the pharmaceutical composition is ~~administered to the subject subcutaneously, intravenously, or intranasally; and~~formulated for administration every two weeks.

~~(d)~~

9. The use of any one of claims 1-8, wherein the pharmaceutical composition is formulated for subcutaneous, intravenous or intranasal administration to the subject.

10. The use of any one of claims 1-9, wherein the subject has nasal polyposis which persists after a treatment regimen with inhaled corticosteroids (INCS) or after the subject stops receiving INCS.

11. The use of any one of claims 1-10, wherein the subject is selected based on one or more of the following criteria:

i) a minimum bilateral nasal polyp score of 5;

ii) an elevated level of one or more genes selected from the group consisting of thymus and activation-regulated chemokine (TARC), eotaxin-3, periostin, carcinoembryonic antigen (CEA), and YKL-40; and

iii) an elevated level of blood eosinophils or sputum eosinophils.

12. The use of any one of claims 1-11, for improving one or more of:

a) 22-item sinonasal outcome test (SNOT-22) score;

b) nasal symptom score;

c) number of nocturnal awakenings;

d) visual analog score (VAS);

e) five-item asthma control questionnaire (ACQ5) score;

f) nasal peak inspiratory flow (NPIF);

g) University of Pennsylvania Smell fication test (UPSIT);

h) Lund-McKay Score; and

i) three-dimensional volumetric measurement of the maxillary sinus,

in particular an increase in one or both of NPIF and UPSIT and/or a decrease in one or more of SNOT-22 score, nasal symptom score, VAS, Lund-McKay Score and 3D-Volumetric Score.

13. The use of any one of claims 1-12, for decreasing a nasal polyp score.

14. The use of any one of claims 1-13, for increasing one or both of NPIF and UPSIT.

15. The use of any one of claims 9-14, wherein the pharmaceutical composition is formulated for subcutaneous administration to the subject with a pen delivery device or an autoinjector, or formulated for subcutaneous or intravenous administration with a standard syringe and needle.

16. The use of any one of claims 1-15, wherein the antibody is dupilumab.

The use of any one of claims 1-16, wherein the pharmaceutical composition is ~~administered to the subject subcutaneously at a dose of 300 mg.~~

~~7. The method of claim 1, wherein~~ formulated for administration with a second therapeutic agent ~~fulfills one or more of the following criteria:~~

17. ~~(a)~~before, after or concurrently with the second therapeutic agent ~~is administered to the subject before, after or concurrent with the pharmaceutical composition;~~.
~~(b)~~
18. The use of claim 17, wherein the second therapeutic agent is selected from the group consisting of an IgE inhibitor, an antibiotic agent, and an anti-fungal agent~~;~~.
~~(c)~~
19. The use of claim 17, wherein the second therapeutic agent comprises an intranasal corticosteroid, optionally wherein the intranasal corticosteroid is mometasone furoate nasal spray (MFNS~~);~~).
~~(d)~~
20. The use of claim 19, wherein the second therapeutic agent comprises an inhaled corticosteroid, optionally wherein the inhaled corticosteroid is fluticasone or budesonide~~; and~~.
~~(e)~~
21. The use of claim 17, wherein the second therapeutic agent comprises a long-acting $beta_2$ agonist, optionally wherein the long-acting $beta_2$ agonist is salmeterol or formoterol.

~~8.~~ The ~~method of claim 1, wherein administration of the antibody or antigen binding fragment thereof is followed by an improvement in~~use of any one ~~or more nasal polyposis associated parameters selected from the group consisting of:~~

~~a) 22-item SinoNasal Outcome Test (SNOT-22) score;~~

~~b) Nasal Symptom Score;~~

~~c) Number of nocturnal awakenings;~~

~~d) Visual Analog Score (VAS) for rhinosinusitis symptom severity;~~

~~e) Five-item Asthma Control Questionnaire (ACQ5) score;~~

f) Nasal peak inspiratory flow (NPIF) ;

g) University of Pennsylvania Smell Identification Test (UPSIT);

h) Lund-McKay Score; and

i) Three dimensional volumetric measurement of the maxillary sinus.

9. The method of claim 1, wherein administration of the antibody or antigen binding fragment thereof is followed by a decrease in nasal polyp score in the patient.

10. A method for treating nasal polyposis, said method comprising: sequentially administering to a subject in need thereof a single initial dose of a pharmaceutical composition comprising an antibody or antigen binding fragment thereof that specifically binds an interleukin-4 receptor (IL-4R), followed by one or more secondary doses of the antibody or antigen binding fragment thereof, wherein the antibody or antigen binding fragment thereof comprises heavy chain and light chain CDR sequences from the heavy chain variably region (HCVR) and light chain variable region (LCVR) sequence pair of SEQ ID NOs:1 and 2, wherein the method optionally treats bilateral nasal polyposis.

11. The method of claim 10, wherein the antibody or antigen-binding fragment thereof that specifically binds IL-4R, comprises light chain CDR sequences of SEQ ID NOs:6, 7, and 8, and heavy chain CDR sequences of SEQ ID NOs:3, 4 and 5.

12. The method of claim 10, wherein the antibody or antigen-binding fragment thereof comprises an HCVR having the amino acid sequence of SEQ ID NO:1 and an LCVR having the amino acid sequence of SEQ ID NO:2.

13. The method of claim 10, wherein the dosing strategy fulfills one or more of the following criteria:

(a) each secondary dose is administered 1 to 15 weeks after the immediately preceding dose;

(b) at least 3 secondary doses of the antibody or antigen binding fragment thereof are administered to the subject, wherein each secondary dose is administered 1 week or 2 weeks after the immediately preceding dose.

14. The method of claim 10, wherein the dosing strategy fulfills one or more of the following criteria:

(a) the initial dose and the one or more secondary doses each comprise 50 mg to 600 mg of the antibody or antigen binding fragment thereof;

(b) the initial dose and the one or more secondary doses each comprise 100 mg to 400 mg;

(c) the initial dose and the one or more secondary doses each comprise 300 mg; and

(d) the initial dose and the one or more secondary doses each comprise an equal amount of the antibody or antigen binding fragment thereof.

15. The method of claim 10, wherein the dosing strategy fulfills one or more of the following criteria:

(a) the initial dose comprises a first amount of the antibody or antigen binding fragment thereof, and the one or more secondary doses each comprise a second amount of the antibody or antigen binding fragment thereof; and

(b) the initial dose comprises a first amount of the antibody or antigen binding fragment thereof, and the one or more secondary doses each comprise a second amount of the antibody or antigen binding fragment thereof, wherein the first amount of the antibody or antigen binding fragment thereof is 1.5x, 2x, 2.5x, 3x, 3.5x or 5x the second amount of antibody or antigen binding fragment thereof; and

(c) the initial dose and the one or more secondary doses comprise equal amounts of the antibody or antigen binding fragment thereof.

22. of claims 1-16.The method of claim 10, wherein the subject has one or more of bilateral nasal polyposis, sinusitis, chronic rhinosinusitis, rhinitis, asthma, aspirin hypersensitivity, non-steroidal anti-inflammatory drug (NSAID) hypersensitivity, or has undergone surgery for nasal polypsbeen prescribed or is currently taking a background therapy for nasal polyposis.
17.

The methoduse of claim 1022, wherein the initial dose and the secondary doses fulfill one or more of the following criteria:

(a) the initial dose and the secondary doses are administered by the same or different routes of administration;

(b) the initial dose and the secondary doses are administered by subcutaneously, intravenously, or intranasally.

18. The method of claim 10, wherein administration of the initial dose and the one or more secondary dosesbackground therapy is followed by an improvement in one or more nasal polyposis associated parameters selected from the group consisting of:

a) 22-item SinoNasal Outcome Test (SNOT-22) score;

b) Nasal Symptom Score;

c) Number of nocturnal awakenings;

d) Visual Analog Score (VAS) for rhinosinusitis symptom severity;

e) Five-item Asthma Control Questionnaire (ACQ5) score;

f) Nasal peak inspiratory flow (NPIF) ;

g) University of Pennsylvania Smell Identification Test (UPSIT);

h) Lund-McKay Score; and

i) Three dimensional volumetric measurement of the maxillary sinus.

19. The method of claim 10, wherein the dosing strategy fulfills one or more of the following criteria:

(a) administration of the antibody or antigen binding fragment thereof is followed by a decrease in nasal polyp score in the patient;

(b) a second therapeutic agent is administered to the subject before, after or concurrent with the initial dose or the one or more secondary doses;

(c) a second therapeutic agent is administered to the subject before, after or concurrent with the initial dose or the one or more secondary doses, wherein the second therapeutic

agent is selected from the group consisting of an IgE inhibitor, an antibiotic agent, and an anti-fungal agent;

23. (d) a second therapeutic agent is administered to the subject before, after or concurrent with the initial dose or the one or more secondary doses, wherein the second therapeutic agent comprises an intranasal corticosteroid, optionally.

24. The use of claim 23, wherein the intranasal corticosteroid is mometasone furoate nasal spray (MFNS);).

(e) a second therapeutic agent is administered to the subject before, after or concurrent with the initial dose or the one or more secondary doses

The use of claim 22, wherein the second therapeutic agent comprises background therapy is an inhaledintranasal corticosteroid, optionally wherein the inhaled corticosteroid is fluticasone or budesonide; and

25. (f) a second therapeutic agent is administered to the subject before, after or concurrent with the initial dose or the one or more secondary doses, wherein the second therapeutic agent further comprises a long-acting beta$_2$ agonist, optionally wherein the long-acting beta$_2$ agonist is salmeterol or formoterol.

20. A method for treating nasal polyposis, the method comprising:

a) selecting a patient based on one or more of the following standards:

i) a minimum bilateral nasal polyp score of 5;

ii) at least two or more of the chronic symptoms

26. The use of claim 25, wherein the background therapy is fluticasone/salmeterol combination therapy.

27. The use of claim 25, wherein the background therapy is budesonide/formoterol combination therapy.

28. The use of sinusitis claim 22, wherein the background therapy is selected from the group consisting of: nasal blockade/obstruction/congestion, anterior or posterior nasal drip, facial pain or pressure a nasal saline, a topical decongestant, a topical anesthetic, a leukotriene antagonist, and reduction or lossa systemic antihistamine.

29. The use of smell; any one of claims 6-28, wherein the initial dose is about 400 mg and the one or more secondary doses are each about 200 mg.

iii) an elevated level

The use of any one or more genes selected from the group consisting of thymusclaims 6-28, wherein the initial dose is about 600 mg and activation-regulated chemokine (TARC), eotaxin-3, periostin, carcinoembryonic antigen (CEA), and YKL-40; and

iv) an elevated level of blood eosinophils or sputum eosinophils; and

b) administering to the selected patient one or more secondary doses of a pharmaceutical composition comprising an antibody or antigen binding fragment thereof that specifically binds an interleukin-4 receptor (IL-4R), wherein the antibody or antigen binding fragment thereof comprises heavy chain and light chain CDR sequences from the heavy chain variable region (HCVR) and light chain variable region (LCVR) sequence pair of SEQ ID NOs:1 and 2,

30. such that one or more of the following criteria are met:each about 300 mg.

i) the patient's nasal polyp score is reduced;

ii) the two or more chronic symptoms of sinusitis are improved;

iii) the level of one or more genes selected from the group consisting of thymus and activation-regulated chemokine (TARC), eotaxin-3, periostin, carcinoembryonic antigen (CEA), and YKL-40; and

iv: the level of blood eosinophils or sputum eosinophils is reduced when compared to the pre-administration level,

wherein the method optionally treats bilateral nasal polyposis.