CLAIMS

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 variable region (HCVR) having the amino acid sequence of SEQ ID NO: 1; and a light chain variable region (LCVR) having the amino acid sequence of SEQ ID NO: 2.

4. The use of any one of claims 1-3, wherein the subject has one or more of asthma, aspirin hypersensitivity, or hypersensitivity to a non-steroidal anti-inflammatory drug (NSAID).

5. The use of any one of claims 1-4, wherein the subject has severe nasal polyposis.

6. The use of any one of claims 1-5, wherein the composition is formulated for administration as a single initial dose and one or more secondary doses.

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 formulated for administration every two weeks.

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.

17. The use of any one of claims 1-16, wherein the pharmaceutical composition is formulated for administration with a second therapeutic agent before, after or concurrently with the second therapeutic agent.

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.

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).

20. The use of claim 19, wherein the second therapeutic agent comprises an inhaled corticosteroid, optionally wherein the inhaled corticosteroid is fluticasone or budesonide.

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.

22. The use of any one of claims 1-16, wherein the subject has been prescribed or is currently taking a background therapy for nasal polyposis.

23. The use of claim 22, wherein the background therapy is an intranasal corticosteroid.

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

25. The use of claim 22, wherein the background therapy is an intranasal corticosteroid and a long-acting beta$_2$ agonist.

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 claim 22, wherein the background therapy is selected from the group consisting of a nasal saline, a topical decongestant, a topical anesthetic, a leukotriene antagonist, and a systemic antihistamine.

29. The use of 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.

30. The use of any one of claims 6-28, wherein the initial dose is about 600 mg and the one or more secondary doses are each about 300 mg.