

What is claimed is:

1. Use of an interleukin-4 receptor (IL-4R) antagonist in the manufacture of a medicament for treating atopic dermatitis (AD) or improving an AD-associated parameter in a subject with moderate-to-severe or severe AD that is not adequately controlled by topical AD medications, wherein the subject is ≥ 6 months to < 6 years of age;

wherein one or more doses of the interleukin-4 receptor (IL-4R) antagonist are to be administered to the subject, and wherein the IL-4R antagonist is an anti-IL-4R antibody, or an antigen-binding fragment thereof, that 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 is a subject with severe AD.

3. The use of claim 1 or 2, wherein:

(i) the subject is inadequately responsive to treatment with a topical corticosteroid (TCS) of medium or higher potency; and/or

(ii) the subject previously was administered a systemic AD medication.

4. The use of any one of claims 1 to 3, wherein:

(i) the subject is aged ≥ 6 months to < 2 years; or

(ii) the subject is aged ≥ 2 to < 6 years.

5. The use of any one of claims 1 to 4, wherein the subject:

(i) has a baseline Investigator's Global Assessment (IGA) score = 4;

(ii) has a baseline Eczema Area and Severity Index (EASI) score ≥ 21 ; and/or

(iii) has a baseline Body Surface Area (BSA) affected by AD $\geq 15\%$.

6. The use of any one of claims 1 to 5, wherein:

(i) the IL-4R antagonist is to be subcutaneously administered at a dose of 3 mg/kg; or

(ii) the IL-4R antagonist is to be subcutaneously administered at a dose of at least 6 mg/kg; or

(iii) the IL-4R antagonist is to be subcutaneously administered at a dose of 6 mg/kg; or

(iv) the IL-4R antagonist is to be subcutaneously administered in an amount that results in a total exposure to the IL-4R antagonist in the subject of at least 130 day·mg/L.

7. The use of any one of claims 1 to 6, wherein multiple doses of the IL-4R antagonist are to be administered to the subject.

8. The use of claim 7, wherein the IL-4R antagonist is to be subcutaneously administered in an amount that results in a total exposure to the IL-4R antagonist in the subject of at least 130 day·mg/L for a period of at least two weeks.

9. The use of any one of claims 1 to 8, wherein the IL-4R antagonist is to be administered to the subject once a week or once every two weeks.

10. The use of any one of claims 1 to 9, wherein:

(i) the subject has a concurrent atopic or allergic condition selected from the group consisting of allergic rhinitis, asthma, food allergy, allergic conjunctivitis, hives, chronic rhinosinusitis, nasal polyps, and eosinophilic esophagitis; or

(ii) the subject has a food allergy.

11. The use of any of claims 1 to 10, wherein the IL-4R antagonist is to be administered in combination with a topical AD medication.

12. The use of claim 11, wherein the topical AD medication is a medium-potency TCS or a low-potency TCS.

13. The use of any one of claims 1 to 12, wherein treatment with the IL-4R antagonist results in:

(i) a reduction in the level of one or more type 2 inflammatory biomarkers in the subject relative to a baseline value; and/or

(ii) a reduction in the level of serum TARC and/or serum total IgE in the subject relative to a baseline value.

14. The use of any one of claims 1 to 13, wherein treatment with the IL-4R antagonist results in an improvement of one or more AD-associated parameters selected from:

(i) a reduction from baseline in IGA score to achieve an IGA score of 0 or 1 by week 4 after administration of the first dose of the IL-4R antagonist;

(ii) a reduction of at least 50% from baseline in an EASI score (EASI-50) by week 3 after administration of the first dose of the IL-4R antagonist;

(iii) a reduction of at least 75% from baseline in an EASI score (EASI-75) by week 3 after administration of the first dose of the IL-4R antagonist;

(iv) a reduction in percentage of BSA affected by AD to less than 40% of BSA by week 3 after administration of the first dose of the IL-4R antagonist; and

(v) a reduction of at 35% from baseline in BSA affected by AD by week 3 after administration of the first dose of the IL-4R antagonist.

15. The use of any one of claims 1 to 14, wherein the AD-associated parameter is determined based on a caregiver reported assessment.

16. The use of any one of claims 1 to 15, wherein treatment with the IL-4R antagonist:

(i) results in an improvement in caregiver reported peak pruritus numerical rating scale (NRS) score; and/or

(ii) results in an improvement in itch.

17. The use of any one of claims 1 to 16, wherein:

(i) the anti-IL-4R antibody or antigen-binding fragment thereof comprises a heavy chain variable region (HCVR) comprising the amino acid sequence of SEQ ID NO:1 and comprises a light chain variable region (LCVR) comprising the amino acid sequence of SEQ ID NO:2; and/or

(ii) the anti-IL-4R antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO:9 and a light chain comprising the amino acid sequence of SEQ ID NO:10; and/or

(iii) the IL-4R antagonist is dupilumab or a bioequivalent thereof.

18. The use of any one of claims 1 to 17, wherein the IL-4R antagonist is contained in a container selected from the group consisting of a glass vial, a syringe, a pre-filled syringe, a pen delivery device, and an autoinjector.

19. The use of claim 18, wherein:

(i) the IL-4R antagonist is contained in a pre-filled syringe; or

(ii) the IL-4R antagonist is contained in an autoinjector; or

(iii) the IL-4R antagonist is contained in a pen delivery device.

20. The use of claim 19, wherein the pre-filled syringe is a single-dose pre-filled syringe.