

Claims

1. An anti-IL-4R single-domain antibody comprising a VHH chain comprising CDR1 as shown in SEQ ID NO: 1, CDR2 as shown in SEQ ID NO: 2, and CDR3 as shown in SEQ ID NO: 3.

2. The anti-IL-4R single-domain antibody of claim 1, wherein the VHH chain comprises the following framework regions (FRs):

(a) FR1 as shown in SEQ ID NO: 4, FR2 as shown in SEQ ID NO: 5, FR3 as shown in SEQ ID NO: 6, and FR4 as shown in SEQ ID NO: 7; or

(b) FR1 as shown in SEQ ID NO: 10, FR2 as shown in SEQ ID NO: 11, FR3 as shown in SEQ ID NO: 12, and FR4 as shown in SEQ ID NO: 13.

3. The anti-IL-4R single-domain antibody of claim 2, wherein the single-domain antibody binds to an interleukin 4 receptor (IL-4R) epitope.

4. The anti-IL-4R single-domain antibody of claim 3, wherein the single-domain antibody comprises a VHH chain of the amino acid sequence as shown in SEQ ID NO: 8 or SEQ ID NO: 14.

5. An anti-IL-4R single-domain antibody Fc fusion protein, wherein the structure from N-terminus to C-terminus of the fusion antibody is shown in Formula Ia or Ib:

A-L-B (Ia);

B-L-A (Ib);

wherein

A is the anti-IL-4R single-domain antibody of claim 3;

B is the Fc fragment of the IgG; and

L is none or a flexible linker.

6. A polynucleotide encoding a protein selected from the group consisting of: the anti-IL-4R single-domain antibody of any one of claims 1-4, or the anti-IL-4R single-domain antibody Fc fusion protein of claim 5.

7. An expression vector containing the polynucleotide of claim 6.

8. A host cell containing the expression vector of claim 7, or in which the polynucleotide of claim 6 is integrated into a genome thereof.

9. A method for producing an anti-IL-4R single-domain antibody or Fc fusion protein thereof, which comprises the steps of:

(a) cultivating the host cell of claim 8 under conditions suitable for the production of a single-domain antibody or Fc fusion protein thereof, thereby obtaining a culture containing the anti-IL-4R single-domain antibody or Fc fusion protein thereof;

(b) isolating or recovering the anti-IL-4R single-domain antibody or Fc fusion protein thereof from the culture; and

(c) purifying and/or modifying the anti-IL-4R single-domain antibody or Fc fusion protein thereof from step (b).

10. An immunoconjugate containing:

5 (a) the anti-IL-4R single-domain antibody of any one of claims 1-4, or the anti-IL-4R single-domain antibody Fc fusion protein of claim 5; and

(b) a coupling moiety selected from the group consisting of: a detectable label, drug, toxin, cytokine, radionuclide, enzyme, nanoparticle, viral coat protein, virus like protein (VLP), and a combination thereof.

11. A pharmaceutical composition which comprises:

10 (i) the anti-IL-4R single-domain antibody of any one of claims 1-4, the anti-IL-4R single-domain antibody Fc fusion protein of claim 5, or the immunoconjugate of claim 10; and

(ii) a pharmaceutically acceptable carrier.

15 12. An antibody comprising one or more VHH chains of the anti-IL-4R single-domain antibody of claim 1.

13. A recombinant protein, which comprises:

(i) the anti-IL-4R single-domain antibody of any one of claims 1-4; and

(ii) a tag sequence to aid expression and/or purification.

14. An IL-4R protein detection reagent, which comprises:

20 (i) the anti-IL-4R single-domain antibody of any one of claims 1-4, the anti-IL-4R single-domain antibody Fc fusion protein of claim 5, or the immunoconjugate of claim 10; and

(ii) a detectologically acceptable carrier.

25 15. A kit for IL-4R protein detection, which comprises the IL-4R protein detection reagent of claim 14, and a specification.

30 16. Use of the anti-IL-4R single-domain antibody of any one of claims 1-4, the anti-IL-4R single-domain antibody Fc fusion protein of claim 5 or the immunoconjugate of claim 10 in the preparation of a medicament for preventing and/or treating a disease or disorder associated with IL-4/IL-4R signaling transduction; wherein the disease or disorder is selected from the group consisting of asthma, atopic dermatitis, arthritis, allergic rhinitis or eczema.

35 17. Use of the anti-IL-4R single-domain antibody of any one of claims 1-4, the anti-IL-4R single-domain antibody Fc fusion protein of claim 5 or the immunoconjugate of claim 10 in the preparation of a reagent, detection plate or kit, wherein the reagent, detection plate or kit is used for detecting IL-4R protein in the sample.

18. The anti-IL-4R single-domain antibody of any one of claims 1-4, the anti-IL-4R single-domain antibody Fc fusion protein of claim 5 or the immunoconjugate of claim 10 for use of the prevention and/or treatment of a disease

or disorder associated with IL-4/IL-4R signaling transduction; wherein the disease or disorder is selected from the group consisting of asthma, atopic dermatitis, arthritis, allergic rhinitis or eczema.

5 19. A non-diagnostic and non-therapeutic method for detecting IL-4R protein in a sample, which comprises the steps of:

(1) contacting the sample with the anti-IL-4R single-domain antibody of any one of claims 1-4, the anti-IL-4R single-domain antibody Fc fusion protein of claim 5 or the immunoconjugate of claim 10;

10 (2) detecting whether an antigen-antibody complex is formed, wherein the formation of the complex indicates the presence of IL-4R protein in the sample.

20. Use of the immunoconjugate of claim 10 for preparing a contrast agent to detect the IL-4R protein *in vivo*.