(p35) and IL-23 (p19) ligand and receptor chains (IL-12Rβ1, IL-12Rβ2, and IL-23R) were individually genotyped. Two SNPs in the IL-23R were highly associated with psoriasis while there was no association with the other ligand and receptor chains (Cargill M, Schrodi SJ, et al. *Am J Hum Genet.* 2007;80(2):273-290). The finding that common variants in both IL-12/23p40 and IL-23R are associated with psoriasis risk provides genetic evidence that the IL-23 pathway plays an important role in psoriasis pathogenesis.

[0007] Current approved therapies for psoriasis include topical agents (eg, corticosteroids, coal tar preparations, retinoids, phototherapy); systemic therapies (eg, methotrexate, retinoids, cyclosporin); and biologics (eg, etanercept, adalimumab, alefacept, ustekinumab). Despite these available therapies many patients remain untreated, do not respond to therapy, or suffer from toxicities associated with systemic or phototherapy, with significant skin involvement and disability.

[0008] It is contemplated herein that there is a need for new modalities for the treatment of psoriasis that specifically target IL-23 without the potential risks associated with inhibition of IL-12. Provided herein are methods for the treatment of psoriasis using fully human therapeutic agents that are able to inhibit native human IL-23 while sparing IL-12.

Summary

In one aspect, there is provided use of an anti-IL-23 antibody in the manufacture of a medicament for treating psoriasis in a subject in need thereof, wherein said medicament is to be administered in an amount and at an interval of: a. 15 – 54 mg every 0.5 – 1.5 months; b. 55 – 149 mg every 1.5 – 4.5 months; c. 150 – 299 mg every 4 – 8 months; or d. 300 – 1100 ng every 4 – 12 months; wherein the anti-IL-23 antibody specifically binds native human IL-23 but spares IL-12, and wherein the anti-IL-23 antibody comprises a. at least one heavy chain variable region comprising CDR1, CDR2 and CDR3 of SEQ ID NO: 1; and at least one light chain variable region comprising CDR1, CDR2 and CDR3 of SEQ ID NO: 2; b. a heavy chain variable region of SEQ ID NO: 1 and a light chain variable region of SEQ ID NO: 2; c. a heavy chain variable region comprising an amino acid sequence having at least 85%, at least 90%, at least 92%, at least 95%, at least 98% or at least 99% sequence identity to SEQ ID NO:1; and a light chain variable region comprising an amino acid sequence having at least 85%, at least 90%, at least 92%, at least 95%, at least 98% or at least 99% sequence identity to SEQ ID NO: 2; or d. is AMG 139 comprising the heavy chain variable region of SEQ ID NO: 1 and the light chain variable region of SEQ ID NO: 2. Also disclosed are methods of treating psoriasis in a subject in need

thereof comprising administering to the subject an anti-IL-23 antibody in an amount and at an interval of: 15 – 54 mg every 0.5 – 1.5 months; 55 – 149 mg every 1.5 – 4.5 months; 150 – 299 mg every 4 – 8 months; or 300 – 1100 mg every 4 – 12 months. In some embodiments, the amount and interval are: 15 – 21 mg every 0.5 – 1.0 month; 55 – 70 mg every 1.5 – 3.0months; 150 – 260 mg every 4 – 6 months; or 300 – 700 mg every 4 – 8 months. In some embodiments, the amount and interval are: 21 mg every month; 70 mg every 3 months; 210mg every 6 months; or 700 mg every 6 months. In some embodiments, the amount and interval are: 210 mg every 3 months or 700 mg every 3 months. In some embodiments, the amount and interval are: 210 mg every 1 month or 700 mg every 1 month. In some embodiments of the methods, the anti-IL23 antibody is administered IV. In some embodiments of the methods, the anti-IL23 antibody is administered SC. In some embodiments of the methods, the anti-IL-23 antibody is AMG 139.

[0009] In another aspect, there is provided use of an amount of an anti-IL-23 antibody in an amount and at an interval sufficient to achieve and/or maintain a quantity of anti-IL-23 antibody per volume of serum of between 12.5 ng /ml and 1000 ng/ml in the manufacture of a medicament for treating psoriasis in a subject in need thereof, wherein the anti-IL-23 antibody specifically binds native human IL-23 but spares IL-12, and wherein the anti-IL-23 antibody comprises a. at least one heavy chain variable region comprising CDR1, CDR2 and CDR3 of SEQ ID NO: 1; and at least one light chain variable region comprising CDR1, CDR2 and CDR3 of SEQ ID NO: 2; b. a heavy chain variable region of SEQ ID NO: 1 and a light chain variable region of SEQ ID NO: 2; c. a heavy chain variable region comprising an amino acid sequence having at least 85%, at least 90%, at least 92%, at least 95%, at least 98% or at least 99% sequence identity to SEQ ID NO:1; and a light chain variable region comprising an amino acid sequence having at least 85%, at least 90%, at least 92%, at least 95%, at least 98% or at least 99% sequence identity to SEQ ID NO: 2; or d. is AMG 139 comprising the heavy chain variable region of SEQ ID NO: 1 and the light chain variable region of SEQ ID NO: 2. Also disclosed are methods of treating psoriasis in a subject in need thereof comprising administering to the subject an amount of an anti-IL-23 antibody in an amount and at an

Claims

What is claimed is:

1. Use of an anti-IL-23 antibody in the manufacture of a medicament for treating psoriasis in a subject in need thereof, wherein said medicament is to be administered in an amount and at an interval of:

a. 15 – 54 mg every 0.5 – 1.5 months;

b. 55 – 149 mg every 1.5 – 4.5 months;

c. 150 – 299 mg every 4 – 8 months; or

d. 300 – 1100 mg every 4 – 12 months.

2. The use of claim 1, wherein the amount and interval are:

a. 15 – 21 mg every 0.5 – 1.0 month;

b. 55 – 70 mg every 1.5 – 3.0months;

c. 150 – 260 mg every 4 – 6 months; or

d. 300 – 700 mg every 4 – 8 months.

3. The use of claim 1, wherein the amount and interval are:

a. 21 mg every month;

b. 70 mg every 3 months;

c. 210mg every 6 months; or

d. 700 mg every 6 months.

4. The use of claim 1, wherein the amount and interval are:

a. 210 mg every 3 months or

b. 700 mg every 3 months.

5. The use of claim 1, wherein the amount and interval are:

a. 210 mg every 1 month or

b. 700 mg every 1 month.

6. Use of an amount of an anti-IL-23 antibody in an amount and at an interval sufficient to achieve and/or maintain a quantity of anti-IL-23 antibody per volume of serum of between 12.5 ng /ml and 1000 ng/ml in the manufacture of a medicament for treating psoriasis in a subject in need thereof.

7. The use of claim 6, wherein the quantity of an anti-IL-23 antibody per volume of serum is at least 10 ng/ml.

8. The use of claim 6, wherein the quantity of an anti-IL-23 antibody per volume of serum is selected from the group consisting of: at least 25 ng/ml; at least 50 ng/ml; at least 60 ng/ml; at least 70 ng/ml; at least 75 ng/ml; and at least 80 ng/ml.

9. The use of claim 6, wherein the quantity of an anti-IL-23 antibody per volume of serum is between 85 ng/ml and 100 ng/ml.

10. The use of claim 6, wherein the quantity of an anti-IL-23 antibody per volume of serum is between 70 ng/ml and 150 ng/ml.

11. The use of claim 6, wherein the quantity of an anti-IL-23 antibody per volume of serum is is between 50 ng/ml and 250 ng/ml.

12. The use of claim 6, wherein the quantity of an anti-IL-23 antibody per volume of serum is is between 40 ng/ml and 500 ng/ml.

13. The use of claim 6, wherein the quantity of an anti-IL-23 antibody per volume of serum is between 25 ng/ml and 750 ng/ml.

14. The use of claim 6, wherein the quantity of an anti-IL-23 antibody per volume of serum is between 10 ng/ml and 1,000 ng/ml.

15. The use according to any of the above claims, wherein the anti-IL23 antibody is to be administered IV.

16. The use according to any of the above claims, wherein the anti-IL23 antibody is to be administered SC.

17. The use according to any of the above claims, wherein the anti-IL-23 antibody is AMG 139.

Claims

What is claimed is:

1. Use of an anti-IL-23 antibody in the manufacture of a medicament for treating psoriasis in a subject in need thereof, wherein said medicament is to be administered in an amount and at an interval of:

a. 15 – 54 mg every 0.5 – 1.5 months;

b. 55 – 149 mg every 1.5 – 4.5 months;

c. 150 – 299 mg every 4 – 8 months; or

d. 300 – 1100 mg every 4 – 12 months;

wherein the anti-IL-23 antibody specifically binds native human IL-23 but spares IL-12, and wherein the anti-IL-23 antibody comprises

a. at least one heavy chain variable region comprising CDR1, CDR2 and CDR3 of SEQ ID NO: 1; and at least one light chain variable region comprising CDR1, CDR2 and CDR3 of SEQ ID NO: 2;

b. a heavy chain variable region of SEQ ID NO: 1 and a light chain variable region of SEQ ID NO: 2;

c. a heavy chain variable region comprising an amino acid sequence having at least 85%, at least 90%, at least 92%, at least 95%, at least 98% or at least 99% sequence identity to SEQ ID NO:1; and a light chain variable region comprising an amino acid sequence having at least 85%, at least 90%, at least 92%, at least 95%, at least 98% or at least 99% sequence identity to SEQ ID NO: 2; or

d. is AMG 139 comprising the heavy chain variable region of SEQ ID NO: 1 and the light chain variable region of SEQ ID NO: 2.

2. The use of claim 1, wherein the amount and interval are:

a. 15 – 21 mg every 0.5 – 1.0 month;

b. 55 – 70 mg every 1.5 – 3.0months;

c. 150 – 260 mg every 4 – 6 months; or

d. 300 – 700 mg every 4 – 8 months.

3. The use of claim 1, wherein the amount and interval are:

a. 21 mg every month;

b. 70 mg every 3 months;

c. 210mg every 6 months; or

d. 700 mg every 6 months.

4. The use of claim 1, wherein the amount and interval are:

a. 210 mg every 3 months or

b. 700 mg every 3 months.

5. The use of claim 1, wherein the amount and interval are:

a. 210 mg every 1 month or

b. 700 mg every 1 month.

6. Use of an amount of an anti-IL-23 antibody in an amount and at an interval sufficient to achieve and/or maintain a quantity of anti-IL-23 antibody per volume of serum of between 12.5 ng /ml and 1000 ng/ml in the manufacture of a medicament for treating psoriasis in a subject in need thereof,

wherein the anti-IL-23 antibody specifically binds native human IL-23 but spares IL-12, and wherein the anti-IL-23 antibody comprises

a. at least one heavy chain variable region comprising CDR1, CDR2 and CDR3 of SEQ ID NO: 1; and at least one light chain variable region comprising CDR1, CDR2 and CDR3 of SEQ ID NO: 2;

b. a heavy chain variable region of SEQ ID NO: 1 and a light chain variable region of SEQ ID NO: 2;

c. a heavy chain variable region comprising an amino acid sequence having at least 85%, at least 90%, at least 92%, at least 95%, at least 98% or at least 99% sequence identity to SEQ ID NO:1; and a light chain variable region comprising an amino acid sequence having at least 85%, at least 90%, at least 92%, at least 95%, at least 98% or at least 99% sequence identity to SEQ ID NO: 2; or

d. is AMG 139 comprising the heavy chain variable region of SEQ ID NO: 1 and the light chain variable region of SEQ ID NO: 2.

7. The use of claim 6, wherein the quantity of an anti-IL-23 antibody per volume of serum is selected from the group consisting of: at least 25 ng/ml; at least 50 ng/ml; at least 60 ng/ml; at least 70 ng/ml; at least 75 ng/ml; and at least 80 ng/ml.

8. The use of claim 6, wherein the quantity of an anti-IL-23 antibody per volume of serum is between 85 ng/ml and 100 ng/ml.

9. The use of claim 6, wherein the quantity of an anti-IL-23 antibody per volume of serum is between 70 ng/ml and 150 ng/ml.

10. The use of claim 6, wherein the quantity of an anti-IL-23 antibody per volume of serum is between 50 ng/ml and 250 ng/ml.

11. The use of claim 6, wherein the quantity of an anti-IL-23 antibody per volume of serum is between 40 ng/ml and 500 ng/ml.

12. The use of claim 6, wherein the quantity of an anti-IL-23 antibody per volume of serum is between 25 ng/ml and 750 ng/ml.

13. The use of claim 6, wherein the quantity of an anti-IL-23 antibody per volume of serum is between 10 ng/ml and 1,000 ng/ml.

14. The use according to any of the above claims, wherein the anti-IL23 antibody is to be administered IV.

15. The use according to any of the above claims, wherein the anti-IL23 antibody is to be administered SC.

16. The use according to any of the above claims, wherein the anti-IL-23 antibody is AMG 139 comprising the heavy chain variable region of SEQ ID NO: 1 and the light chain variable region of SEQ ID NO: 2.