Summary

[0012] In one aspect, there is provided use of an anti-IL-23 antibody in the manufacture of a medicament for treating Crohn's disease in a subject in need thereof, wherein said medicament is to be administered to the subject 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. Disclosed herein are methods of treating Crohn's disease 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.

[0013] 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 Crohn's disease 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 herein are methods of treating Crohn's disease 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 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 some embodiments, the quantity of an anti-IL-23 antibody per volume of serum is at least 10 ng/ml. In some embodiments, 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. In some embodiments, the quantity of an anti-IL-23 antibody per volume of serum is between 85 ng/ml and 100 ng/ml. In some embodiments, the quantity of an anti-IL-23 antibody per volume of serum is between 70 ng/ml and 150 ng/ml. In some embodiments the quantity of an anti-IL-23 antibody per volume of serum is is between 50 ng/ml and 250 ng/ml. In some embodiments, the quantity of an anti-IL-23 antibody per volume of serum is is between 40 ng/ml and 500 ng/ml. In some embodiments, the quantity of an anti-IL-23 antibody per volume of serum is between 25 ng/ml and 750 ng/ml. In some embodiments, the quantity of an anti-IL-23 antibody per volume of serum is between 10 ng/ml and 1,000 ng/ml. 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.

Claims

What is claimed is:

1. Use of an anti-IL-23 antibody in the manufacture of a medicament for treating Crohn's disease in a subject in need thereof, wherein said medicament is to be administered to the subject 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. 210 mg 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 Crohn's disease 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 Crohn's disease in a subject in need thereof, wherein said medicament is to be administered to the subject 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. 210 mg 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 Crohn's disease 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.