

22, which may mediate the development of the epidermal hyperplasia and tissue inflammation observed in psoriasis.

There is a need for treatment options for inflammatory diseases, in particular psoriasis, psoriatic arthritis, axial (spinal) spondyloarthritis (ax-SpA), including ankylosing
5 spondylitis and non-radiographic ax-SpA, that lead to favorable outcomes for patients, for example in terms of efficacy, safety and/or tolerability of the treatment.

Summary

The present disclosure addresses the above needs and provides methods for treating
10 inflammatory diseases, in particular methods comprising administering an anti-IL-23A antibody to a patient in certain amounts and/or at certain intervals. A method of the present disclosure is for the treatment of psoriasis or psoriatic arthritis. A method of the present disclosure is for the treatment of axial (spinal) spondyloarthritis (ax-SpA), including ankylosing spondylitis (AS) and non-radiographic ax-SpA. Accordingly, a
15 method of the present disclosure is for the treatment of ankylosing spondylitis (AS) and a method of the present disclosure is for the treatment of non-radiographic ax-SpA.

The methods of the present disclosure provide the advantage of enabling patients to experience clinical improvement while receiving fewer administrations of the anti-IL-23A
20 antibody.

The present disclosure provides a method for treating an inflammatory disease, for treating psoriasis, psoriatic arthritis or axial (spinal) spondyloarthritis (ax-SpA), including ankylosing spondylitis and non-radiographic ax-SpA, comprising administering to a
25 patient an anti-IL-23A antibody, said method comprising:

- a) administering an initial dose of the anti-IL-23A antibody to the patient;
- b) administering a first maintenance dose of the anti-IL-23A antibody to the patient 4 to 24 weeks, for example 4 to 16 weeks, for example 4 to 12 weeks, after said initial dose is administered; and

- c) administering at least one additional maintenance dose to the patient 4 to 24 weeks, for example 4 to 16 weeks, for example 4 to 12 weeks, after said first maintenance dose is administered.

The present disclosure provides a method for treating an inflammatory disease, for treating psoriasis, psoriatic arthritis or axial (spinal) spondyloarthritis (ax-SpA), including ankylosing spondylitis and non-radiographic ax-SpA, comprising administering to a patient an anti-IL-23A antibody, said method comprising:

- a) administering an initial dose of the anti-IL-23A antibody to the patient;
- b) administering a first maintenance dose of the anti-IL-23A antibody to the patient 8 to 24 weeks, for example 8 to 16 weeks, for example 8 to 12 weeks, for example 6 to 24 weeks, for example 6 to 16 weeks, for example 6 to 12 weeks, after said initial dose is administered; and
- c) administering at least one additional maintenance dose to the patient 8 to 24 weeks, for example 8 to 16 weeks, for example 8 to 12 weeks, for example 6 to 24 weeks, for example 6 to 16 weeks, for example 6 to 12 weeks, after said first maintenance dose is administered.

In one example, the first maintenance dose is administered to the patient 4, 6, 8, 12, 16, 20 or 24 weeks after the initial dose is administered.

In one example, the at least one additional maintenance dose is administered to the patient 4, 6, 8, 12, 16, 20 or 24 weeks after the first maintenance dose is administered.

In one example, the first maintenance dose is administered to the patient 4, 6, 8, 12, 16, 20 or 24 weeks after the initial dose is administered and the at least one additional maintenance dose is administered to the patient 4, 6, 8, 12, 16, 20 or 24 weeks after the first maintenance dose is administered.

In additional examples:

the first maintenance dose is administered to the patient 4 weeks after the initial dose is administered and the at least one additional maintenance dose is administered to the patient 4 weeks after the first maintenance dose is administered; or
the first maintenance dose is administered to the patient 6 weeks after the initial dose is administered and the at least one additional maintenance dose is administered to the patient 6 weeks after the first maintenance dose is administered; or
the first maintenance dose is administered to the patient 8 weeks after the initial dose is administered and the at least one additional maintenance dose is administered to the patient 8 weeks after the first maintenance dose is administered; or
the first maintenance dose is administered to the patient 12 weeks after the initial dose is administered and the at least one additional maintenance dose is administered to the patient 12 weeks after the first maintenance dose is administered; or
the first maintenance dose is administered to the patient 16 weeks after the initial dose is administered and the at least one additional maintenance dose is administered to the patient 16 weeks after the first maintenance dose is administered; or
the first maintenance dose is administered to the patient 20 weeks after the initial dose is administered and the at least one additional maintenance dose is administered to the patient 20 weeks after the first maintenance dose is administered; or
the first maintenance dose is administered to the patient 24 weeks after the initial dose is administered and the at least one additional maintenance dose is administered to the patient 24 weeks after the first maintenance dose is administered.

In one example, in any one of the methods above, the initial dose comprises 15 to 300 mg, for example 15 to 250 mg, for example 90 to 180 mg, of the anti- IL-23A antibody.

In one example, in any one of the methods above, the first maintenance dose and the at least one additional maintenance dose comprise 15 to 300 mg, for example 15 to 250 mg, for example 90 to 180 mg, of the anti- IL-23A antibody.

In one example, in any one of the methods above, the initial dose comprises 70 to 90 mg, 80 to 100 mg, 90 to 110 mg, 100 to 120 mg, 110 to 130 mg, 120 to 140 mg, 130 to 150 mg, 140 to 160 mg, 150 to 170 mg, 160 to 180 mg, 170 to 190 mg, 180 to 200 mg, 190 to 210 mg, 200 to 220 mg, 210 to 230 mg, 220 to 240 mg, 230 to 250 mg, 240 to 260 mg, 250 to 270 mg, 260 to 280 mg, 270 to 290 mg or 280 to 300 mg of the anti- IL-23A antibody.

In one example, in any one of the methods above, the first maintenance dose and the at least one additional maintenance dose comprise 70 to 90 mg, 80 to 100 mg, 90 to 110 mg, 100 to 120 mg, 110 to 130 mg, 120 to 140 mg, 130 to 150 mg, 140 to 160 mg, 150 to 170 mg, 160 to 180 mg, 170 to 190 mg, 180 to 200 mg, 190 to 210 mg, 200 to 220 mg, 210 to 230 mg, 220 to 240 mg, 230 to 250 mg, 240 to 260 mg, 250 to 270 mg, 260 to 280 mg, 270 to 290 mg or 280 to 300 mg of the anti- IL-23A antibody.

In one example, in any one of the methods above, the initial dose comprises 18, 20, 30, 40, 50, 60, 70, 80, 90, 100, 110, 120, 130, 140, 150, 160, 170, 180, 190, 200, 210, 220, 230, 240, 250, 260, 270, 280, 290 or 300 mg of the anti- IL-23A antibody. In one example, in any one of the methods above, the initial dose comprises 75 mg of the anti- IL-23A antibody.

In one example, in any one of the methods above, the first maintenance dose and the at least one additional maintenance dose comprise 18, 20, 30, 40, 50, 60, 70, 80, 90, 100, 110, 120, 130, 140, 150, 160, 170, 180, 190, 200, 210, 220, 230, 240, 250, 260, 270, 280, 290 or 300 mg of the anti- IL-23A antibody. In one example, in any one of the methods above, the first maintenance dose and the at least one additional maintenance dose comprise 75 mg of the anti- IL-23A antibody.

In one example, in any one of the methods above, the initial dose, the first maintenance dose and the at least one additional maintenance dose comprise 18, 20, 30, 40, 50, 60, 70, 80, 90, 100, 110, 120, 130, 140, 150, 160, 170, 180, 190, 200, 210, 220, 230, 240, 250, 260, 270, 280, 290 or 300 mg of the anti- IL-23A antibody. In one

example, in any one of the methods above, the initial dose, the first maintenance dose and the at least one additional maintenance dose comprise 75 mg of the anti- IL-23A antibody.

The present disclosure provides a method for treating an inflammatory disease, for treating psoriasis, psoriatic arthritis or axial (spinal) spondyloarthritis (ax-SpA), including ankylosing spondylitis and non-radiographic ax-SpA, comprising administering to a patient an anti-IL-23A antibody, said method comprising:

- a) administering an initial dose of the anti-IL-23A antibody to the patient;
- b) administering a first maintenance dose of the anti-IL-23A antibody to the patient 12 weeks after said initial dose is administered; and
- c) administering at least one additional maintenance dose to the patient 12 weeks after said first maintenance dose is administered.

In one example, in said method, the initial dose and the maintenance dose comprise 150 mg of said anti-IL-23A antibody. In one example, in said method, the initial dose and the maintenance dose comprise 75 mg of said anti-IL-23A antibody.

- 5 The present disclosure provides a method for treating an inflammatory disease, for treating psoriasis, psoriatic arthritis or axial (spinal) spondyloarthritis (ax-SpA), including ankylosing spondylitis and non-radiographic ax-SpA, comprising administering to a patient an anti-IL-23A antibody, said method comprising:
- a) administering an initial dose of the anti-IL-23A antibody to the patient;
 - b) administering a first maintenance dose of the anti-IL-23A antibody to the patient 8 weeks after said initial dose is administered; and
 - c) administering at least one additional maintenance dose to the patient 8 weeks after said first maintenance dose is administered.

In one example, in said method, the initial dose and the maintenance dose comprise 90 mg of said anti-IL-23A antibody. In one example, in said method, the initial dose and the maintenance dose comprise 150 mg of said anti-IL-23A antibody.

The present disclosure provides a method for treating an inflammatory disease, for treating psoriasis, psoriatic arthritis or axial (spinal) spondyloarthritis (ax-SpA), including ankylosing spondylitis and non-radiographic ax-SpA, comprising administering to a

5 patient an anti-IL-23A antibody, said method comprising:

- a) administering an initial dose of the anti-IL-23A antibody to the patient;
- b) administering a first maintenance dose of the anti-IL-23A antibody to the patient 16 weeks after said initial dose is administered; and
- c) administering at least one additional maintenance dose to the patient 16 weeks after said first maintenance dose is administered.

In one example, in said method, the initial dose and the maintenance dose comprise 150 mg of said anti-IL-23A antibody.

The present disclosure provides a method for treating an inflammatory disease, for treating psoriasis, psoriatic arthritis or axial (spinal) spondyloarthritis (ax-SpA), including ankylosing spondylitis and non-radiographic ax-SpA, comprising administering to a

10 patient an anti-IL-23A antibody, said method comprising:

- a) administering an initial dose of the anti-IL-23A antibody to the patient;
- b) administering a first maintenance dose of the anti-IL-23A antibody to the patient 6 weeks after said initial dose is administered; and
- c) administering at least one additional maintenance dose to the patient 6 weeks after said first maintenance dose is administered.

In one example, in said method, the initial dose and the maintenance dose comprise 150 mg of said anti-IL-23A antibody.

The present disclosure provides a method for treating an inflammatory disease, for treating psoriasis, psoriatic arthritis or axial (spinal) spondyloarthritis (ax-SpA), including ankylosing spondylitis and non-radiographic ax-SpA, comprising administering to a patient an anti-IL-23A antibody, said method comprising:

- a) administering an initial dose of the anti-IL-23A antibody to the patient;
- b) administering a first maintenance dose of the anti-IL-23A antibody to the patient 4 weeks after said initial dose is administered; and
- c) administering at least one additional maintenance dose to the patient 4 weeks after said first maintenance dose is administered.

In one example, in said method, the initial dose and the maintenance dose comprise 150 mg of said anti-IL-23A antibody.

The present disclosure further provides a method for treating an inflammatory disease, for treating psoriasis, psoriatic arthritis or axial (spinal) spondyloarthritis (ax-SpA), including ankylosing spondylitis and non-radiographic ax-SpA, comprising administering to a patient an anti-IL-23A antibody, said method comprising:

- a) administering an initial dose of said anti-IL-23A antibody to the patient;
- b) administering a loading dose of said anti-IL-23A antibody to the patient 1 to 6 weeks after said initial dose is administered;
- c) administering a first maintenance dose of said anti-IL-23A antibody to the patient 8 to 24 weeks, for example 8 to 16 weeks, for example 8 to 12 weeks, for example 6 to 24 weeks, for example 6 to 16 weeks, for example 6 to 12 weeks, after said loading dose is administered; and
- d) administering at least one additional maintenance dose to the patient 8 to 24 weeks, for example 8 to 16 weeks, for example 8 to 12 weeks, for example 6 to 24 weeks, for example 6 to 16 weeks, for example 6 to 12 weeks, after said first maintenance dose is administered.

In one example, the loading dose is administered to the patient 1, 2, 3, 4, 5 or 6 weeks after the said initial dose is administered.

In one example, the first maintenance dose is administered to the patient 6, 8, 12, 16, 20 or 24 weeks after the loading dose is administered.

In one example, the at least one additional maintenance dose is administered to the patient 6, 8, 12, 16, 20 or 24 weeks after the first maintenance dose is administered.

In one example, the first maintenance dose is administered to the patient 6, 8, 12, 16, 20 or 24 weeks after the initial dose is administered and the at least one additional maintenance dose is administered to the patient 6, 8, 12, 16, 20 or 24 weeks after the first maintenance dose is administered.

In one example, the first maintenance dose is administered to the patient 6, 8, 12, 16, 20 or 24 weeks after the loading dose is administered and the at least one additional maintenance dose is administered to the patient 6, 8, 12, 16, 20 or 24 weeks after the first maintenance dose is administered.

In additional examples:

the first maintenance dose is administered to the patient 6 weeks after the initial dose is administered and the at least one additional maintenance dose is administered to the patient 6 weeks after the first maintenance dose is administered; or

the first maintenance dose is administered to the patient 8 weeks after the initial dose is administered and the at least one additional maintenance dose is administered to the patient 8 weeks after the first maintenance dose is administered; or

the first maintenance dose is administered to the patient 12 weeks after the initial dose is administered and the at least one additional maintenance dose is administered to the patient 12 weeks after the first maintenance dose is administered; or

the first maintenance dose is administered to the patient 16 weeks after the initial dose is administered and the at least one additional maintenance dose is administered to the patient 16 weeks after the first maintenance dose is administered; or

the first maintenance dose is administered to the patient 20 weeks after the initial dose is administered and the at least one additional maintenance dose is administered to the patient 20 weeks after the first maintenance dose is administered; or

the first maintenance dose is administered to the patient 24 weeks after the initial dose is administered and the at least one additional maintenance dose is administered to the patient 24 weeks after the first maintenance dose is administered.

In additional examples:

the first maintenance dose is administered to the patient 6 weeks after the loading dose is administered and the at least one additional maintenance dose is administered to the patient 6 weeks after the first maintenance dose is administered; or

the first maintenance dose is administered to the patient 8 weeks after the loading dose is administered and the at least one additional maintenance dose is administered to the patient 8 weeks after the first maintenance dose is administered; or

the first maintenance dose is administered to the patient 12 weeks after the loading dose is administered and the at least one additional maintenance dose is administered to the patient 12 weeks after the first maintenance dose is administered; or

the first maintenance dose is administered to the patient 16 weeks after the loading dose is administered and the at least one additional maintenance dose is administered to the patient 16 weeks after the first maintenance dose is administered; or

the first maintenance dose is administered to the patient 20 weeks after the loading dose is administered and the at least one additional maintenance dose is administered to the patient 20 weeks after the first maintenance dose is administered; or

the first maintenance dose is administered to the patient 24 weeks after the loading dose is administered and the at least one additional maintenance dose is administered to the patient 24 weeks after the first maintenance dose is administered.

In one example, in any one of the methods above, the initial dose comprises 15 to 300 mg, for example 15 to 250 mg, for example 90 to 180 mg, of the anti- IL-23A antibody.

In one example, in any one of the methods above, the loading dose comprises 15 to 300 mg, for example 15 to 250 mg, for example 90 to 180 mg, of the anti- IL-23A antibody.

In one example, in any one of the methods above, the first maintenance dose and the at least one additional maintenance dose comprise 15 to 300 mg, for example 15 to 250 mg, for example 90 to 180 mg, of the anti- IL-23A antibody.

In one example, in any one of the methods above, the initial dose comprises 70 to 90 mg, 80 to 100 mg, 90 to 110 mg, 100 to 120 mg, 110 to 130 mg, 120 to 140 mg, 130 to 150 mg, 140 to 160 mg, 150 to 170 mg, 160 to 180 mg, 170 to 190 mg, 180 to 200 mg, 190 to 210 mg, 200 to 220 mg, 210 to 230 mg, 220 to 240 mg, 230 to 250 mg, 240 to 260 mg, 250 to 270 mg, 260 to 280 mg, 270 to 290 mg or 280 to 300 mg of the anti- IL-23A antibody.

In one example, in any one of the methods above, the loading dose comprises 70 to 90 mg, 80 to 100 mg, 90 to 110 mg, 100 to 120 mg, 110 to 130 mg, 120 to 140 mg, 130 to 150 mg, 140 to 160 mg, 150 to 170 mg, 160 to 180 mg, 170 to 190 mg, 180 to 200 mg, 190 to 210 mg, 200 to 220 mg, 210 to 230 mg, 220 to 240 mg, 230 to 250 mg, 240 to 260 mg, 250 to 270 mg, 260 to 280 mg, 270 to 290 mg or 280 to 300 mg of the anti- IL-23A antibody.

In one example, in any one of the methods above, the first maintenance dose and the at least one additional maintenance dose comprise 70 to 90 mg, 80 to 100 mg, 90 to 110 mg, 100 to 120 mg, 110 to 130 mg, 120 to 140 mg, 130 to 150 mg, 140 to 160 mg, 150 to 170 mg, 160 to 180 mg, 170 to 190 mg, 180 to 200 mg, 190 to 210 mg, 200 to

220 mg, 210 to 230 mg, 220 to 240 mg, 230 to 250 mg, 240 to 260 mg, 250 to 270 mg, 260 to 280 mg, 270 to 290 mg or 280 to 300 mg of the anti- IL-23A antibody.

In one example, in any one of the methods above, the initial dose comprises 18, 20, 30, 40, 50, 60, 70, 80, 90, 100, 110, 120, 130, 140, 150, 160, 170, 180, 190, 200, 210, 220, 230, 240, 250, 260, 270, 280, 290 or 300 mg of the anti-IL-23A antibody. In one example, in any one of the methods above, the initial dose comprises 75 mg of the anti-IL-23A antibody.

In one example, in any one of the methods above, the first maintenance dose and the at least one additional maintenance dose comprise 18, 20, 30, 40, 50, 60, 70, 80, 90, 100, 110, 120, 130, 140, 150, 160, 170, 180, 190, 200, 210, 220, 230, 240, 250, 260, 270, 280, 290 or 300 mg of the anti-IL-23A antibody. In one example, in any one of the methods above, the first maintenance dose and the at least one additional maintenance dose comprise 75 mg of the anti-IL-23A antibody.

In one example, in any one of the methods above, the initial dose and the loading dose comprise 18, 20, 30, 40, 50, 60, 70, 80, 90, 100, 110, 120, 130, 140, 150, 160, 170, 180, 190, 200, 210, 220, 230, 240, 250, 260, 270, 280, 290 or 300 mg of the anti-IL-23A antibody. In one example, in any one of the methods above, the initial dose and the loading dose comprise 75 mg of the anti-IL-23A antibody.

In one example, in any one of the methods above, the initial dose, the loading dose, the first maintenance dose and the at least one additional maintenance dose comprise 18, 20, 30, 40, 50, 60, 70, 80, 90, 100, 110, 120, 130, 140, 150, 160, 170, 180, 190, 200, 210, 220, 230, 240, 250, 260, 270, 280, 290 or 300 mg of the anti-IL-23A antibody. In one example, in any one of the methods above, the initial dose, the loading dose, the first maintenance dose and the at least one additional maintenance dose comprise 75 mg of the anti-IL-23A antibody.

The present disclosure further provides a method for treating an inflammatory disease, for treating psoriasis, psoriatic arthritis or axial (spinal) spondyloarthritis (ax-SpA), including ankylosing spondylitis and non-radiographic ax-SpA, comprising administering to a patient an anti-IL-23A antibody, said method comprising:

- a) administering an initial dose of said anti-IL-23A antibody to the patient;
- b) administering a loading dose of said anti-IL-23A antibody to the patient 4 weeks after said initial dose is administered;
- c) administering a first maintenance dose of said anti-IL-23A antibody to the patient 12 weeks after said loading dose is administered; and
- d) administering at least one additional maintenance dose to the patient 12 weeks after said first maintenance dose is administered.

In one example, in said method, the initial dose, the loading dose and the maintenance dose comprise 150 mg of said anti-IL-23A antibody. In one example, in said method, the initial dose and the loading dose comprise 300 mg of said anti-IL-23A antibody and the maintenance dose comprises 150 mg of said anti-IL-23A antibody.

In one example, in said method, the initial dose and the loading dose comprise 180 mg of said anti-IL-23A antibody and the maintenance dose comprises 90 mg of said anti-IL-23A antibody. In one example, in said method, the initial dose, the loading dose and the maintenance dose comprise 75 mg of said anti-IL-23A antibody.

The present disclosure further provides a method for treating an inflammatory disease, for treating psoriasis, psoriatic arthritis or axial (spinal) spondyloarthritis (ax-SpA), including ankylosing spondylitis and non-radiographic ax-SpA, comprising administering to a patient an anti-IL-23A antibody, said method comprising:

- a) administering an initial dose of said anti-IL-23A antibody to the patient;
- b) administering a loading dose of said anti-IL-23A antibody to the patient 4 weeks after said initial dose is administered;

- c) administering a first maintenance dose of said anti-IL-23A antibody to the patient 8 weeks after said loading dose is administered; and
- d) administering at least one additional maintenance dose to the patient 8 weeks after said first maintenance dose is administered.

In one example, in said method, the initial dose, the loading dose and the maintenance dose comprise 90 mg of said anti-IL-23A antibody. In one example, in said method, the initial dose, the loading dose and the maintenance dose comprise 150 mg of said anti-IL-23A antibody.

The present disclosure further provides a method for treating an inflammatory disease, for treating psoriasis, psoriatic arthritis or axial (spinal) spondyloarthritis (ax-SpA), including ankylosing spondylitis and non-radiographic ax-SpA, comprising administering to a patient an anti-IL-23A antibody, said method comprising:

- a) administering an initial dose of said anti-IL-23A antibody to the patient;
- b) administering a loading dose of said anti-IL-23A antibody to the patient 4 weeks after said initial dose is administered;
- c) administering a first maintenance dose of said anti-IL-23A antibody to the patient 16 weeks after said loading dose is administered; and
- d) administering at least one additional maintenance dose to the patient 16 weeks after said first maintenance dose is administered.

In one example, in said method, the initial dose, the loading dose and the maintenance dose comprise 150 mg of said anti-IL-23A antibody.

The present disclosure further provides a method for treating an inflammatory disease, for treating psoriasis, psoriatic arthritis or axial (spinal) spondyloarthritis (ax-SpA), including ankylosing spondylitis and non-radiographic ax-SpA, comprising administering to a patient an anti-IL-23A antibody, said method comprising:

- a) administering an initial dose of said anti-IL-23A antibody to the patient;
- b) administering a loading dose of said anti-IL-23A antibody to the patient 4 weeks after said initial dose is administered;
- c) administering a first maintenance dose of said anti-IL-23A antibody to the patient 6 weeks after said loading dose is administered; and
- d) administering at least one additional maintenance dose to the patient 6 weeks after said first maintenance dose is administered.

In one example, in said method, the initial dose, the loading dose and the maintenance dose comprise 150 mg of said anti-IL-23A antibody.

In one example, the present disclosure further provides a method for treating an inflammatory disease comprising administering to a patient 15 to 300 mg, for example 15 to 250 mg, for example 90 to 180 mg, of an anti-IL-23A antibody. In one example, the inflammatory disease is psoriasis, psoriatic arthritis or axial (spinal) spondyloarthritis (ax-SpA), including ankylosing spondylitis and non-radiographic ax-SpA.

In one example, the method comprises administering to a patient 70 to 90 mg, 80 to 100 mg, 90 to 110 mg, 100 to 120 mg, 110 to 130 mg, 120 to 140 mg, 130 to 150 mg, 140 to 160 mg, 150 to 170 mg, 160 to 180 mg, 170 to 190 mg, 180 to 200 mg, 190 to 210 mg, 200 to 220 mg, 210 to 230 mg, 220 to 240 mg, 230 to 250 mg, 240 to 260 mg, 250 to 270 mg, 260 to 280 mg, 270 to 290 mg or 280 to 300 mg of an anti-IL-23A antibody.

In one example, the method comprises administering to a patient 18, 20, 30, 40, 50, 60, 70, 80, 90, 100, 110, 120, 130, 140, 150, 160, 170, 180, 190, 200, 210, 220, 230, 240, 250, 260, 270, 280, 290 or 300 mg of an anti-IL-23A antibody. In one example, the method comprises administering to a patient 75 mg of an anti-IL-23A antibody.

In one example, the anti-IL-23A antibody is administered as an an initial dose, a loading dose or a maintenance dose.

The present disclosure further provides a method for treating an inflammatory disease, for treating psoriasis or psoriatic arthritis, comprising administering to a patient an anti-IL-23A antibody, said method comprising:

- a) administering an initial dose of said anti-IL-23A antibody to the patient; and
- b) administering a second dose of said anti-IL-23A antibody to the patient when the patient no longer maintains a certain PASI score, for example PASI 90, PASI 75, PASI 100 or PASI 50.

In one example, the initial dose and the second dose are doses as described herein.

The present disclosure further provides a method for treating an inflammatory disease, for treating psoriasis or psoriatic arthritis, comprising administering to a patient an anti-IL-23A antibody, said method comprising:

- a) administering an initial dose of said anti-IL-23A antibody to the patient;
- b) administering a loading dose of said anti-IL-23A antibody to the patient 1 to 6 weeks, for example 4 weeks, after said initial dose is administered; and
- c) administering a third dose of said anti-IL-23A antibody to the patient when the patient no longer maintains a certain PASI score, for example PASI 90, PASI 75, PASI 100 or PASI 50.

In one example, the initial dose, the loading dose and the third dose are doses as described herein.

In one example, in any one of the methods above, the anti-IL-23A antibody is Antibody A, Antibody B, Antibody C or Antibody D.

In one example, in any one of the methods above, the method is for treating plaque psoriasis, for example chronic plaque psoriasis.

In one example, in any one of the methods above, the method is for treating moderate to severe chronic plaque psoriasis, for example in a patient who is a candidate for systemic therapy or phototherapy.

In one example, in any one of the methods above, the method is for treating moderate to severe chronic plaque psoriasis, for example in a patient who failed to respond to, or who has a contraindication to, or is intolerant to other systemic therapy including ciclosporin, methotrexate, psoralen or ultraviolet-A light (PUVA)

In one example, in any one of the methods above, the method is for treating pustular psoriasis.

- 5 In one example, in any one of the methods above, the method is for treating erythrodermic psoriasis (also known as psoriatic erythroderma).

In one example, in any one of the methods above, the method is for treating psoriatic arthritis, for example active psoriatic arthritis.

10

In one example, the anti-IL-23A antibody is used alone or in combination with one or more non-biologic DMARDs (Disease-Modifying Antirheumatic Drug), for example for treating psoriatic arthritis, for example active psoriatic arthritis, for example to reduce signs and symptoms. In one example, the anti-IL-23A antibody is used or indicated to

- 15 inhibit the progression of structural damage, and/or improve physical function.

In one example, the anti-IL-23A antibody is used alone or in combination with methotrexate (MTX), for example for the treatment of psoriatic arthritis, for example active psoriatic arthritis, for example when the response to previous non-biological DMARD therapy has been inadequate. In one example, the anti-IL-23A antibody is used to reduce the rate of progression of peripheral joint damage as measured by X-ray and/or to improve physical function.

In one example, in any one of the methods above, the anti-IL-23A antibody is administered by subcutaneous administration.

In one example, in a method of the present disclosure, 90 - 180 mg of the anti-IL-23 antibody is administered to the patient every 6 – 12 weeks, for example every 8 - 12 weeks, with or without a loading dose.

5

In one example, in any one of the methods above, the patient is an adult patient.

The present disclosure provides an anti-IL-23A antibody for use in the treatment of a disease as described herein.

10

The present disclosure provides an anti-IL-23A antibody for use in the treatment of a disease, for example an inflammatory disease, for example psoriasis, psoriatic arthritis or axial (spinal) spondyloarthritis (ax-SpA), including Ankylosing Spondylitis and non-radiographic ax-SpA, by administration in certain amounts and/or at certain intervals as described herein.

15

The present disclosure provides for the use of an anti-IL-23A antibody for the preparation of a medicament for the treatment of a disease as described herein.

The present disclosure provides for the use of an anti-IL-23A antibody for the preparation of a medicament for the treatment of a disease, for example an inflammatory disease, for example psoriasis, psoriatic arthritis or axial (spinal) spondyloarthritis (ax-SpA), including Ankylosing Spondylitis and non-radiographic ax-SpA, by administration in certain amounts and/or at certain intervals as described herein.

In one example, in any one of the methods or uses above, the anti-IL-23A antibody is disclosed below.

In one example, the anti-IL-23A antibody comprises a light chain variable region comprising the amino acid sequence of SEQ ID NO:1 (*CDR1-L*); the amino acid sequence of SEQ ID NO:2 (*CDR2-L*); and the amino acid sequence of SEQ ID NO:3 (*CDR3-L*); and a heavy chain variable region comprising the amino acid sequence of
5 SEQ ID NO: 4, 7, 8 or 9 (*CDR1-H*); the amino acid sequence of SEQ ID NO:5 (*CDR2-H*); and the amino acid sequence of SEQ ID NO:6 (*CDR3-H*).

In one example, the anti-IL-23A antibody comprises a light chain variable region comprising the amino acid sequence of SEQ ID NO:1 (*CDR1-L*); the amino acid
10 sequence of SEQ ID NO:2 (*CDR2-L*); and the amino acid sequence of SEQ ID NO:3 (*CDR3-L*); and a heavy chain variable region comprising the amino acid sequence of SEQ ID NO:4 (*CDR1-H*); the amino acid sequence of SEQ ID NO:5 (*CDR2-H*); and the amino acid sequence of SEQ ID NO:6 (*CDR3-H*).

15 In one example, the anti-IL-23A antibody comprises a light chain variable region comprising the amino acid sequence of SEQ ID NO:1 (*CDR1-L*); the amino acid sequence of SEQ ID NO:2 (*CDR2-L*); and the amino acid sequence of SEQ ID NO:3 (*CDR3-L*); and a heavy chain variable region comprising the amino acid sequence of SEQ ID NO:7 (*CDR1-H*); the amino acid sequence of SEQ ID NO:5 (*CDR2-H*); and the
20 amino acid sequence of SEQ ID NO:6 (*CDR3-H*).

In one example, the anti-IL-23A antibody comprises a light chain variable region comprising the amino acid sequence of SEQ ID NO:1 (*CDR1-L*); the amino acid sequence of SEQ ID NO:2 (*CDR2-L*); and the amino acid sequence of SEQ ID NO:3
25 (*CDR3-L*); and a heavy chain variable region comprising the amino acid sequence of SEQ ID NO:8 (*CDR1-H*); the amino acid sequence of SEQ ID NO:5 (*CDR2-H*); and the amino acid sequence of SEQ ID NO:6 (*CDR3-H*).

In one example, the anti-IL-23A antibody comprises a light chain variable region
30 comprising the amino acid sequence of SEQ ID NO:1 (*CDR1-L*); the amino acid sequence of SEQ ID NO:2 (*CDR2-L*); and the amino acid sequence of SEQ ID NO:3

(*CDR3-L*); and a heavy chain variable region comprising the amino acid sequence of SEQ ID NO:9 (*CDR1-H*); the amino acid sequence of SEQ ID NO:5 (*CDR2-H*); and the amino acid sequence of SEQ ID NO:6 (*CDR3-H*).

5 In one example, the anti-IL-23A antibody comprises a light chain variable region comprising the amino acid sequence of any one of SEQ ID NO:10, 11, 12 or 13; and a heavy chain variable region comprising the amino acid sequence any one of SEQ ID NO:14, 15, 16 or 17.

10 In one example, the anti-IL-23A antibody comprises a light chain variable region comprising the amino acid sequence of SEQ ID NO:11 and a heavy chain variable region comprising the amino acid sequence SEQ ID NO:14.

In one example, the anti-IL-23A antibody comprises a light chain variable region
15 comprising the amino acid sequence of SEQ ID NO:11 and a heavy chain variable region comprising the amino acid sequence SEQ ID NO:15.

In one example, the anti-IL-23A antibody comprises a light chain variable region
comprising the amino acid sequence of SEQ ID NO:10 and a heavy chain variable
20 region comprising the amino acid sequence SEQ ID NO:14.

In one example, the anti-IL-23A antibody comprises a light chain variable region
comprising the amino acid sequence of SEQ ID NO:10 and a heavy chain variable
region comprising the amino acid sequence SEQ ID NO:15.

25

In one example, the anti-IL-23A antibody comprises the amino acid sequence SEQ ID NO:14 or 15 linked to a human IgG1, IgG2, IgG3, IgG4, IgM, IgA or IgE heavy chain constant region. In one example, the anti-IL-23A antibody comprises the amino acid sequence of SEQ ID NO: 14 or 15 linked to a human IgG1 heavy chain constant region.

30 In one example, the anti-IL-23A antibody comprises the amino acid sequence of SEQ ID NO:10 or 11 linked to a human kappa or lambda light chain constant region.

In one example, the anti-IL-23A antibody comprises the amino acid sequence of SEQ ID NO:14 or 15 linked to a human IgG1 heavy chain constant region; and the amino acid sequence of SEQ ID NO: 10 or 11 linked to a human kappa light chain constant region.

- 5 In one example, the anti-IL-23A antibody is a humanized monoclonal antibody comprising a light chain variable region comprising the amino acid sequence selected from the group consisting of any one of SEQ ID NO:10, 11, 12 and 13 and a heavy chain variable region comprising the amino acid sequence selected from the group consisting of any one of SEQ ID NO:14, 15, 16 and 17.

10

In one example, the anti-IL-23A antibody is a humanized monoclonal antibody comprising a light chain variable region comprising the amino acid sequence of SEQ ID NO:11 and a heavy chain variable region comprising the amino acid sequence SEQ ID NO:14.

15

In one example, the anti-IL-23A antibody is a humanized monoclonal antibody comprising a light chain variable region comprising the amino acid sequence of SEQ ID NO:11 and a heavy chain variable region comprising the amino acid sequence SEQ ID NO:15.

20

In one example, the anti-IL-23A antibody is a humanized monoclonal antibody comprising a light chain variable region comprising the amino acid sequence of SEQ ID NO:10 and a heavy chain variable region comprising the amino acid sequence SEQ ID NO:14.

25

In one example, the anti-IL-23A antibody is a humanized monoclonal antibody comprising a light chain variable region comprising the amino acid sequence of SEQ ID NO:10 and a heavy chain variable region comprising the amino acid sequence SEQ ID NO:15.

In one example, the anti-IL-23A antibody comprises a light chain comprising the amino acid sequence of SEQ ID NO:18 or 21 and a heavy chain comprising the amino acid sequence of SEQ ID NO:19 or 20.

- 5 In one example, the anti-IL-23A antibody comprises a light chain comprising the amino acid sequence of SEQ ID NO:18 and a heavy chain comprising the amino acid sequence of SEQ ID NO:19.

- 10 In one example, the anti-IL-23A antibody comprises a light chain comprising the amino acid sequence of SEQ ID NO:18 and a heavy chain comprising the amino acid sequence of SEQ ID NO:20.

- 15 In one example, the anti-IL-23A antibody comprises a light chain comprising the amino acid sequence of SEQ ID NO:21 and a heavy chain comprising the amino acid sequence of SEQ ID NO:19.

- 20 In one example, the anti-IL-23A antibody comprises a light chain comprising the amino acid sequence of SEQ ID NO: 21 and a heavy chain comprising the amino acid sequence of SEQ ID NO: 20.

In one example, the anti-IL-23A antibody is Antibody A, Antibody B, Antibody C or Antibody D.

- 25 In one example, the anti-IL-23A antibody is as disclosed in WO2007/005955, WO2007/024846, WO2007/027714, WO2007/076524, WO2008/103432 or WO2012/061448.

In one aspect, the present disclosure provides a pharmaceutical composition for use in treating psoriatic arthritis comprising an anti-IL-23A antibody comprising a light chain comprising the amino acid sequence of SEQ ID NO: 18 and a heavy chain comprising the amino acid sequence of SEQ ID NO: 19, to be administered to a patient by the method comprising:

- a) a first dose of 150 mg of said anti-IL-23A antibody is to be administered to the patient;
- b) a second dose of 150 mg of said anti-IL-23A antibody is to be administered to the patient 4 weeks after said first dose is administered; and
- c) a first maintenance dose of 150 mg of said anti-IL-23A antibody is to be administered to the patient 12 weeks after said second dose is administered.

In another aspect, the present disclosure provides use of an anti-IL-23A antibody comprising a light chain comprising the amino acid sequence of SEQ ID NO: 18 and a heavy chain comprising the amino acid sequence of SEQ ID NO: 19 in the manufacture of a medicament for treating psoriatic arthritis, wherein the medicament is to be administered to a patient by the method comprising:

- a) a first dose of 150 mg of said anti-IL-23A antibody is to be administered to the patient;
- b) a second dose of 150 mg of said anti-IL-23A antibody is to be administered to the patient 4 weeks after said first dose is administered; and
- c) a first maintenance dose of 150 mg of said anti-IL-23A antibody is to be administered to the patient 12 weeks after said second dose is administered.

In another aspect, the present disclosure provides a pharmaceutical composition for use in treating psoriatic arthritis comprising an anti-IL-23A antibody comprising a light chain comprising the amino acid sequence of SEQ ID NO: 18 and a heavy chain comprising the amino acid sequence of SEQ ID NO: 19, to be administered to a patient by the method comprising:

- a) a first dose of 75 mg of said anti-IL-23A antibody is to be administered to the patient;
 - b) a second dose of 75 mg of said anti-IL-23A antibody is to be administered to the patient 4 weeks after said first dose is administered; and
 - c) a first maintenance dose of 75 mg of said anti-IL-23A antibody is to be administered
- 5 to the patient 12 weeks after said second dose is administered.

In another aspect, the present disclosure provides use of an anti-IL-23A antibody comprising a light chain comprising the amino acid sequence of SEQ ID NO: 18 and a heavy chain comprising the amino acid sequence of SEQ ID NO: 19 in the manufacture

10 of a medicament for treating psoriatic arthritis, wherein the medicament is to be administered to a patient by the method comprising:

- a) a first dose of 75 mg of said anti-IL-23A antibody is to be administered to the patient;
 - b) a second dose of 75 mg of said anti-IL-23A antibody is to be administered to the patient 4 weeks after said first dose is administered; and
 - c) a first maintenance dose of 75 mg of said anti-IL-23A antibody is to be administered
- 15 to the patient 12 weeks after said second dose is administered.

Brief Description of the Figures

Figure 1: Rate of patients with >50% reductions from baseline pain-VAS (%).

20 Figure 2: Achievement of PASI 50 over time (observed).

Claims

1. A pharmaceutical composition for use in treating psoriatic arthritis comprising an anti-IL-23A antibody comprising a light chain comprising the amino acid sequence of SEQ ID NO: 18 and a heavy chain comprising the amino acid sequence of SEQ ID NO: 19, to be administered to a patient by the method comprising:
 - a) a first dose of 150 mg of said anti-IL-23A antibody is to be administered to the patient;
 - b) a second dose of 150 mg of said anti-IL-23A antibody is to be administered to the patient 4 weeks after said first dose is administered; and
 - 10 c) a first maintenance dose of 150 mg of said anti-IL-23A antibody is to be administered to the patient 12 weeks after said second dose is administered.
2. Use of an anti-IL-23A antibody comprising a light chain comprising the amino acid sequence of SEQ ID NO: 18 and a heavy chain comprising the amino acid sequence of SEQ ID NO: 19 in the manufacture of a medicament for treating psoriatic arthritis, wherein the medicament is to be administered to a patient by the method comprising:
 - a) a first dose of 150 mg of said anti-IL-23A antibody is to be administered to the patient;
 - b) a second dose of 150 mg of said anti-IL-23A antibody is to be administered to the patient 4 weeks after said first dose is administered; and
 - 20 c) a first maintenance dose of 150 mg of said anti-IL-23A antibody is to be administered to the patient 12 weeks after said second dose is administered.
3. The pharmaceutical composition for use according to claim 1 or the use according to claim 2, said method further comprising:
 - 25 maintenance doses of 150 mg of said anti-IL-23A antibody are to be administered to the patient every 12 weeks after said first maintenance dose is administered.

4. The pharmaceutical composition for use according to claim 1 or 3, or the use according to claim 2 or 3, wherein said anti-IL-23A antibody is to be administered by subcutaneous administration.
- 5 5. The pharmaceutical composition for use according to anyone of claims 1, 3 or 4, or the use according to anyone of claims 2 to 4, wherein the patient achieves a Psoriasis Area and Severity Index (PASI) score of 90 (PASI 90).
6. The pharmaceutical composition for use according to anyone of claims 1 or 3 to 5, or
10 the use according to anyone of claims 2 to 5, wherein the patient achieves a American College of Rheumatology (ACR) score of 20 (ACR 20).
7. A pharmaceutical composition for use in treating psoriatic arthritis comprising an anti-IL-23A antibody comprising a light chain comprising the amino acid sequence of SEQ ID
15 NO: 18 and a heavy chain comprising the amino acid sequence of SEQ ID NO: 19, to be administered to a patient by the method comprising:
 - a) a first dose of 75 mg of said anti-IL-23A antibody is to be administered to the patient;
 - b) a second dose of 75 mg of said anti-IL-23A antibody is to be administered to the patient 4 weeks after said first dose is administered; and
 - 20 c) a first maintenance dose of 75 mg of said anti-IL-23A antibody is to be administered to the patient 12 weeks after said second dose is administered.
8. Use of an anti-IL-23A antibody comprising a light chain comprising the amino acid sequence of SEQ ID NO: 18 and a heavy chain comprising the amino acid sequence of
25 SEQ ID NO: 19 in the manufacture of a medicament for treating psoriatic arthritis, wherein the medicament is to be administered to a patient by the method comprising:
 - a) a first dose of 75 mg of said anti-IL-23A antibody is to be administered to the patient;

- b) a second dose of 75 mg of said anti-IL-23A antibody is to be administered to the patient 4 weeks after said first dose is administered; and
- c) a first maintenance dose of 75 mg of said anti-IL-23A antibody is to be administered to the patient 12 weeks after said second dose is administered.

5

9. The pharmaceutical composition for use according to claim 7 or the use according to claim 8, said method further comprising:

maintenance doses of 75 mg of said anti-IL-23A antibody are to be administered to the patient every 12 weeks after said first maintenance dose is administered.

10

10. The pharmaceutical composition for use according to claim 7 or 9, or the use according to claim 8 or 9, wherein said anti-IL-23A antibody is to be administered by subcutaneous administration.

15 11. The pharmaceutical composition for use according to anyone of claims 7, 9 or 10, or the use according to anyone of claims 8 to 10, wherein the patient achieves a Psoriasis Area and Severity Index (PASI) score of 90 (PASI 90).

20 12. The pharmaceutical composition for use according to anyone of claims 7 or 9 to 11, or the use according to anyone of claims 8 to 11, wherein the patient achieves a American College of Rheumatology (ACR) score of 20 (ACR 20).