METHODS OF TREATING INFLAMMATORY DISEASES

Technical Field of the Invention

This invention generally relates to method of treating inflammatory diseases, for example Crohn's Disease (CD), utilizing anti-IL-23A antibodies.

Background of the Invention

Crohn's Disease (CD) is a chronic relapsing, remitting inflammatory disease of the gastrointestinal tract characterized by abdominal pain, fever, and bloody or mucus-containing diarrhea. The disease affects the gastrointestinal tract discontinuously from mouth to anus, but most commonly the ileum and colon (40%), followed by the small bowel only (30%), and the colon only (25%). It occurs in a relatively young population and there is no marked sex difference.

The incidence of CD seems to be increasing with more recent estimates varying from 7.9 to 20.2 cases/100,000, and a prevalence of 161 to 319 cases/100,000 in North America and Europe. Mucosal lesions may be complicated by perforation and fistula formation, which may require hospitalization for medical or surgical management.

There is a need for treatment options for inflammatory diseases, in particular Crohn's Disease, 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 inflammatory diseases, in particular methods comprising administering an anti-IL-23A antibody to a patient in certain amounts and/or at certain intervals. In one example, a method of the present disclosure is for the treament of Crohn's Disease. In one example, a method of the present disclosure is for the treament of ulcerative colitis. 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 antibody.

In one example, the present disclosure provides a method for treating an inflammatory disease, in one example for treating Crohn's Disease, comprising (a) administering to a patient a dose of an anti-IL-23A antibody at week 0, at week 4 and at week 8 by intravenous infusion, wherein the doses of the anti-IL-23A antibody comprise 200 mg or 600 mg of the antibody. In one example, the method further comprises (b) administering to the patient three doses of the anti-IL-23A antibody, for example at week 14, at week 18 and at week 22 by intravenous infusion, wherein the doses of the anti-IL-23A antibody comprise 600 mg of the antibody. In one example, the method further comprises (c) administering to the patient one or more doses of the anti-IL-23A antibody at 8 weeks intervals by subcutaneous injection, for example four doses of the anti-IL-23A antibody at 8 weeks intervals by subcutaneous injection, for example at week 26, at week 34, at week 42 and at week 50, wherein the one or more doses of the anti-IL-23A antibody comprise 180 mg of the antibody.

In one example, at week 12, a patient is evaluated for deep remission, for example defined as reaching clinical remission (CDAI score <150) and endoscopic remission (CDEIS ≤ 4). In one example, for a patient with initial isolated ileitis endoscopic remission is defined by CDEIS ≤ 2.

In one example, the present disclosure provides a method for treating an inflammatory disease, in one example for treating Crohn's Disease, comprising (a) administering to a patient a dose of an anti-IL-23A antibody at week 0, at week 4 and at week 8 by intravenous infusion, wherein the doses of the anti-IL-23A antibody comprise 200 mg or 600 mg of the antibody. In one example, the method further comprises (b) administering to the patient one or more doses of the anti-IL-23A antibody at 8 weeks intervals by subcutaneous injection, for example four doses of the anti-IL-23A antibody at 8 weeks intervals by subcutaneous injection, for example at week 26, at week 34, at week 42 and at week 50, wherein the one or more doses of the anti-IL-23A antibody comprise 180 mg of the antibody.

In one example, at week 12, a patient is evaluated for deep remission, for example defined as reaching clinical remission (CDAI score <150) and endoscopic remission (CDEIS ≤ 4). In one example, for a patient with initial isolated ileitis endoscopic remission is defined by CDEIS ≤ 2.

In one example, the present disclosure provides a method for treating an inflammatory disease, in one example for treating Crohn's Disease, comprising administering to a patient 180 mg of the anti-IL-23A antibody at 8 weeks intervals by subcutaneous injection.

In one example, the present disclosure provides a method for treating an inflammatory disease, in one example for treating Crohn's Disease, comprising administering to a patient an anti-IL-23A antibody, said method comprising administering at least one induction dose of the anti-IL-23A antibody to the patient, wherein said induction dose comprises 200 to 1,200 mg of the anti-IL-23A antibody, for example 450 to 1,200 mg of the anti-IL-23A antibody. In one example, the induction dose comprises 200 mg, 450 mg, 600 mg, 900 mg or 1,200 mg of the anti-IL-23A antibody. In one example, 1, 2 or 3 induction doses are administered to the patient. In one example, 2 or 3 inductions doses are administered, for example at 4 weeks intervals. In one example, the induction dose(s) is administered by intravenous infusion.

In one example, the induction doses comprise 200 mg of the anti-IL-23A antibody and three inductions doses are administered to the patient at 4 weeks intervals.
In one example, the induction doses comprise 450 mg of the anti-IL-23A antibody and three inductions doses are administered to the patient at 4 weeks intervals.

In one example, the induction doses comprise 600 mg of the anti-IL-23A antibody and three inductions doses are administered to the patient at 4 weeks intervals.
In one example, the induction doses comprise 900 mg of the anti-IL-23A antibody and three inductions doses are administered to the patient at 4 weeks intervals.
In one example, the induction doses comprise 1,200 mg of the anti-IL-23A antibody and three inductions doses are administered to the patient at 4 weeks intervals.

In one example, at least one additional induction dose of the anti-IL-23A antibody is administered to the patient after the last induction dose above. In one example, an additional induction dose comprises 200 to 1,200 mg of the anti-IL-23A antibody, for example 450 to 1,200 mg of the anti-IL-23A antibody. In one example, an additional induction dose comprises 200 mg, 450 mg, 600 mg, 900 mg or 1,200 mg of the anti-IL-23A antibody. In one example, 1, 2 or 3 additional induction doses are administered to the patient. In one example, 2 or 3 additional inductions doses are administered, for example at 4 weeks intervals. In one example, the additional induction dose(s) is administered by intravenous infusion.

In oneexample, the patient has a CDAI score of 220-450 before the administration of the first induction dose.

In one example, the patient achieves clinical remission after the administration of the one or more induction doses. In one example, the patient achieves a CDAI score of less than 150 after the administration of the one or more induction doses. In one example, the patient achieves a PRO-2 score equal to or less than 75 after the administration of the one or more induction doses. In one example, the patient achieves a CDAI score of less than 150 and a PRO-2 score equal to or less than 75 after the administration of the one or more induction doses.

In one example, the present disclosure further provides a method for inducing clinical remission of Crohn’s Disease in a patient comprising administering to the patient an anti-IL-23 antibody as described above or herein. In one 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 inducing remission of Crohn's Disease in a patient, wherein: a) said anti-IL-23A antibody is to be administered in 3 induction doses each of 600 mg or 1,200 mg to the patient at 4 weeks intervals, and wherein the patient achieves a CDAI score of <150 within 12 weeks following the administration of the first induction dose.

In one example, the present disclosure further provides a method for inducing clinical response to Crohn's Disease in a patient comprising administering to the patient an anti-IL-23 antibody as described above or herein.

In one example, the method further comprises administering a first maintenance dose of the anti-IL-23A antibody to the patient after the last induction dose is administered and administering at least one additional maintenance dose to the patient 4 to 12 weeks after said first maintenance dose is administered. In one example, the first maintenance dose is administered 2 to 8 weeks, for example 4 to 6 weeks, for example 2 weeks, 4 weeks, 6 weeks or 8 weeks, after the last induction dose is administered. In one example, the at least one additional maintenance dose is administered to the patient 4, 8 or 12 weeks after the first maintenance dose is administered.

In one example, the first maintenance dose comprises 150 to 300 mg of the anti-IL-23A antibody. In one example, the first maintenance dose comprises 150 mg, 225 mg or 300 mg of the anti-IL-23A antibody. In one example, the first maintenance dose comprises 180 mg or 270 mg of the anti-IL-23A antibody.
In one example, the at least one additional maintenance dose comprises 150 to 300 mg of the anti-IL-23A antibody. In one example, the at least one additional maintenance dose comprises 150 mg, 225 mg or 300 mg of the anti-IL-23A antibody. In one example, the at least one additional maintenance dose comprises 180 mg or 270 mg of the anti-IL-23A antibody.
In one example, the first maintenance dose and the at least one additional maintenance dose comprise 150 to 300 mg of the anti-IL-23A antibody. In one example, the first maintenance dose and the at least one additional maintenance dose comprise 150 mg, 225 mg or 300 mg of said anti-IL-23A antibody. In one example, the first maintenance dose and the at least one additional maintenance dose comprise 180 mg or 270 mg of said anti-IL-23A antibody.
In one example, a maintenance dose is administered by subcutaneous injection.

In one example, the maintenance doses comprise 150 mg of the anti-IL-23A antibody and are administered to the patient at 4 weeks intervals.
In one example, the maintenance doses comprise 150 mg of the anti-IL-23A antibody and are administered to the patient at 8 weeks intervals.
In one example, the maintenance doses comprise 225 mg of the anti-IL-23A antibody and are administered to the patient at 8 weeks intervals.

In one example, the maintenance doses comprise 225 mg of the anti-IL-23A antibody and are administered to the patient at 12 weeks intervals.
In one example, the maintenance doses comprise 300 mg of the anti-IL-23A antibody and are administered to the patient at 8 weeks intervals.
In one example, the maintenance doses comprise 300 mg of the anti-IL-23A antibody and are administered to the patient at 12 weeks intervals.

In one example, the patient maintains clinical remission after the administration of the one or more maintenance doses. In one example, the patient maintains a CDAI score of less than 150 after the administration of the one or more maintenance doses. In one example, the patient maintains a PRO-2 score equal to or less than 75 after the administration of the one or more maintenance doses. In one example, the patient maintains a CDAI score of less than 150 and a PRO-2 score equal to or less than 75 after the administration of the one or more maintenance doses.

In one example, the present disclosure further provides a method for maintaining clinical remission of Crohn’s Disease in a patient comprising administering to the patient an anti-IL-23 antibody as described above or herein.

In one example, the present disclosure further provides a method for maintaining clinical response to Crohn’s Disease in a patient comprising administering to the patient an anti-IL-23 antibody as described above or herein.

In one example, the present disclosure further provides a method for treating Crohn’s Disease by inducing and maintaining clinical remission in a patient comprising administering to the patient an anti-IL-23 antibody as described above or herein.

In one example, the present disclosure further provides a method for maintaining endoscopic remission of Crohn's Disease in a patient comprising administering to the patient an anti-IL-23 antibody as described above or herein.

In one example,the present disclosure provides a method for inducing clinical remission of Crohn's Disease comprising administering to a patient an anti-IL-23A antibody, said method comprising administering at least one induction dose of said anti-IL-23A antibody to the patient, wherein said induction dose comprises 200 to 1,200 mg of said anti-IL-23A antibody. In one example, the induction dose comprises 450 to 1,200 mg of said anti-IL-23A antibody. In one example, the induction dose comprises 200 mg, 450 mg, 600 mg, 900 mg or 1,200 mg of said anti-IL-23A antibody. In one example, 1, 2 or 3 induction doses are administered to the patient. In one example, 2 or 3 inductions doses are administered at 4 weeks intervals. In one example, the induction dose(s) is/are administered by intravenous infusion. In one example, the patient has a CDAI score of 220-450 before said administration. In one example, the patient achieves a CDAI score of less than 150. In one example, the patient achieves a PRO-2 score equal to or less than 75.

In one example, the method further comprises maintaining clinical remission of Crohn's disease, said method further comprising administering a first maintenance dose of said anti-IL-23A antibody to the patient after the last induction dose is administered, and administering at least one additional maintenance dose to the patient 4 to 12 weeks after said first maintenance dose is administered. In one example, the first maintenance dose is administered 2 to 8 weeks, for example 4 to 6 weeks, for example 2 weeks, 4 weeks, 6 weeks or 8 weeks, after the last induction dose is administered. In one example, the at least one additional maintenance dose is administered to the patient 4, 8 or 12 weeks after after said first maintenance dose is administered. In one example, the first maintenance dose comprises 150 to 300 mg of said anti-IL-23A antibody. In one example, the first maintenance dose comprises 150 mg, 225 mg or 300 mg

of said anti-IL-23A antibody. In one example, the first maintenance dose comprises 180 mg or 270 mg of said anti-IL-23A antibody. In one example, the at least one additional maintenance dose comprises 150 to 300 mg of said anti-IL-23A

antibody. In one example, the at least one additional maintenance dose comprises 150 mg, 225 mg or 300 mg of said anti-IL-23A antibody. In one example, the at least one additional maintenance dose comprises 180 mg or 270 mg of said anti-IL-23A antibody. In one example, the first maintenance dose and said at least one additional maintenance dose comprise 150 to 300 mg of said anti-IL-23A antibody. In one example, the first maintenance dose and said at least one additional maintenance dose comprise 150 mg, 225 mg or 300 mg of said anti-IL-23A antibody. In one example, the first maintenance dose and said at least one additional maintenance dose comprise 180 mg or 270 mg of said anti-IL-23A antibody. In one example, the maintenance dose is administered by subcutaneous injection. In one example, the patient maintains a CDAI score of less than 150. In one example, the patient maintains a PRO-2 score equal to or less than 75.

In one example, the present disclosure provides a method for treating an inflammatory disease, in one examplefor treating Crohn’s Disease, comprising administering to a patient 150 to 1,200 mg of an anti-IL-23A antibody. In one example, the method comprises administering to a patient 200 mg to 1,200 mg of an anti-IL-23A antibody, for example 450 to 1,200 mg of an anti-IL-23A antibody. In one example, the method comprises administering to a patient 200 mg, 450 mg, 600 mg, 900 mg or 1,200 mg of an anti-IL-23A antibody. In one example, the method comprises administering to a patient 150 to 300 mg of an anti-IL-23A antibody. In one example, the method comprises administering to a patient 150 mg, 225 mg or 300 mg of an anti-IL-23A antibody. In one example, the method comprises administering to a patient 180 mg or 270 mg of an anti-IL-23A antibody.

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 Crohn's Disease, for example moderately to severely active Crohn's Disease. In one example, in the context of a method of the present disclosure a patient is naïve to, or was previously

treated with anti-TNF therapy. In one example, in the context of a method of the present disclosure a patient was previously treated with one, two, three or more TNF antagonist(s). In one example, the patient is a patient who had an inadequate response with, was intolerant to, or demonstrated dependence on corticosteroids. In one example, the patient is a patient who had an inadequate response with, lost response, or was intolerant to an immunomodulator, a TNFα inhibitor (or TNF antagonist) or an integrin inhibitor. In one example, the treatment is by inducing and maintaining clinical remission, corticosteroid-free remission, endoscopic remission and mucosal healing.

In one example, a patient to be treated by a method according ot the present disclosure has a CDAI score of 220-450.

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

In one example, in any one of the methods above, the method is for treating ulcerative colitis.

In one example, the present disclosure provides an anti-IL-23A antibody for use in the treament of a disease, for example an inflammatory disease, for example Crohn's Disease, by administration in certain amounts and/or at certain intervals as described herein. In one example, the inflammatory disease is ulcerative colitis.

In one example, 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 Crohn's Disease, by administration in certain amounts and/or at certain intervals as described herein. In one example, the inflammatory disease is ulcerative colitis.

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 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 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)*.

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 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 *(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 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)*.

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.

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 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 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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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 example, the present disclosure provides a method for detecting the presence or absence of a beneficial response in a patient after administration of an IL-23A antagonist, comprising: a) obtaining a biological sample from the patient; b) measuring in said sample the level of expression of one or more genes; c) comparing the level in b) to the level of expression of the one or more genes in a control; and d) determining whether or not the difference in levels between the sample and the control reflects a beneficial response in the patient, wherein the one or more genes is one or more genes described herein. In one example, the patient suffers from Crohns' Disease. In one example, the biological sample is a colon tissue or a ileum tissue. In one example, the biological sample is taken from the upper gatrointestinal (GI) tract, for example the stomach or the esophagus. In one example, the IL-23A antagonist is an anti-IL-23A antibody or an antigen binding fragment thereof, for example Antibody A, Antibody B, Antibody C or Antibody D.

Brief Description of the Figures

Figure 1: Trial Design. Deep remission, defined as achieving clinical remission (CDAI score < 150) and CDEIS remission (CDEIS score ≤ 4 or 2 or less in patients with initial isolated ileitis).

Figure 2A and 2B: Proportion of patients with clinical remission (A) or clinical response (B) at week 4, week 8 and week 12. Clinical remission is defined as a CDAI score <150. Clinical response is either a CDAI score <150 or a CDAI reduction from baseline of ≥100 points. Patients in which prohibited concomitant medication to treat Crohn's disease was used prior to Week 12 were considered as treatment failures. Full analysis set was used for these analyses. *p<0.05 versus placebo, **p<0.005 versus placebo, ***p<0.001 versus placebo.

Figure 3A-D: Median CDAI scores over time (A), median CRP over time (B), median percent change in FCP from baseline (C), median percent change in IL-22 from baseline (D). *p <0.001, Bonferroni adjusted p-value for 600 mg Antibody A versus placebo. **p <0.05, Bonferroni adjusted p-value for 600 mg Antibody A versus placebo.

Claims

1. 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 inducing remission of Crohn's Disease in a patient, wherein:
    a) said anti-IL-23A antibody is to be administered in 3 induction doses each of 600 mg or 1,200 mg to the patient at 4 weeks intervals, and wherein the patient achieves a CDAI score of <150 within 12 weeks following the administration of the first induction dose.

2. The use according to claim 1, wherein said induction doses comprise 600 mg of said anti-IL-23A antibody.

3. The use according to claim 1, wherein said induction doses comprise 1,200 mg of said anti-IL-23A antibody.

4. The use according to any one of claims 1 to 3, wherein said induction doses are to be administered by intravenous infusion.

5. The use according to anyone of claims 1 to 4, wherein said patient achieves a PRO-2 score equal to or less than 75 within 12 weeks following the administration of the first induction dose.

6. The use according to any one of claims 1 to 5, wherein the treatment further comprises maintaining remission of moderately to severe active Crohn's disease by
    b) said anti-IL-23A antibody is to be administered subcutaneously as a first maintenance dose of 180 mg to the patient after the last induction dose is administered, wherein said first maintenance dose is administered 2 to 8 weeks after the last induction dose is administered; and
    c) an additional maintenance dose of 180 mg of said anti-IL-23A antibody is to be administered subcutaneously to the patient every 8 weeks after said first maintenance dose is administered.

7. The use according to claim 6, wherein said patient maintains a CDAI score of less than 150.

8. The use according to claim 6, wherein said patient maintains a PRO-2 score equal to or less than 75.