Feagan B G *et al.*, Gastroenterology, Vol. 150, No. 4, Supplement 1, S1266, Abstract 812a, 2016).

Treatment regimens for CD with anti-IL-23p19 antibodies are disclosed in WO 2014/143540 Al and WO 2017/048901 Al.

There remains a need for treatment options for CD that lead to favourable outcomes for patients, for example, in terms of efficacy, safety and/or tolerability of the treatment. In particular, there remains a need for treatment options in the form of dosage regimen of mirikizumab that provides optimal efficacy in the treatment of CD.

SUMMARY

In a first aspect, the present disclosure refers to a use of mirikizumab in the manufacture of a medicament for treating Crohn's Disease (CD) in a patient, wherein

a) three induction doses of the medicament are to be administered to the patient by intravenous injection, wherein each induction dose comprises about 900 mg of mirikizumab; and

b) maintenance dose(s) of the medicament are to be administered to the patient by subcutaneous injection at about 4 week or about 8 week intervals, wherein the first maintenance dose is to be administered about 4 weeks or about 8 weeks after the last induction dose is administered and wherein each maintenance dose comprises about 200 mg or about 300 mg of mirikizumab,

wherein the CD is moderate to severe CD.

In another aspect, the present disclosure refers to mirikizumab for use in the treatment of CD in a patient, wherein

a) three induction doses of mirikizumab are to be administered to the patient, wherein each induction dose comprises about 900 mg of mirikizumab; and

b) maintenance dose(s) of mirikizumab are to be administered to the patient after the last induction dose is administered and wherein each maintenance dose comprises about 200 mg or about 300 mg of mirikizumab,

wherein the CD is moderate to severe CD.

DESCRIPTION

Accordingly, in a first aspect of the present invention, there is a provided a method for treating CD comprising administering mirikizumab to a patient, said method comprising:

a) administering at least one induction dose of mirikizumab to the patient, wherein the induction dose comprises about 200 mg to about 1200 mg of mirikizumab; and

b) administering at least one maintenance dose of mirikizumab to the patient after the last induction dose is administered, wherein the maintenance dose comprises about 100 mg to about 600 mg of mirikizumab.

In a further embodiment of the method of the present invention, the CD is moderate to severe CD.

In a still further embodiment of the method of the present invention, the patient is conventional-failed.

In an alternative embodiment of the method of the present invention, the patient is biologic-experienced.

In an alternative further embodiment of the method of the present invention, the patient is biologic-failed.

In a still further embodiment of the method of the present invention, the at least one induction dose comprises about 200 mg, about 300 mg, about 400 mg, about 500 mg, about 600 mg, about 700 mg, about 800 mg, about 900 mg, about 1000 mg, about 1100 mg or about 1200 mg of mirikizumab.

In a preferred embodiment of the method of the present invention, the at least one induction dose comprises about 900 mg of mirikizumab.

CLAIMS:

1. Use of mirikizumab in the manufacture of a medicament for treating Crohn's Disease (CD) in a patient, wherein
   a) three induction doses of the medicament are to be administered to the patient by intravenous injection, wherein each induction dose comprises about 900 mg of mirikizumab; and
   b) maintenance dose(s) of the medicament are to be administered to the patient by subcutaneous injection at about 4 week or about 8 week intervals, wherein the first maintenance dose is to be administered about 4 weeks or about 8 weeks after the last induction dose is administered and wherein each maintenance dose comprises about 200 mg or about 300 mg of mirikizumab,

   wherein the CD is moderate to severe CD.

2. The use according to claim 1, wherein the patient is conventional-failed.

3. The use according to claim 1, wherein the patient is biologic-experienced.

4. The use according to claim 1, wherein the patient is biologic-failed.

5. The use according to any one of claims 1-4, wherein three induction doses of the medicament are to be administered at about 4 week intervals and the first maintenance dose is to be administered about 4 weeks after the last induction dose is administered.

6. Mirikizumab for use in the treatment of CD in a patient, wherein
   a) three induction doses of mirikizumab are to be administered to the patient, wherein each induction dose comprises about 900 mg of mirikizumab; and
   b) maintenance dose(s) of mirikizumab are to be administered to the patient after the last induction dose is administered and wherein each maintenance dose comprises about 200 mg or about 300 mg of mirikizumab,

   wherein the CD is moderate to severe CD.

7. Mirikizumab for use in the treatment of CD according to claim 6, wherein the patient is conventional-failed.

8. Mirikizumab for use in the treatment of CD according to claim 6, wherein the patient is biologic-experienced.

9. Mirikizumab for use in the treatment of CD according to claim 6, wherein the patient is biologic-failed.

10. Mirikizumab for use in the treatment of CD according to any one of claims 6-9, wherein three induction doses of mirikizumab are to be administered at about 4 week intervals and the first maintenance dose is to be administered about 4 weeks after the last induction dose is administered.