CLAIMS

What is claimed is:

1. Use of a humanized anti-α4β7 antibody in the manufacture of a medicament for the treatment of inflammatory bowel disease in a patient,

wherein the humanized anti-α4β7 antibody comprises an antigen binding region of nonhuman origin and at least a portion of an antibody of human origin, wherein the humanized anti-α4β7 antibody has binding specificity for the α4β7 complex, wherein the antigen-binding region comprises the CDRs:

Light chain: CDR1 SEQ ID NO:11
CDR2 SEQ ID NO:12 and
CDR3 SEQ ID NO:13 and

Heavy chain: CDR1 SEQ ID NO:8
CDR2 SEQ ID NO:9 and
CDR3 SEQ ID NO:10,

wherein the medicament is for administration to the patient according to the following dosing regimen:

a) an initial dose of 300 mg of the humanized anti-α4β7 antibody;

b) followed by a second subsequent dose of 300 mg of the humanized anti-α4β7 antibody two weeks after the initial dose; and

c) followed by a third subsequent dose of 300 mg of the humanized anti-α4β7 antibody six weeks after the initial dose.

2. The use according to claim 1, wherein the dosage regimen further comprises

d) a fourth and subsequent doses of 300 mg of the humanized anti-α4β7 antibody every four weeks after the third subsequent dose of the humanized anti-α4β7 antibody.

3. The use according to claim 1, wherein the dosage regimen further comprises

d) a fourth and subsequent doses of 300 mg of the humanized anti-α4β7 antibody every eight weeks after the third subsequent dose of the humanized anti-α4β7 antibody.

4. The use of claim 1, wherein clinical response is induced.

5. The use of any one of claims 1 to 3, wherein clinical response and clinical remission are induced.

6. The use of claim 5, wherein the clinical response and clinical remission are durable.

7. Use of a humanized anti-α4β7 antibody in the manufacture of a medicament for treatment of inflammatory bowel disease in a patient,

wherein the humanized anti-α4β7 antibody comprises an antigen binding region of nonhuman origin and at least a portion of an antibody of human origin, wherein the humanized anti-α4β7 antibody has binding specificity for the α4β7 complex, wherein the antigen-binding region comprises the CDRs:

Light chain: CDR1 SEQ ID NO:11 and
CDR2 SEQ ID NO:12 and
CDR3 SEQ ID NO:13 and
Heavy chain: CDR1 SEQ ID NO:8 and
CDR2 SEQ ID NO:9 and
CDR3 SEQ ID NO:10, and

wherein the medicament is for administration to the patient at a dose of 300 mg of the humanized anti-α4β7 antibody every four weeks.

8. Use of a humanized anti-α4β7 antibody in the manufacture of a medicament for treatment of inflammatory bowel disease in a patient,

wherein the humanized anti-α4β7 antibody comprises an antigen binding region of nonhuman origin and at least a portion of an antibody of human origin, wherein the humanized anti-α4β7 antibody has binding specificity for the α4β7 complex, wherein the antigen-binding region comprises the CDRs:

Light chain: CDR1 SEQ ID NO:11 and
CDR2 SEQ ID NO:12 and
CDR3 SEQ ID NO:13 and
Heavy chain: CDR1 SEQ ID NO:8 and

CDR2 SEQ ID NO:9 and

CDR3 SEQ ID NO:10, and

wherein the medicament is for administration to the patient at a dose of 300 mg of the humanized anti-α4β7 antibody every eight weeks.

9. The use of claim 7 or 8, wherein remission is maintained.

10. The use according to any one of claims 1 to 9, wherein the medicament is suitable for administration to the patient as an intravenous infusion.

11. The use of claim 10, wherein the humanized anti-α4β7 antibody is for administration to the patient over 30 minutes.

12. The use of any one of claims 1 to 11, wherein the patient had a lack of an adequate response with, lost response to, or was intolerant to treatment with at least one of an immunomodulator, a tumor necrosis factor-alpha antagonist, a corticosteroid, or combinations thereof.

13. The use of claim 12, wherein the tumor necrosis factor-alpha antagonist is infliximab.

14. The use of any one of claims 1 to 13, wherein the dosing regimen results in mucosal healing in patients suffering from moderate to severely active ulcerative colitis.

15. The use of any one of claims 1 to 14, wherein the dosing regimen results in a reduction, elimination or reduction and elimination of corticosteroids use by the patient.

16. The use of any one of claims 1 to 11, where the patient previously received treatment with at least one corticosteroid for the inflammatory bowel disease.

17. The use of any one of claims 1 to 16, wherein the humanized anti-α4β7 antibody is for administration in a final dosage form at a concentration of between 1.0 mg/mL to 1.4 mg/mL.

18. The use of claim 17, wherein the humanized anti-α4β7 antibody is for administration in a final dosage form of 1.2 mg/mL.

19. The use of any one of claims 1 to 18, wherein the dosing regimen does not alter the ratio of CD4 to CD8 in cerebrospinal fluid of patients receiving said treatment.

20. The use of any one of claims 1 to 19, wherein the patient is a person 65 years of age or older.

21. Use of an anti-α4β7 antibody in the manufacture of a medicament for treating a human patient having inflammatory bowel disease, wherein the patient had a lack of an adequate response with, lost response to, or was intolerant to a TNF alpha antagonist, wherein the anti-α4β7 antibody is an IgG isotype; comprises a light chain comprising a CDR1 as set forth in SEQ ID NO: 11, a CDR2 as set forth in SEQ ID NO:12, and a CDR3 as set forth in SEQ ID NO:13; and comprises a heavy chain comprising a CDR1 as set forth in SEQ ID NO: 8, a CDR2 as set forth in SEQ ID NO:9, and a CDR3 as set forth in SEQ ID NO:10, wherein the antibody is for intravenous administration to the patient according to the following dosing regimen: a first dose of 300 mg of the antibody, a second dose of 300 mg of the antibody two weeks after the first dose, and a third dose of 300 mg of the antibody six weeks after the first dose.

22. Use of an anti-α4β7 antibody in the manufacture of a medicament for treating a human patient having inflammatory bowel disease, wherein the patient had a lack of an adequate response with, lost response to, or was intolerant to corticosteroids, wherein the anti-α4β7 antibody is an IgG isotype; comprises a light chain comprising a CDR1 as set forth in SEQ ID NO: 11, a CDR2 as set forth in SEQ ID NO:12, and a CDR3 as set forth in SEQ ID NO:13; and comprises a heavy chain comprising a CDR1 as set forth in SEQ ID NO: 8, a CDR2 as set forth in SEQ ID NO:9, and a CDR3 as set forth in SEQ ID NO:10.

23. Use of an anti-α4β7 antibody in the manufacture of a medicament for treating a human patient having inflammatory bowel disease, wherein the patient had a lack of an adequate response with, lost response to, or was intolerant to an

immunomodulator, wherein the anti-α4β7 antibody is an IgG isotype; comprises a light chain comprising a CDR1 as set forth in SEQ ID NO: 11, a CDR2 as set forth in SEQ ID NO:12, and a CDR3 as set forth in SEQ ID NO:13; and comprises a heavy chain comprising a CDR1 as set forth in SEQ ID NO: 8, a CDR2 as set forth in SEQ ID NO:9, and a CDR3 as set forth in SEQ ID NO:10.

24. The use of any one of claims 1 to 23, wherein inflammatory bowel disease is Crohn's disease, pouchitis, celiac disease, or ulcerative colitis.

25. The use of claim 24, wherein the inflammatory bowel disease is ulcerative colitis.

26. The use of claim 24, wherein the inflammatory bowel disease is moderate to severely active ulcerative colitis.

27. The use of any one of claims 1 to 26, wherein the antibody is an IgG1 isotype.

28. The use of any one of claims 1 to 26, wherein the antibody comprises a light chain variable region comprising amino acids 20 to 131 of SEQ ID NO: 4, and a heavy chain variable region comprising amino acids 20 to 140 of SEQ ID NO: 2.

29. The use of any one of claims 1 to 26, wherein the antibody comprises a heavy chain comprising amino acids 20 to 470 of SEQ ID NO:2, and a light chain comprising amino acids 20 to 238 of SEQ ID NO:4.

30. The use of any one of claims 1 to 26, wherein the anti-α4β7 antibody is vedolizumab.

31. Use of a humanized anti-α4β7 antibody in the manufacture of a medicament for the treatment of patient having an inflammatory disease associated with mucosal tissues,

wherein the humanized anti-α4β7 antibody comprises an antigen binding region of nonhuman origin and at least a portion of an antibody of human origin, wherein the humanized anti-α4β7 antibody has binding specificity for the α4β7 complex, wherein the antigen-binding region comprises the CDRs:

Light chain: CDR1 SEQ ID NO:11 and

CDR2 SEQ ID NO:12 and
CDR3 SEQ ID NO:13 and
Heavy chain: CDR1 SEQ ID NO:8 and
CDR2 SEQ ID NO:9 and
CDR3 SEQ ID NO:10,

wherein the medicament is for administration to the patient according to the following dosing regimen:

a) an initial dose of 300 mg of the humanized anti-α4β7 antibody;

b) followed by a second subsequent dose of 300 mg of the humanized anti-α4β7 antibody two weeks after the initial dose; and

c) followed by a third subsequent dose of 300 mg of the humanized anti-α4β7 antibody six weeks after the initial dose.

32. The use according to claim 31, wherein the dosage regimen further comprises

d) a fourth and subsequent doses of 300 mg of the humanized anti-α4β7 antibody every four weeks after the third subsequent dose of the humanized anti-α4β7 antibody.

33. The use according to claim 1, wherein the dosage regimen further comprises

d) a fourth and subsequent doses of 300 mg of the humanized anti-α4β7 antibody every eight weeks after the third subsequent dose of the humanized anti-α4β7 antibody.

34. Use of a humanized anti-α4β7 antibody in the manufacture of a medicament for treatment of a patient having an inflammatory disease associated with mucosal tissues,

wherein the humanized anti-α4β7 antibody comprises an antigen binding region of nonhuman origin and at least a portion of an antibody of human origin, wherein the humanized anti-α4β7 antibody has binding specificity for the α4β7 complex, wherein the antigen-binding region comprises the CDRs:

Light chain: CDR1 SEQ ID NO:11 and
CDR2 SEQ ID NO:12 and
CDR3 SEQ ID NO:13 and

Heavy chain: CDR1 SEQ ID NO:8 and
CDR2 SEQ ID NO:9 and
CDR3 SEQ ID NO:10, and

wherein the medicament is for administration to the patient at a dose of 300 mg of the humanized anti-α4β7 antibody every four weeks.

35. Use of a humanized anti-α4β7 antibody in the manufacture of a medicament for treatment of a patient having an inflammatory disease associated with mucosal tissues,

wherein the humanized anti-α4β7 antibody comprises an antigen binding region of nonhuman origin and at least a portion of an antibody of human origin, wherein the humanized anti-α4β7 antibody has binding specificity for the α4β7 complex, wherein the antigen-binding region comprises the CDRs:

Light chain: CDR1 SEQ ID NO:11 and
CDR2 SEQ ID NO:12 and
CDR3 SEQ ID NO:13 and
Heavy chain: CDR1 SEQ ID NO:8 and
CDR2 SEQ ID NO:9 and
CDR3 SEQ ID NO:10, and

wherein the medicament is for administration to the patient at a dose of 300 mg of the humanized anti-α4β7 antibody every eight weeks.

36. The use according to any one of claims 31 to 35, wherein the inflammatory disease associated with mucosal tissue is graft versus host disease.

37. Use of a humanized anti-α4β7 antibody in the manufacture of a medicament for the treatment of human immunodeficiency virus in a patient, wherein the medicament is for administration to the patient at a dose of 300 mg of the humanized anti-α4β7 antibody every four weeks.

38. The use according to any one of claims 31 to 37, wherein the medicament is suitable for administration to the patient as an intravenous infusion.

39. The use of claim 38, wherein the humanized anti-α4β7 antibody is for administration to the patient over 30 minutes.

40. The use of any one of claims 31 to 39, wherein the antibody is an IgG1 isotype.

41. The use of any one of claims 31 to 39, wherein the antibody comprises a light chain variable region comprising amino acids 20 to 131 of SEQ ID NO: 4, and a heavy chain variable region comprising amino acids 20 to 140 of SEQ ID NO: 2.

42. The use of any one of claims 31 to 39, wherein the antibody comprises a heavy chain comprising amino acids 20 to 470 of SEQ ID NO:2, and a light chain comprising amino acids 20 to 238 of SEQ ID NO:4.

43. The use of any one of claims 31 to 39, wherein the anti-α4β7 antibody is vedolizumab.