# CLAIMS

**What is claimed is:**

1. A method of treating an individual with Crohn's Disease comprising: administering to the individual in need thereof a pharmaceutical dosage form comprising a therapeutically effective amount of (*R*)-2-(7-(4-cyclopentyl-3-(trifluoromethyl)benzyloxy)-1,2,3,4-tetrahydrocyclopenta[*b*]indol-3-yl)acetic acid (Compound 1), or a pharmaceutically acceptable salt thereof.

2. The method of claim 1, wherein the individual has demonstrated an inadequate response to, loss of response to, or intolerance of to at least one agent for the treatment of Crohn's Disease chosen from glucocorticosteroids, immunosuppressants, and biologics.

3. The method of claim 1 or 2, wherein the dosage form is administered under fasted conditions.

4. The method of claim 1 or 2, wherein the dosage form is administered under fed conditions.

5. The method of any one of the preceding claims, wherein the therapeutically effective amount is equivalent to about 0.5 to about 5.0 mg of Compound 1.

6. The method of claim 5, wherein the therapeutically effective amount is in an amount equivalent to 2 mg of Compound 1.

7. The method of claim 5, wherein the therapeutically effective amount is in an amount equivalent to 3 mg of Compound 1.

8. The method of any one of the preceding claims, wherein the dosage form is administered without titration.

9. The method of claim 5, wherein the individual is administered an amount equivalent to 2 mg of Compound 1 for a first time period and subsequently an amount equivalent to 3 mg of Compound 1 for a second time period.

10. The method of any one of the preceding claims, wherein the Compound 1, or a pharmaceutically acceptable salt thereof is administered orally.

11. The method of any one of the preceding claims, wherein the Compound 1, or a pharmaceutically acceptable salt thereof, is formulated as a capsule or tablet suitable for oral administration.

12. The method of any one of the preceding claims, wherein the Compound 1, or a pharmaceutically acceptable salt thereof, is selected from:

Compound 1;

a calcium salt of Compound 1; and

an L-arginine salt of Compound 1.

13. The method of claim 12, wherein the Compound 1, or a pharmaceutically acceptable salt thereof, is an L-arginine salt of Compound 1.

14. The method of claim 13, wherein the Compound 1, or a pharmaceutically acceptable salt thereof, is an anhydrous, non-solvated crystalline form of an L-arginine salt of Compound 1.

15. The method of claim 12, wherein the Compound 1, or a pharmaceutically acceptable salt thereof, is an anhydrous, non-solvated crystalline form of Compound 1.

16. The method of any one of the preceding claims, wherein the therapeutically effective amount of Compound 1, or a pharmaceutically acceptable salt thereof, is administered once daily to the individual.

17. The method of any one of the preceding claims, wherein the method is non-gender specific.

18. The method of any one of the preceding claims, wherein the individual was previously administered at least one agent selected from: a TNFα antagonist, an integrin antagonist, and an immunosuppressive agent.

19. The method of claim 18, wherein the individual had an inadequate response with, lost response to, or was intolerant to the at least one agent.

20. The method of any one of the preceding claims, wherein treating comprises inducing and/or maintaining clinical response; improving endoscopic appearance of the mucosa; and/or inducing and/or maintaining clinical remission.

21. The method of any one of the preceding claims, wherein said administering results in no serious adverse events.

22. The method of any one of the preceding claims, wherein the Compound 1 is administered without substantially inducing an acute heart rate reduction or heart block in the individual.

23. The method of any one of the preceding claims, further comprising monitoring for adverse events during the administration of Compound 1, or a pharmaceutically acceptable salt thereof, and optionally, interrupting or terminating the administration of Compound 1, or a pharmaceutically acceptable salt thereof.

24. The method of any one of the preceding claims, wherein said individual has moderately to severely active Crohn's Disease.

25. The method of claim 24, wherein said individual has moderately active Crohn's Disease.

26. The method of claim 24, wherein said individual has severely active Crohn's Disease.

27. The method of any one of the preceding claims, wherein said individual has had inadequate response to conventional therapy.

28. The method of claim 27, wherein said conventional therapy is selected from at least one of corticosteroids, immunosuppressants, and biologics.

29. The method of claim 27, wherein said conventional therapy is selected from at least one of prednisone, budesonide, 6-mercaptopurine, azathioprine, methotrexate, infliximab, adalimumab, or certolizumab pegol.

30. The method of any one of the preceding claims, wherein said individual is not co-administered a TNFα inhibitor.

31. The method of any one of the preceding claims, wherein Compound 1 is the sole active ingredient administered to the individual for treatment of said Crohn's Disease.

32. A method of treating an individual with Crohn's Disease comprising:

administering an induction dose of Compound 1, or a pharmaceutically acceptable salt thereof, to the individual in need thereof for an induction phase, wherein the induction phase comprises at least 14 weeks; and

administering a maintenance dose of Compound 1, or a pharmaceutically acceptable salt thereof, to the individual in need thereof for a maintenance phase.

33. The method of claim 32, wherein the induction dose comprises an amount equivalent to 3 mg of Compound 1.

34. The method of any one of claim 32 or claim 33, wherein the maintenance dose comprises an amount equivalent to 2 mg of Compound 1.

35. The method of any one of claims 32-34, wherein the maintenance phase comprises at least 38 weeks.

36. The method of any one of claims 32-35, wherein the Compound 1 or a pharmaceutically acceptable salt thereof is administered at a frequency of once a day during both the induction dose and the maintenance dose.

37. The method of any one of claims 32-36, wherein said individual has moderately to severely active Crohn's disease.

38. A compound that is (R)-2-(7-(4-cyclopentyl-3-(trifluoromethyl)benzyloxy)-1,2,3,4-tetrahydrocyclopenta[b]indol-3-yl)acetic acid (Compound 1), or a pharmaceutically acceptable salt thereof, for use in a method of treatment of Crohn's Disease in an individual.

39. A compound that is (R)-2-(7-(4-cyclopentyl-3-(trifluoromethyl)benzyloxy)-1,2,3,4-tetrahydrocyclopenta[b]indol-3-yl)acetic acid (Compound 1), or a pharmaceutically acceptable salt thereof, for use in a method of treatment of Crohn's Disease in an individual, wherein the method comprises:
administering an induction dose of the compound to the individual for an induction phase, wherein the induction phase comprises at least 14 weeks; and
administering a maintenance dose of the compound to the individual for a maintenance phase.

40. The compound for use according to claim 39, wherein the induction dose comprises an amount equivalent to 3 mg of Compound 1.

41. The compound for use according to claim 39 or 40, wherein the maintenance dose comprises an amount equivalent to 2 mg of Compound 1.

42. The compound for use according to any one of claims 39-41, wherein the maintenance phase comprises at least 38 weeks.

43. The compound for use according to any one of claims 39-42, wherein the compound is administered at a frequency of once a day during both the induction dose and the maintenance dose.

44. The compound for use according to any one of claims 39-43, wherein said individual has moderately to severely active Crohn's Disease.

45. Use of a compound that is (R)-2-(7-(4-cyclopentyl-3-(trifluoromethyl)benzyloxy)-1,2,3,4-tetrahydrocyclopenta[b]indol-3-yl)acetic acid (Compound 1), or a pharmaceutically acceptable salt thereof, in the manufacture of a medicament for use in a method of treatment of moderately to severely active Crohn's Disease in an individual.

46. Use of a compound that is (R)-2-(7-(4-cyclopentyl-3-(trifluoromethyl)benzyloxy)-1,2,3,4-tetrahydrocyclopenta[b]indol-3-yl)acetic acid (Compound 1), or a pharmaceutically acceptable salt thereof, in the manufacture of a medicament for use in a method of treatment of moderately to severely active Crohn's Disease in an individual, wherein the method comprises:

administering an induction dose of the compound to the individual for an induction phase, wherein the induction phase comprises at least 14 weeks; and

administering a maintenance dose of the compound to the individual for a maintenance phase.

47. Use according to claim 46, wherein the induction dose comprises an amount equivalent to 3.0 mg of Compound 1.

48. Use according to claim 46 or 47, wherein the maintenance dose comprises an amount equivalent to 2.0 mg of Compound 1.

49. Use according to any one of claims 46-48, wherein the maintenance phase comprises at least 38 weeks.

50. Use according to any one of claims 46-49, wherein the compound is administered at a frequency of once a day during both the induction dose and the maintenance dose.

51. A method of treating an individual with Crohn's Disease comprising:

administering an induction dose of Compound 1, or a pharmaceutically acceptable salt thereof, to the individual in need thereof for an induction phase, wherein the induction phase comprises at least 14 weeks;

testing the individual for a clinical response; and

if the individual demonstrates a clinical response, administering a maintenance dose of Compound 1, or a pharmaceutically acceptable salt thereof, to the individual in need thereof for a maintenance phase.

52. The method of claim 51, wherein the induction dose comprises an amount equivalent to 3 mg of Compound 1.

53. The method of any one of claim 51 or claim 52, wherein the maintenance dose comprises an amount equivalent to 2 mg of Compound 1.

54. The method of any one of claims 51-53, wherein the maintenance phase comprises at least 38 weeks.

55. The method of any one of claims 51-54, wherein the Compound 1 or a pharmaceutically acceptable salt thereof is administered at a frequency of once a day during both the induction dose and the maintenance dose.

56. The method of any one of claims 51-55, wherein said individual has moderately to severely active Crohn's disease.

57. The method of any one of claims 51-56, wherein the clinical response is a Simple Endoscopic Score in Crohn's Disease (SES-CD) less than or equal to 4 and at least 2-point reduction from baseline with no sub-score > 1.

58. The method of any one of claims 51-56, wherein the clinical response is a greater than or equal to 50% decrease from baseline in SES-CD.

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