Claims

1. A composition including rifabutin, clarithromycin, and clofazimine for the treatment of an auto-immune disease.

2. The composition of claim 1 further comprising an antibiotic selected from daptomycin, clindamycin, rifampicin, erythromycin, oleandomycin, roxithromycin, azithromycin, kanamycin, gentamycin, tobramycin, streptomycin, neomycin, paromomycin, ethambutol, isoniazid, minocyclin, tetracycline.

3. The composition of claim 1 further comprising at least one vitamin.

4. The composition of claim 3 wherein said at least one vitamin comprises Vitamin D.

5. The composition of claim 1 wherein the auto-immune disease is multiple sclerosis.

6. The composition of claim 1 wherein the autoimmune disease is Hashimoto's Thyroiditis, Melkersson-Rosenthal syndrome or Sarcoidosis.

7. The composition of claim 1 formulated for oral administration.

8. The composition of claim 1 formulated for intravenous administration.

9. The composition of claim 1 further comprising an absorption enhancer

10. The composition of claim 9 wherein said absorption enhancer comprises polyethylene glycol.

11. The composition of claim 1 further comprising an anti-inflammatory agent.

12. The composition of claim 11 wherein said anti-inflammatory agent comprises one or a combination of 5-aminosalicylic acid, azathioprine or methotrexate.

13. The composition of claim 1 further comprising a cyclin dependent kinase inhibitor.

14. The composition of claim 13 wherein said cyclin dependent kinase inhibitor comprises R-roscovitine or Flavopiridol.

15. A composition comprising rifabutin, clarithromycin, and clofazimine for the treatment of multiple sclerosis in a subject.

16. The composition of claim 15 formulated for oral administration.

17. The composition of claim 15 formulated for intravenous administration.

18. The composition of claim 15 wherein said rifabutin, clarithromycin, and clofazimine are co-formulated into a single dosage form.

19. The composition of claim 15 further comprising an absorption enhancer

20. The composition of claim 19 wherein said absorption enhancer comprises polyethylene glycol.

21. The composition of claim 15 further comprising Vitamin D.

22. The composition of claim 15 further comprising an anti-inflammatory agent.

23. The composition of claim 22 wherein said anti-inflammatory agent comprises one or a combination of 5-aminosalicylic acid, azathioprine or methotrexate.

24. The composition of claim 23 further comprising a cyclin dependent kinase inhibitor.

25. The composition of claim 24 wherein said cyclin dependent kinase inhibitor comprises R-roscovitine or Flavopiridol.

26. A combination of antibiotic agents selected from rifabutin, clarithromycin and clofazimine for the treatment of an autoimmune disease.

27. The combination of antibiotic agents of claim 26 for the treatment of multiple sclerosis.

28. The combination of antibiotic agents of claim 26 formulated into a single dosage form.

29. The combination of antibiotic agents of claim 26 wherein each antibiotic agent is formulated in a separate dosage form to the other antibiotic agents.

30. The combination of antibiotic agents of claim 26 wherein two of the antibiotic agents are co-formulated in a single dosage form and the other antibiotic agent is formulated in a separate dosage form.

31. A composition including rifabutin, clarithromycin, and clofazimine for the treatment or prevention of a relapse episode in a patient suffering from an auto-immune disease.

32. A composition comprising rifabutin, clarithromycin, and clofazimine for the treatment or prevention of a relapse episode of multiple sclerosis in a subject

33. A method of treating an auto-immune disease comprising administering an effective amount of rifabutin, clarithromycin and clofazimine to a subject suffering from said auto-immune disease.

34. The method of claim 33 wherein at least two of the antibiotics are administered to said subject simultaneously.

35. The method of claim 33 wherein said rifabutin, clarithromycin, and clofazimine are administered separately.

36. The method of claim 33 wherein said rifabutin, clarithromycin, and clofazimine are administered together.

37. The method of claim 33 wherein said rifabutin, clarithromycin, and clofazimine are co-formulated to form a single dosage unit.

38. The method of claim 33 wherein said autoimmune disease is multiple sclerosis.

39. A method of treating an auto-immune disease comprising administering a composition comprising rifabutin, clarithromycin and clofazimine and at least one pharmaceutically acceptable excipient to a subject suffering from said auto-immune disease.

40. The method of claim 39 wherein said treating of said autoimmune disease comprises at least an amelioration of one or more symptom associated with said autoimmune disease.

41. The method of claim 39 wherein said autoimmune disease is multiple sclerosis.

42. The method of claim 41 wherein said treatment of multiple sclerosis comprises at least an amelioration of one or more symptoms associated with multiple sclerosis.

43. The method of claim 42 wherein said one or more symptoms associated with multiple sclerosis are selected from one or more of weakness and/or numbness in one or more limbs; tingling of the extremities and tight band-like sensations around the trunk or limbs; dragging or poor control of one or both legs to spastic or ataxic parepesis; hyperactive tendon reflexes; disappearance of abdominal reflexes; Lhermitte's sign; retrobulbar or optic neuritis; unsteadiness in walking; brain stem symptoms (diplopia, vertigo, vomiting); disorders of micturition; hemiplegia; trigeminal neuralgia; other pain syndromes; nystagmus and ataxia; cerebellar-type ataxia; Charcot's triad; diplopia; bilateral internuclear ophthalmoplegia; myokymia or paralysis of facial muscles; deafness; tinnitus; unformed auditory hallucinations; vertigo and vomiting; transient facial anesthesia or of trigeminal neuralgia; bladder dysfunction; euphoria; depression; dementia, dull, aching pain in the low back; sharp, burning, poorly localized pains in a limb or both legs and girdle pains; abrupt attacks of neurologic deficit; dysarthria and ataxia; paroxysmal pain and dysesthesia in a limb; flashing lights; paroxysmal itching; and/or tonic seizures, taking the form of flexion (tonic) spasm of the hand, wrist, and elbow with extension of the lower limb.

44. The method of claim 41 wherein said treatment of multiple sclerosis comprises at least an amelioration of one or more symptoms selected from one or more of: reducing the number of inflammatory episodes suffered by the subject, slowing the progression of the disease in said subject or reducing or at least slowing down the development of brain lesions in the subject.

45. The method of claim 39 wherein said composition comprises one or more further antibiotic selected from daptomycin, clindamycin, rifampicin, erythromycin, oleandomycin, roxithromycin, azithromycin, kanamycin, gentamycin, tobramycin, streptomycin, neomycin, paromomycin, ethambutol, isoniazid, minocyclin, tetracycline is administered to said subject.

46. The method of claim 39 wherein said composition further comprises at least one vitamin.

47. The method of claim 46 wherein said at least one vitamin comprises Vitamin D.

48. The method of claim 39 wherein said composition is administered to said subject orally.

49. The method of claim 48 wherein said composition is administered to said subject intravenously.

50. The method of claim 39 wherein said composition further comprises an absorption enhancer

51. The method of claim 50 wherein said absorption enhancer comprises polyethylene glycol.

52. The method of claim 51 wherein said composition further comprises an anti-inflammatory agent.

53. The method of claim 52 wherein said anti-inflammatory agent comprises one or a combination of 5-aminosalicylic acid, azathioprine or methotrexate.

54. The method of claim 39 wherein said composition further comprises a cyclin dependent kinase inhibitor.

55. The method of claim 54 wherein said cyclin dependent kinase inhibitor comprises R-roscovitine or flavopiridol.

56. A method of treating or preventing a relapse episode of an auto-immune disease in a subject comprising administering an effective amount of rifabutin, clarithromycin and clofazimine to a subject suffering from an autoimmune disease.

57. A method of treating or preventing a relapse episode of multiple sclerosis in a subject comprising administering an effective amount of rifabutin, clarithromycin and clofazimine to a subject suffering from multiple sclerosis.

58. A process for the formulation of a composition for use in the treatment of an autoimmune disease; said process including

dispersing a first antibiotic in polyethylene glycol (PEG) to form a first antibiotic/PEG dispersion; and subsequently

mixing said first antibiotic/PEG dispersion with two or more different antibiotics.

59. The process of claim 58 wherein said first antibiotic comprises clofazimine.

60. The process of claim 58 wherein said clofazimine/PEG dispersion is subsequently mixed with clarithromycin and rifabutin.

61. A method of treating of an auto-immune disease in a subject comprising administering rifabutin, clarithromycin and clofazimine to said subject to substantially reduce or diminish the pathological processes which occur after the onset of a disability resulting from said auto-immune disease.

CLAIMS

1. A composition comprising:

an effective amount of rifabutin;

an effective amount of clarithromycin; and

an effective amount of clofazimine,

wherein the effective amounts of rifabutin, clarithromycin, and clofazimine are sufficient to enable treatment of a subject suffering from an autoimmune disease by targeting cytokines or cytokine receptors.

2. The composition of claim 1 further comprising an antibiotic selected from the group consisting of daptomycin, clindamycin, rifampicin, erythromycin, oleandomycin, roxithromycin, azithromycin, kanamycin, gentamycin, tobramycin, streptomycin, neomycin, paromomycin, ethambutol, isoniazid, minocyclin, and tetracycline.

3. The composition of claim 1 wherein the autoimmune disease is a disease of the central nervous system.

4. The composition of claim 1 wherein the autoimmune disease is multiple sclerosis.

5. The composition of claim 1 wherein the autoimmune disease is Hashimoto's Thyroiditis, Melkersson-Rosenthal syndrome or Sarcoidosis.

6. The composition of claim 1 formulated for oral administration.

7. The composition of claim 1 formulated for intravenous administration.

8. The composition of claim 1 wherein the clofazimine is dispersed in an absorption enhancer.

9. The composition of claim 8 wherein the absorption enhancer is polyethylene glycol.

10. The composition of claim 1 further comprising an anti-inflammatory agent selected from one or a combination of 5-aminosalicylic acid, azathioprine or methotrexate.

11. Use of an effective amount of rifabutin, clarithromycin, and clofazimine in the preparation of a medicament for the therapeutic and/or prophylactic treatment of an autoimmune disease that is characterized by an increase in cytokines.