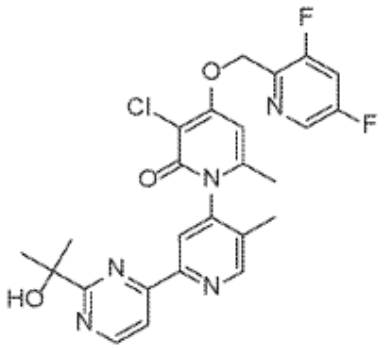
CLAIMS

1. ~~A method for treating an inflammatory condition, said method comprising:~~ ~~administering, to a human subject having an inflammatory condition, an oral dose of 5 mg/day to 300 mg/day of~~ Use of Compound I



(I)

,

or a derivative thereof in the manufacture of a medicament for ~~to~~ treating ~~said~~ an inflammatory condition in a human subject, wherein an oral dose of 5 mg/day to 300 mg/day of Compound I is to be administered to the human subject having the inflammatory condition.

2. The ~~method~~ use of claim 1, wherein 50 mg/day of the compound is to be administered to said subject.

3. The ~~method~~ use of claim 1, wherein 100 mg/day of the compound is to be administered to said subject.

4. The ~~method~~ use of claim 1, wherein 160 mg/day of the compound is to be administered to said subject.

5. The ~~method~~ use of claim 1, wherein 200 mg/day of the compound is to be administered to said subject.

6. The ~~method~~ use of claim 1, wherein 240 mg/day of the compound is to be administered to said subject.

7. The ~~method~~ use of any one of claims 1-6, wherein the compound is to be administered once a day.

8. The ~~method~~ use of any one of claims 1–6, wherein the compound is to be administered twice a day.

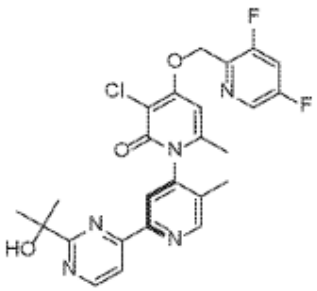
9. The ~~method~~ use of claim 1, wherein 50 mg of the compound is to be administered to the subject twice daily.

10. The ~~method~~ use of claim 1, wherein 80 mg of the compound is to be administered to the subject twice daily.

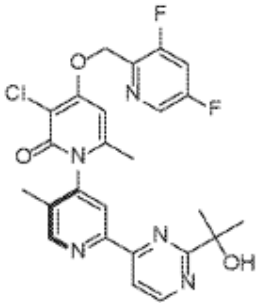
11. The ~~method~~ use of claim 1, wherein 120 mg of the compound is to be administered to the subject twice daily.

12. The ~~method~~ use of any one of claims 1-11, wherein Compound I is deuterated.

13. The ~~method~~ use of any one of claims 1-12, wherein Compound I comprises the Compound (P)-I



(P)-I and the Compound (M)-I



(M)-I, in a molar ratio of (P)-I to (M)-I of about 4:1.

14. The ~~method~~ use of claim 13, wherein the molar ratio of (P)-I to (M)-I is about 9:1.

15. The ~~method~~ use of claim 13, wherein the molar ratio of (P)-I to (M)-I is about 99:1.

16. The ~~method~~ use of any one of claims 1-12, wherein Compound I comprises the Compound (P)-I substantially free of Compound (M)-I.

17. The ~~method~~ use of any one of claims 1-16, wherein Compound (P)-I is a free base.

18. The ~~method~~ use of claim any one of 1-17, wherein Compound (P)-I is a crystalline form.

19. The ~~method~~ use of claim 18, wherein the crystalline form of Compound (P)-I is crystalline Form A characterized by an PXRD pattern having a peak expressed in degrees 2θ at about 9.78 ± 0.2.

20. The ~~method~~ use of claim 18, wherein the crystalline form of Compound (P)-I is the crystalline Form A characterized by an PXRD pattern having peaks expressed in degrees 2θ at 9.78 ± 0.2 and 15.51 ± 0.2.

21. The ~~method~~ use of claim 18, wherein the crystalline form of Compound (P)-I is the crystalline Form A characterized by an PXRD pattern having peaks expressed in degrees 2θ at 9.78 ± 0.2, 15.51 ± 0.2, 19.6 ± 0.2, and 25.92 ± 0.2.

22. The ~~method~~ use of any one of claims 1-21, wherein the inflammatory condition is rheumatoid arthritis.

23. The ~~method~~ use of any one of claims 1-21, wherein the inflammatory condition is psoriatic arthritis.

24. The ~~method~~ use of any one of claims 1-21, wherein the inflammatory condition is a cryopyrin-associate periodic syndrome.

25. The ~~method~~ use of any one of claims 1-21, wherein the inflammatory condition is Hidradenitis suppurativa.

26. The ~~method~~ use of any one of claim 1-21, wherein the inflammatory condition is selected from the group consisting of psoriasis, juvenile idiopathic arthritis, ulcerative colitis, Crohn's disease, ankylosing spondylitis, pancreatic cancer, metastatic breast cancer, gout, recurrent pericarditis, and idiopathic pulmonary fibrosis.

27. The ~~method~~ use of any one of claims 1–21, wherein 50 mg of the compound is to be administered to a subject having rheumatoid arthritis twice daily.

28. The ~~method~~ use of any one of claim 1-21, wherein 80 mg of the compound is to be administered to a subject having rheumatoid arthritis twice daily.

29. The ~~method~~ use of any one of claim 1-21, wherein 120 mg of the compound is to be administered to a subject having rheumatoid arthritis twice daily.

30. The ~~method~~ use of any one of claims 27–29, wherein said administering is to be carried out under conditions effective to inhibit progression of joint damage, improve synovitis, or both in said subject as assessed by magnetic resonance imaging (MRI).

31. The ~~method~~ use of any one of claims 1–30, wherein said administering is to be carried out under conditions effective to significantly reduce *in vivo* serum levels of one or more inflammatory cytokines as compared to *in vivo* serum levels of the one or more inflammatory cytokines in a subject administered a placebo.

32. The ~~method~~ use of claim 31, wherein the one or more inflammatory cytokines is selected from the group consisting of TNF-α, IL-1β, IL-6, IL-8, IFNγ, IL-17, IL-18, IL-1α, and IL-1RA.

33. The ~~method~~ use of any one of claims 1–32, wherein ~~administering further comprises:~~

~~administering~~ one or more additional therapeutic agents are to be administered in conjunction with Compound I.

34. The ~~method~~ use of claim 33, wherein said one or more additional therapeutic agents is to be administered simultaneously with Compound I.

35. The ~~method~~ use of claim 33, wherein said one or more additional therapeutic agents is to be administered sequentially with Compound I.

36. The ~~method~~ use of any one of claims 33-34, wherein the one or more additional therapeutic agents is selected from the group consisting of an anti-inflammatory drug, an anti-atherosclerotic drug, an immunosuppressive drug, an immunomodulatory drug, a cytostatic drug, an angiogenesis inhibitor, a kinase inhibitor, a cytokine blocker, and an inhibitor of cell adhesion molecules.

37. The ~~method~~ use of any one of claims 1–36, wherein the compound is formulated as a solid dosage form selected from a tablet, a capsule, a lozenge, a sachet, a powder, granules, and orally dispersible film.

38. The ~~method~~ use of claim 37, wherein the solid dosage form is a tablet.

39. The ~~method~~ use of any one of claims 1–38, wherein the compound is to be administered as an immediate release formulation.

40. The ~~method~~ use of any one of claims 1–38, wherein the compound is to be administered as a controlled release formulation.