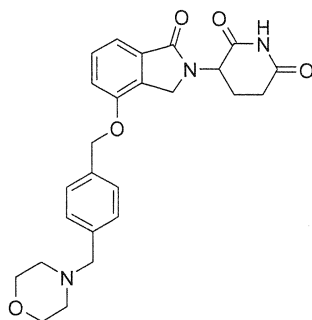


What is claimed is:

1. A compound for use in ~~method~~ for treating, preventing or managing an immune-related disease or an inflammatory disease, ~~comprising administering to a patient in need thereof an effective amount of a compound and wherein the compound corresponds to~~ of formula I



I,

or a pharmaceutically acceptable salt, solvate, hydrate, stereoisomer, tautomer or racemic mixture thereof.

2. The ~~method~~ compound of claim 1, wherein the compound is (S)-3-[4-(4-morpholin-4-ylmethylbenzyloxy)-1-oxo-1,3-dihydro-isoindo-2-yl]piperidine-2,6-dione or a pharmaceutically acceptable salt, solid form, solvate, hydrate, tautomer, stereoisomer or racemate thereof.

3. The ~~compound~~ method of claim 1, wherein the compound is (S)-3-[4-(4-morpholin-4-ylmethylbenzyloxy)-1-oxo-1,3-dihydro-isoindo-2-yl]piperidine-2,6-dione.

4. The compound ~~method~~ of claim 1, wherein the compound is (S)-3-[4-(4-morpholin-4-ylmethylbenzyloxy)-1-oxo-1,3-dihydro-isoindo-2-yl]piperidine-2,6-dione hydrochloride.

5. The ~~method~~ compound of any of claims 1-4, wherein the disease is systemic lupus erythematosus, scleroderma, lupus pernio, sarcoidosis, Sjögren syndrome, ANCA-induced vasculitis, anti-phospholipid syndrome or myasthenia gravis.

6. The compound ~~method~~ of any of claims 1-5, wherein the disease is systemic lupus erythematosus.

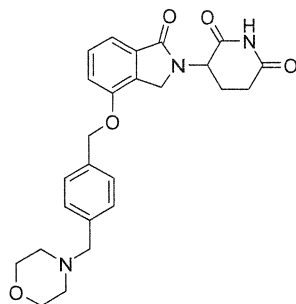
7. The compound ~~method~~ of any of claims 1-6, wherein the disease is severe systemic lupus erythematosus.

8. The compound ~~method~~ of any of claims 1-4, wherein the disease is scleroderma.

9. The compound ~~method~~ of claim 8, wherein the scleroderma is localized, systemic, limited or diffuse scleroderma.

10. The compound ~~method~~ of claim 9, wherein the systemic scleroderma comprises CREST syndrome.

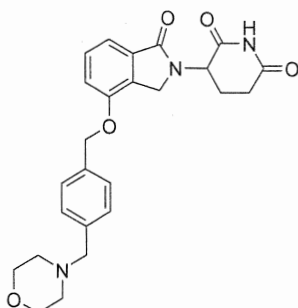
11. A compound for use in method for reducing, inhibiting or preventing a symptom of systemic lupus erythematosus ~~comprising administering to a patient having the symptom of systemic lupus erythematosus an effective amount of a compound~~, wherein the symptom is selected from the group consisting of joint pain, joint swelling, arthritis, chest pain when taking a deep breath, fatigue, fever with no other cause, general discomfort, uneasiness, hair loss, mouth sores, swollen lymph nodes, sensitivity to sunlight, skin rash, headaches, numbness, tingling, seizures, vision problems, personality changes, abdominal pain, nausea, vomiting, abnormal heart rhythms, coughing up blood and difficulty breathing, patchy skin color and Raynaud's phenomenon, and wherein the compound corresponds to formula I



I,

or a pharmaceutically acceptable salt, solvate, hydrate, stereoisomer, tautomer or racemic mixture thereof.

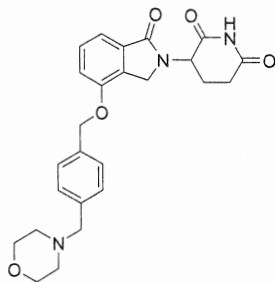
12. A compound for use in method for reducing, inhibiting or preventing a symptom of scleroderma, ~~comprising administering to a patient having the symptom of scleroderma an effective amount of a compound~~, wherein the symptom is selected from the group consisting of (i) gradual hardening, thickening, and tightening of the skin; (ii) skin discoloration; (iii) numbness of extremities; (iv) shiny skin; (v) small white lumps under the surface of the skin that erupt into a chalky white fluid; (vi) Raynaud's esophageal dysfunction; (vii) telangiectasia; (viii) pain and/or stiffness of the joints; (ix) swelling of the hands and feet; (x) itching of the skin; (xi) stiffening and curling of the fingers; (xii) ulcers on the outside of certain joints, such as knuckles and elbows; (xiii) digestive problems, such as heartburn, difficulty in swallowing, diarrhea, irritable bowel, and constipation; (xiv) fatigue and weakness; (xv) shortness of breath; (xvi) arthritis; (xvii) hair loss; (xviii) internal organ problems; (xix) digital ulcers; and (xx) digital auto-amputation, and wherein the compound corresponds to formula I



I,

or a pharmaceutically acceptable salt, solvate, hydrate, stereoisomer, tautomer or racemic mixture thereof.

13. A ~~method~~compound for use in improving the modified Rodnan skin score, reducing or improving the skin thickness, reducing or improving skin induration, improving the pulmonary function, improving the dermatology quality of life index, improving the carbon monoxide diffusing capacity, improving the Mahler Dyspnea index, improving the Saint George's Respiratory Questionnaire score, improving the UCLA scleroderma clinical trial consortium gastrointestinal tract score, improving flow-mediated dilatation or improving or increasing the six minute walk distance of a patient having scleroderma, ~~comprising administering to the patient an effective amount of,~~ wherein the compound corresponds to compound I having formula:



I,

or a pharmaceutically acceptable salt, solvate, hydrate, stereoisomer, tautomer or racemic mixture thereof.

14. The ~~compound method~~ of any of claims 11-13, wherein the compound is (S)-3-[4-(4-morpholin-4-ylmethylbenzyloxy)-1-oxo-1,3-dihydro-isoindo-2-yl]piperidine-2,6-dione or a pharmaceutically acceptable salt, solid form, solvate, hydrate, tautomer, stereoisomer or racemate thereof.

15. The ~~compound method~~ of any of claims 11-13, wherein compound is (S)-3-[4-(4-morpholin-4-ylmethylbenzyloxy)-1-oxo-1,3-dihydro-isoindo-2-yl]piperidine-2,6-dione.

16. The ~~compound method~~ of any of claims 11-13, wherein compound is (S)-3-[4-(4-morpholin-4-ylmethylbenzyloxy)-1-oxo-1,3-dihydro-isoindo-2-yl]piperidine-2,6-dione hydrochloride.

17. The ~~compound method~~ of any of claims 1-16 further comprising administering a second active agent is an anti-inflammatory or immunomodulatory compound.

18. The ~~compound method~~ of any of claims 1-17, wherein the effective amount of the compound I is about 0.005 mg/kg to about 10 mg/kg of the patient's body weight.

19. A ~~compound for use in method~~ for modulating activity of a B cell comprising contacting the cell with an effective amount of the compound, wherein the compound is (S)-3-[4-(4-morpholinomorpholin-4-ylmethylbenzyloxy)-1-oxo-1,3-dihydro-isoindo-2-yl]piperidine-2,6-dione or a pharmaceutically acceptable salt, solid form, solvate, hydrate, tautomer, stereoisomer or racemate thereof.

20. A ~~compound for use in method~~ for modulating activity of a T cell comprising contacting the cell with an effective amount of the compound, wherein the compound is (S)-3-[4-(4-morpholinomorpholin-4-ylmethylbenzyloxy)-1-oxo-1,3-dihydro-isoindo-2-yl]piperidine-2,6-dione or a pharmaceutically acceptable salt, solid form, solvate, hydrate, tautomer, stereoisomer or racemate thereof.

21. A method of identifying a subject who is likely to be responsive to a treatment of a disease, disorder, or condition with a treatment compound, comprising:

- a) determining the level of a biomarker in a biological sample obtained from the subject, wherein the biomarker is CD44, CD83 or combination thereof; and
- b) comparing the level of the biomarker in the biological sample from the subject to a reference level of the biomarker;

wherein the subject is likely to be responsive to the treatment if the level of the biomarker in the biological sample obtained from the subject is altered as compared to the reference level of the biomarker.

22. A method of identifying a subject who is likely to be responsive to a treatment of a disease, disorder, or condition with a treatment compound, comprising:

- a) determining the level of a biomarker in a biological sample obtained from the subject, wherein the biomarker is CD44, CD83 or combination thereof;
- b) determining the level of the biomarker in a control sample; and
- c) comparing the level of the biomarker in the biological sample from the subject to the level of the biomarker in the control sample;

wherein the subject is likely to be responsive to the treatment if the level of the biomarker in the biological sample from the subject is altered as compared to the level of the biomarker in the control sample.

23. A method of predicting the responsiveness of a subject to a treatment of a disease, disorder, or condition with a treatment compound, comprising:

- a) determining the level of a biomarker in a biological sample obtained from the subject,

wherein the biomarker is CD44, CD83 or combination thereof; and

b) comparing the level of the biomarker in the biological sample to a reference level of the biomarker;

wherein the difference between the level of the biomarker in the biological sample from the subject and the reference level of the biomarker correlates with the responsiveness of the subject to the treatment.

24. A method of predicting the responsiveness of a subject to a treatment of a disease, disorder, or condition with a treatment compound, comprising:

a) determining the level of a biomarker in a biological sample obtained from the subject, wherein the biomarker is CD44, CD83 or combination thereof;

b) determining the level of the biomarker in a control sample; and

c) comparing the level of the biomarker in the biological sample from the subject to the level of the biomarker in the control sample;

wherein the difference between the level of the biomarker in the biological sample from the subject and the level of the biomarker in the control sample correlates with the responsiveness of the subject to the treatment.

25. A method of monitoring the efficacy of a treatment of a disease, disorder, or condition in a subject treated with a treatment compound, comprising:

~~a) obtaining a first biological sample from the subject;~~

~~b~~a) determining the level of a biomarker in ~~the~~a first biological sample that had been obtained from the subject, wherein the biomarker is the CD44, CD83 or combination thereof;

~~e) administering the treatment compound to the subject;~~

~~d) thereafter obtaining a second biological sample from the subject;~~

~~e~~b) determining the level of the biomarker in ~~the~~a second biological sample that had been obtained from the subject after administration of the treatment compound, and

~~f~~c) comparing the levels of the biomarker in the first and second biological samples;

wherein the subject is responsive to the treatment if the level of the biomarker in the second biological sample of the subject is altered as compared to the level of the biomarker in the first biological sample of the subject.

26. A method of monitoring the compliance of a subject with a treatment of a disease, disorder, or condition with a treatment compound, comprising:

~~a) obtaining a biological sample from the subject;~~

~~b~~a) determining the level of a biomarker in ~~the~~a biological sample that had been obtained from the subject, wherein the biomarker is CD44, CD83 or combination thereof; and

eb) comparing the level of the biomarker with the level of the biomarker in a control untreated sample from the subject;
wherein the change in the level of the biomarker in the biological sample in comparison with the level of the biomarker in the control sample indicates the compliance of the subject with the treatment.

27. The method of any of claims 21 to 36, wherein the treatment compound is an immunomodulatory compound.

28. The method of claim 27, wherein the treatment compound is (*S*)-3-(4-((4-(morpholinomethyl)benzyl)oxy)-1-oxoisindolin-2-yl)piperidine-2,6-dione.

29. The method of claim 28, wherein the treatment compound is (*S*)-3-(4-((4-(morpholinomethyl)benzyl)oxy)-1-oxoisindolin-2-yl)piperidine-2,6-dione hydrochloride.