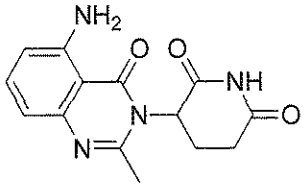
5. SUMMARY

[0009] Provided herein are methods of treating, managing, ameliorating and/or preventing diseases, disorders and/or conditions associated with immune-related and inflammatory diseases comprising administering a therapeutically effective amount of a compound of formula I



Compound I,

or a pharmaceutically acceptable salt, solvate, hydrate, stereoisomer, tautomer, racemic mixture, co-crystal, clathrate, or polymorph thereof.

[0009a] In one aspect, there is provided the use of compound 3-(5-amino-2-methyl-4-oxoquinazolin-3(4*H*)-yl)piperidine-2,6-dione, or a pharmaceutically acceptable salt, solvate, hydrate, stereoisomer, tautomer, racemic mixture, co-crystal, clathrate, or polymorph thereof, for the manufacture of a medicament for treating, preventing or managing an immune-related disease or an inflammatory disease, whereby the compound is to be administered in an effective amount to a patient in need thereof, wherein the disease is systemic lupus erythematosus, scleroderma, Sjögren syndrome, ANCA-induced vasculitis, anti-phospholipid syndrome or myasthenia gravis.

[0009b] In another aspect, there is provided the use of the compound 3-(5-amino-2-methyl-4-oxoquinazolin-3(4*H*)-yl)piperidine-2,6-dione, or a pharmaceutically acceptable salt, solvate, hydrate, stereoisomer, tautomer or racemic mixture thereof, for the manufacture of a medicament for reducing, inhibiting or preventing a symptom of systemic lupus erythematosus, 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, whereby the compound is to be administered in an effective amount to a patient in need thereof.

[0009c] In another aspect, there is provided the use of the compound 3-(5-amino-2-methyl-4-oxoquinazolin-3(4*H*)-yl)piperidine-2,6-dione or a pharmaceutically acceptable salt, solvate, hydrate, stereoisomer, tautomer, racemic mixture, co-crystal, clathrate, or polymorph thereof , for the manufacture of a medicament for reducing, inhibiting or preventing a symptom of scleroderma, 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 esophagaeal 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, whereby the compound is to be administered in an effective amount to a patient in need thereof.

[0009d] In another aspect, there is provided the use of the compound 3-(5-amino-2-methyl-4-oxoquinazolin-3(4*H*)-yl)piperidine-2,6-dione, or a pharmaceutically acceptable salt, solvate, hydrate, stereoisomer, tautomer, racemic mixture, co-crystal, clathrate, or polymorph thereof , for the manufacture of a medicament for 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, , whereby the compound is to be administered in an effective amount to a patient in need thereof.

[0010] In one embodiment, the compound is 3-(5-amino-2-methyl-4-oxoquinazolin-3(4*H*)-yl)piperidine-2,6-dione.

[0011] In certain embodiments, the disease is selected from lupus, scleroderma, Sjögren syndrome, ANCA-induced vasculitis, anti-phospholipid syndrome and myasthenia gravis.

[0012] In one embodiment, provided herein are methods of modulating, *e.g.*, reducing, lymphocytic activity, including activity of B cells and/or T cells, comprising contacting B cell and/or T cell with an effective amount of Compound I.

[0013] Also provided herein are pharmaceutical compositions, single unit dosage forms, and kits suitable for use in treating, preventing, ameliorating and/or managing diseases, disorders and/or conditions associated immune-related and inflammatory diseases, which comprise Compound I, optionally in combination with one or more other therapeutic agents.

[0014] In certain embodiments, Compound I is administered in combination with one or more therapeutic agents, *i.e.*, pharmaceutical agents that are modulators of lymphocytic activity, including activity of B cells and/or T cells activity. The combinations encompass simultaneous as well as sequential administration.

6. BRIEF DESCRIPTION OF DRAWINGS

[0015] FIG. 1 illustrates the effect of 3-(5-amino-2-methyl-4-oxoquinazolin-3(4*H*)-yl)piperidine-2,6-dione on cytokine and chemokine production in anti-CD3- stimulated human T cells, expressed as absolute amount produced.