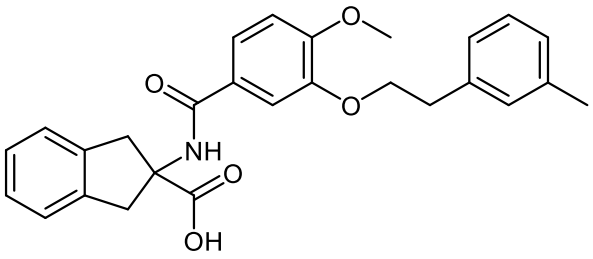
or a pharmaceutically acceptable salt thereof, for a dosing period of at least about 24 consecutive weeks.

[0005] Also provided is a method for reducing fibrosis in a cell or tissue, the method comprising contacting the cell or tissue with 2-(4-methoxy-3-(3-methylphenethoxy)benzamido)-2,3-dihydro-1H-indene-2-carboxylic acid (Compound 1)



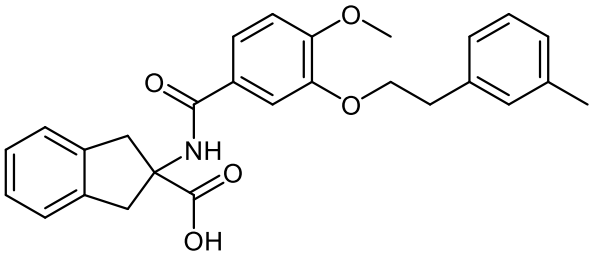
(Compound 1)

or a pharmaceutically acceptable salt thereof, in an amount and for a time sufficient to decrease or inhibit the fibrosis.

[0006] These and other aspects of the disclosure will be apparent upon reference to the following detailed description. To this end, various references are set forth herein which describe in more detail certain background information, procedures, compounds, and/or compositions, and are each hereby incorporated by reference in their entirety.

SUMMARY

[0006a] In an aspect of the present disclosure, there is provided a use of 2-(4-methoxy-3-(3-methylphenethoxy)benzamido)-2,3-dihydro-1H-indene-2-carboxylic acid (Compound 1)



(Compound 1)

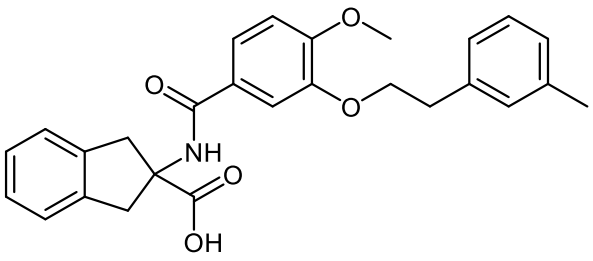
or a pharmaceutically acceptable salt thereof, in the manufacture of a medicament for treating systemic sclerosis in a patient in need thereof, wherein Compound 1, or the pharmaceutically acceptable salt thereof is to be administered to the patient for a dosing period of at least about 24 consecutive weeks.

BRIEF DESCRIPTION OF DRAWINGS

[0007] **FIG. 1** depicts a histogram demonstrating the median percent change from baseline for various biomarkers after treatment with Compound 1.

DETAILED DESCRIPTION

[0008] As used herein, “Compound 1” means 2-(4-methoxy-3-(3-methylphenethoxy)benzamido)-2,3-dihydro-1H-indene-2-carboxylic acid or 2-[4-methoxy-3-(2-m-tolyl-ethoxy)-benzoylamino]-indane-2-carboxylic acid, including crystalline forms thereof.

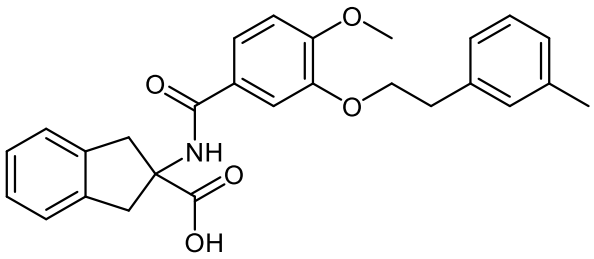


(Compound 1)

CLAIMS

What is claimed is:

1. ~~A method of treating systemic sclerosis in a patient in need thereof, comprising administering to the patient a therapeutically effective amount~~ Use of 2-(4-methoxy-3-(3-methylphenethoxy)benzamido)-2,3-dihydro-1H-indene-2-carboxylic acid (Compound 1)



(Compound 1)

or a pharmaceutically acceptable salt thereof, in the manufacture of a medicament for treating systemic sclerosis in a patient in need thereof, wherein Compound 1, or the pharmaceutically acceptable salt thereof is to be administered to the patient for a dosing period of at least about 24 consecutive weeks.

2. The ~~method~~use of claim 1, wherein the systemic sclerosis is chosen from limited cutaneous systemic sclerosis, diffuse cutaneous systemic sclerosis, and systemic sclerosis sine scleroderma.

3. The ~~method~~use of claim 2, wherein the systemic sclerosis is diffuse cutaneous systemic sclerosis.

4. The ~~method~~use of claim 3, wherein the systemic sclerosis is early diffuse cutaneous systemic sclerosis.

5. The ~~method~~use of any one of the preceding claims, wherein the dosing period is at least 36 weeks.

6. The ~~method~~use of any one of the preceding claims, wherein the dosing period is at least 52 weeks.

7. The ~~method~~use of any one of the preceding claims, wherein Compound 1, or a pharmaceutically acceptable salt thereof, is to be administered orally.

8. The ~~method~~use of claim 7, wherein 300 mg (on a free acid equivalent weight basis) of Compound 1, or a pharmaceutically acceptable salt thereof, is to be administered at least once daily.

9. The ~~method~~use of claim 7, wherein 300 mg (on a free acid equivalent weight basis) of Compound 1, or a pharmaceutically acceptable salt thereof, is to be administered twice daily.

10. The ~~method~~use of any one of the preceding claims, ~~further comprising administering~~ wherein one or more additional therapies are to be further administered.

11. The ~~method~~use of claim 10, wherein the one or more additional therapies are chosen from an immunosuppressant, T-cell-directed, B-cell directed therapy, autologous hematopoietic stem cell transplantation, a chemokine ligand receptor antagonist, a DNA methylation inhibitor, a histone deacetylase inhibitor, a statin, an endothelin receptor antagonist, a phosphodiesterase type V inhibitor, a prostacyclin analog, an inhibitor of cytokine synthesis and/or signaling, corticosteroids, nonsteroidal anti-inflammatory drugs, light therapy, and blood pressure medications.

12. The ~~method~~use of any one of the preceding claims, wherein said treatment with Compound 1, or a pharmaceutically acceptable salt thereof, results in a CRISS score of greater or equal to 0.60.

13. The ~~method~~use of any one of the preceding claims, wherein said treatment with Compound 1, or a pharmaceutically acceptable salt thereof, results in a reduction in skin fibrosis as measured by mRSS change of ≥ 5.

14. The ~~method~~use of any one of the preceding claims, wherein treatment with Compound 1, or a pharmaceutically acceptable salt thereof, results in an improvement in HAQ-DI of ≥ 0.14.