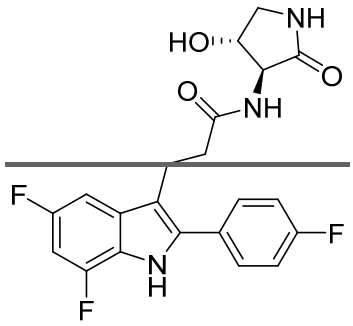
Claims

1. A method of treating APOL1-mediated disease comprising administering to a patient in need thereof Compound I:



Compound I

a deuterated derivative thereof, and/or a pharmaceutically acceptable salt of Compound I or deuterated derivative thereof and in a daily amount of 2 mg to 100 mg.

2. The method of claim 1, wherein the APOL1-mediated disease is APOL1 mediated kidney disease.

3. The method of claim 2, wherein the APOL1-mediated kidney disease is APOL1-dependent focal segmental glomerulosclerosis (FSGS).

4. The method of claim 2, wherein the APOL1-mediated kidney disease is non-diabetic kidney disease (NDKD).

5. The method according to any one of claims 1-4, wherein the patient has an *APOL1* genotype.

6. The method according to any one of claims 1-4, wherein the patient has nephrotic range proteinuria.

7. The method according to any one of claims 1-4, wherein the patient does not have nephrotic range proteinuria.

8. The method according to any one of claims 1-7, wherein Compound I, a deuterated derivative thereof, and/or a pharmaceutically acceptable salt of Compound I or deuterated derivative thereof is administered in a daily amount of 5 mg to 200 mg, 10 mg to 150 mg, 15 mg to 100 mg, 20 mg to 80 mg, 25 to 75 mg, 30 to 60 mg, or 15 mg to 45 mg.

9. The method according to any one of claims 1-7, wherein Compound I, a deuterated derivative thereof, and/or a pharmaceutically acceptable salt of Compound I or deuterated derivative thereof is administered in a daily amount of 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 55 mg, 60 mg, 65 mg, 70 mg, 75 mg, 80 mg, 85 mg, 90 mg, or 100 mg.

10. The method according to any one of claims 1-9, wherein Compound I, a deuterated derivative thereof, and/or a pharmaceutically acceptable salt of Compound I or deuterated derivative thereof is administered in a daily amount of 15 mg, or 45 mg.

11. The method according to any one of claims 1-10, wherein Compound I, a deuterated derivative thereof, and/or a pharmaceutically acceptable salt of Compound I or deuterated derivative thereof is administered once daily or multiple times daily.

12. The method according to any one of claims 1-10, wherein Compound I, a deuterated derivative thereof, and/or a pharmaceutically acceptable salt of Compound I or deuterated derivative thereof is administered every 24 hours (q24h).

13. The method according to any one of claims 1-12, wherein the method comprises administering Compound I or a deuterated derivative thereof.

14. The method according to any one of claims 1-12, wherein the method comprises administering a pharmaceutically acceptable salt of Compound I or a deuterated derivative thereof.

~~15. The method according to any one of claims 1-14, wherein the Compound I, a deuterated derivative thereof, and/or a pharmaceutically acceptable salt of Compound I or deuterated derivative thereof is comprised in a pharmaceutical composition.~~

~~16. The method according to claim 15, wherein the pharmaceutical composition is a tablet.~~

~~17. The method according to claim 16, wherein the tablet is suitable for oral administration.~~

~~18. The method according to claim 17, wherein the tablet for oral administration comprises 15 mg of Compound I.~~

~~19. The method according to any one of claims 16-18, wherein the tablet comprises cellulose, croscarmellose sodium, and/or sodium stearyl fumarate.~~

~~20. The method according to claim 19, wherein the tablet further comprises a coating comprising polyvinyl alcohol (PVA), polyethylene glycol (PEG), titanium dioxide, and talc.~~

~~21. The method according to any one of claims 1-20, wherein the patient is in the fasted state.~~

~~22. The method according to any one of claims 1-20, wherein the patient is in the fed state.~~

~~23. The method according to any one of claims 1-22, wherein Compound I, a deuterated derivative thereof, and/or a pharmaceutically acceptable salt of Compound I or deuterated derivative thereof is administered in combination with one or more therapeutic agents selected from an angiotensin converting enzyme (ACE) inhibitor, an angiotensin receptor blocker (ARB), a sodium-glucose co-transporter-2 (SGLT2) inhibitor, a renin inhibitor, a neprilysin inhibitor, a systemic corticosteroid, tacrolimus, cyclosporine, mycophenolate, and a mineralocorticoid receptor antagonist.~~

~~24. The method according to claim 23, wherein the systemic corticosteroid is prednisone or a prednisone equivalent.~~

~~25. The method according to any one of claims 1-22, wherein Compound I, a deuterated derivative thereof, and/or a pharmaceutically acceptable salt of Compound I or deuterated derivative thereof is administered in combination with one or more therapeutic agents selected from an angiotensin converting enzyme (ACE) inhibitor, an angiotensin receptor blocker (ARB), a renin inhibitor, and a prednisone equivalent.~~

~~26. The method according to any one of claims 1-22, wherein Compound I, a deuterated derivative thereof, and/or a pharmaceutically acceptable salt of Compound I or deuterated derivative thereof is administered in combination with an ACE inhibitor (ACEi) and an ARB.~~

~~27. The method according to any one of claims 1-22, wherein Compound I, a deuterated derivative thereof, and/or a pharmaceutically acceptable salt of Compound I or deuterated derivative thereof is administered in combination with an ACEi, an ARB, and prednisone.~~

~~28. The method according to any one of claims 1-27, wherein the patient is not co-administered with any immunosuppressant other than a systemic corticosteroid, tacrolimus, cyclosporine, and mycophenolate.~~

~~29. The method of any one of claims 1-28, wherein Compound I is substantially pure crystalline Form A.~~

~~30. The method of any one of claims 1-28, wherein Compound I is crystalline Form A.~~

~~31. A pharmaceutical composition comprising 5 mg to 200 mg, 10 mg to 150 mg, 15 mg to 100 mg, 20 mg to 80 mg, 25 to 75 mg, 30 to 60 mg, or 15 mg to 45 mg Compound~~

~~I, a deuterated derivative thereof, and/or a pharmaceutically acceptable salt of Compound I or deuterated derivative thereof.~~

~~32. The pharmaceutical composition according to claim 31, wherein the composition comprises 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 55 mg, 60 mg, 65 mg, 70 mg, 75 mg, 80 mg, 85 mg, 90 mg, or 100 mg of Compound I, a deuterated derivative thereof, and/or a pharmaceutically acceptable salt of Compound I or deuterated derivative thereof.~~

~~33. The pharmaceutical composition according to claim 32, wherein the composition comprises 15 mg of Compound I.~~

~~34. The pharmaceutical composition according to claim 32, wherein the composition comprises 30 mg of Compound I.~~

~~35. The pharmaceutical composition according to claim 32, wherein the composition comprises 45 mg of Compound I.~~

~~36. The pharmaceutical composition according to claim 32, wherein the composition comprises 60 mg of Compound I.~~

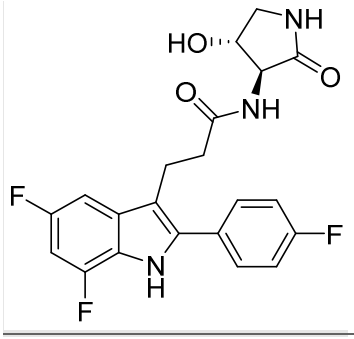
~~37. The pharmaceutical composition according to claim 32, wherein the composition comprises 75 mg of Compound I.~~

~~38. The pharmaceutical composition of any one of claims 31 to 37, wherein Compound I is substantially pure crystalline Form A.~~

~~39. The pharmaceutical composition of any one of claims 31 to 37, wherein Compound I is crystalline Form A.~~

1. A pharmaceutical composition comprising one or more compound(s) selected from

(a) Compound I:



Compound I,

(b) a deuterated derivative of Compound I,

(c) a pharmaceutically acceptable salt of Compound I, and

(d) a pharmaceutically acceptable salt of a deuterated derivative of Compound I,

in an amount equivalent to 2 mg to 250 mg, 10 mg to 150 mg, 15 mg to 100 mg, 20 mg to 80 mg, 25 to 75 mg, 30 to 60 mg, or 15 mg to 45 mg of Compound I.

2. The pharmaceutical composition according to claim 1, wherein the composition comprises the one or more compound(s) selected from Compound I, a deuterated derivative of Compound I, a pharmaceutically acceptable salt of Compound I, and a pharmaceutically acceptable salt of a deuterated derivative of Compound I, in an amount equivalent to 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 55 mg, 60 mg, 65 mg, 70 mg, 75 mg, 80 mg, 85 mg, 90 mg, or 100 mg of Compound I.

3. The pharmaceutical composition according to claim 1 or claim 2, wherein the composition comprises 15 mg of Compound I.

4. The pharmaceutical composition according to claim 1 or claim 2, wherein the composition comprises 30 mg of Compound I.

5. The pharmaceutical composition according to claim 1 or claim 2, wherein the composition comprises 45 mg of Compound I.

6. The pharmaceutical composition according to claim 1 or claim 2, wherein the composition comprises 60 mg of Compound I.

7. The pharmaceutical composition according to claim 1 or claim 2, wherein the composition comprises 75 mg of Compound I.

8. The pharmaceutical composition according to any one of claims 1-7, wherein Compound I is substantially pure crystalline Form A.

9. The pharmaceutical composition according to any one of claims 1-8, wherein Compound I is crystalline Form A.

10. The pharmaceutical composition according to any one of claims 1-9, wherein the pharmaceutical composition is formulated for administration in a daily amount equivalent to 15 mg, or 45 mg of Compound I.

11. The pharmaceutical composition according to any one of claims 1-10, wherein the pharmaceutical composition is formulated for administration once daily or multiple times daily.

12. The pharmaceutical composition according to any one of claims 1-11, wherein the pharmaceutical composition is formulated for administration every 24 hours (q24h).

13. The pharmaceutical composition according to any one of claims 1-12, wherein the pharmaceutical composition comprises Compound I or a deuterated derivative thereof.

14. The pharmaceutical composition according to any one of claims 1-12, wherein the pharmaceutical composition comprises a pharmaceutically acceptable salt of Compound I or a deuterated derivative of Compound I.

15. The pharmaceutical composition according to any one of claims 1-14, wherein the pharmaceutical composition is in the form of a tablet.

16. The pharmaceutical composition according to claim 15, wherein the tablet is suitable for oral administration.

17. The pharmaceutical composition according to claim 15 or claim 16, wherein the tablet comprises one or more additional ingredients selected from cellulose, croscarmellose sodium, and sodium stearyl fumarate.

18. The pharmaceutical composition according to any one of claims 15-17, wherein the tablet further comprises a coating comprising polyvinyl alcohol (PVA), polyethylene glycol (PEG), titanium dioxide, and talc.

19. The pharmaceutical composition according to any one of claims 6-18, formulated for administration to a patient in a fasted state.

20. The pharmaceutical composition according to any one of claims 6-18, formulated for administration to a patient in a fed state.

21. The pharmaceutical composition according to any one of claims 1-20, wherein the pharmaceutical composition is formulated for administration in combination with one or more therapeutic agents selected from an angiotensin converting enzyme (ACE) inhibitor, an angiotensin receptor blocker (ARB), a sodium-glucose co-transporter-2 (SGLT2) inhibitor, a renin inhibitor, a neprilysin inhibitor, a systemic corticosteroid, tacrolimus, cyclosporine, mycophenolate, and a mineralocorticoid receptor antagonist.

22. The pharmaceutical composition according to claim 21, wherein the systemic corticosteroid is prednisone or a prednisone equivalent.

23. The pharmaceutical composition according to any one of claims 1-22, wherein the pharmaceutical composition is formulated for administration in combination with one or more therapeutic agents selected from an angiotensin converting enzyme (ACE) inhibitor, an angiotensin receptor blocker (ARB), a renin inhibitor, and a prednisone equivalent.

24. The pharmaceutical composition according to claim 23, wherein the pharmaceutical composition is formulated for administration in combination with an ACE inhibitor (ACEi) and an ARB.

25. The pharmaceutical composition according to claim 23, wherein the pharmaceutical composition is formulated for administration in combination with an ACEi, an ARB, and prednisone.

26. The pharmaceutical composition according to any one of claims 1-25, wherein the patient is not formulated for co-administration with any immunosuppressant other than a systemic corticosteroid, tacrolimus, cyclosporine, and mycophenolate.

27. The pharmaceutical composition according to any one of claims 1-26, wherein the pharmaceutical composition is formulated for administration to a patient in need thereof and in a daily amount of 2 mg to 250 mg.

28. Use of the pharmaceutical composition according to any one of claims 1-27, in the manufacture of a medicament for the treatment of APOL1-mediated disease.

29. The use according to claim 28, wherein the APOL1-mediated disease is APOL1 mediated kidney disease.

30. The use according to claim 29, wherein the APOL1-mediated kidney disease is APOL1-dependent focal segmental glomerulosclerosis (FSGS).

31. The use according to claim 29, wherein the APOL1-mediated kidney disease is non-diabetic kidney disease (NDKD).

32. The use according to any one of claims 28-31, wherein the composition is formulated for treatment of a patient that has an *APOL1* genotype.

33. The use according to any one of claims 28-32, wherein the composition is formulated for treatment of a patient that has nephrotic range proteinuria.

34. The use according to any one of claims 28-32, wherein the composition is formulated for treatment of a patient that does not have nephrotic range proteinuria.

35. The pharmaceutical composition according to any one of claims 1-27, for use in therapy.