CLAIMS

What is claimed is:

1. Use of pirfenidone in the manufacture of a medicament for the treatment of COVID-19 and/or COVID-19 disease caused by a SARS-CoV-2 variant thereof in a subject in need thereof, wherein pirfenidone is to be administered to the subject.

2. Use of pirfenidone in the manufacture of a medicament for the treatment or prevention of viremia caused by a virus in a subject in need thereof, wherein pirfenidone is to be administered to the subject.

3. Use of pirfenidone in the manufacture of a medicament for the treatment or prevention of viremia-induced disease in a subject in need thereof, wherein pirfenidone is to be administered to the subject.

4. Use of pirfenidone in the manufacture of a medicament for the treatment or prevention of an infection with a virus in a subject in need thereof, wherein pirfenidone is to be administered to the subject.

5. Use of pirfenidone in the manufacture of a medicament for the inhibition of (a) an inflammatory response or (b) a cascade by one or more pro-inflammatory cytokines in a subject in need thereof, wherein pirfenidone is to be administered to the subject.

6. Use of pirfenidone in the manufacture of a medicament for the reduction of elevated levels of one or more markers of inflammation in a subject in need thereof with viremia caused by a virus, wherein pirfenidone is to be administered to the subject.

7. The use of any one of claims 1-6, wherein pirfenidone is formulated in:

(a) extended-release pills, wherein each of the extended-release pills comprises pirfenidone and one or more excipients; or

(b) sustained-release pills, wherein each of the sustained-release pills comprises pirfenidone and one or more excipients.

8. The use of claim 7, wherein each of the extended-release pills or sustained-release pills comprises:

(a) approximately 100 mg to approximately 850 mg of pirfenidone; or

(b) approximately 600 mg of pirfenidone.

9. The use of claim 7 or 8, wherein a C_{max} from a first dose of the extended-release pills or sustained-release pills is between approximately:

(a) 1.0 μg/mL to 10.0 μg/mL; or

(b) 1.0 μg/mL to 4.0 μg/mL.

10. The use of any one of claims 7-9, wherein a T_{max} from a first dose of the extended-release pills or sustained-release pills is between approximately:

(a) 1.5 hours to approximately 8.0 hours; or

(b) 3.0 hours to approximately 5.0 hours.

11. The use of any one of claims 7-10, wherein the one or more excipients are selected from the group consisting of compression binders, diluents, disintegrants, coating agents, rate-controlling polymers, anti-caking agents, adsorbents, lubricants, and glidants.

12. The use of any one of claims 7-11, wherein each of the sustained-release pills or extended-release pills comprises:

a) approximately 100 mg to approximately 850 mg of pirfenidone;
b) microcrystalline cellulose;
c) low viscosity HPMC;
d) high viscosity HPMC;
e) silicon dioxide; and
f) sodium stearyl fumarate;

optionally, wherein each of the sustained-release pills or extended-release pills comprises:

i) approximately 100 mg to approximately 850 mg of pirfenidone;
ii) approximately 100 mg to 125 mg microcrystalline cellulose;
iii) approximately 50.0 mg to 100.0 mg low viscosity HPMC;
iv) approximately 30.0 mg to 50.0 mg high viscosity HPMC;
v) approximately 5.0 mg to 10.0 mg silicon dioxide; and
vi) approximately 5.0 mg to 10.0 mg sodium stearyl fumarate.

13. The use of any one of claims 7-12, wherein the sustained-release pills or extended-release pills are formulated as tablets, capsules, or gel capsules.

14. The use of any one of claims 2, 3, and 6-13, wherein the viremia is:

(a) selected from the group consisting of primary viremia, secondary viremia, active viremia, and passive viremia; and/or

(b) caused by an RNA virus or a DNA virus; wherein the RNA virus is a coronavirus.

15. The use of claim 14, wherein the coronavirus is:

(a) severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2);

(b) SARS-CoV-2 variant of B.1.1.7, B.1.351, B.1.525, B.1.526, P.1, B.1.427, B.1.429, and/or SARS-CoV-2 variants with the Q677P and/or L452R mutations;

(c) severe acute respiratory syndrome-associated coronavirus (SARS-CoV); or

(d) Middle East respiratory syndrome coronavirus (MERS-CoV).

16. The use of any one of claims 1-15, wherein the subject develops fibrosis;

optionally, wherein the fibrosis is lung fibrosis or liver fibrosis.

17. The use of any one of claims 1-16, comprising:

(a) blocking and/or reducing an inflammatory response;

(b) inhibiting the inflammatory response by one or more pro-inflammatory cytokines; optionally, wherein the inflammatory response:

(i) is a cascade by the one or more pro-inflammatory cytokines; or

(ii) results in acute respiratory distress syndrome (ARDS).

18. The use of any one of claims 1-17, wherein the subject has elevated levels of one or more:

(a) markers of inflammation; optionally, wherein the one or more markers of inflammation are selected from the group consisting of D-dimers, C-reactive protein (CRP), ferritin, and lactic acid dehydrogenase (LDH); and/or

(b) pro-inflammatory cytokines; optionally, wherein the one or more pro-inflammatory cytokines are selected from the group consisting of TNF-α, IFN-γ, IL-1β, IL-6, and IL-12.

19. The use of any one of claims 1-18, wherein the subject has:

(a) high viral burden and elevated levels of one or more markers of inflammation;

(b) high viral burden has low levels of cycle threshold (Ct);

(c) pneumonia;

(d) lung inflammation and/or lung fibrosis;

(e) acute respiratory distress syndrome (ARDS);

(f) COVID-19; and/or

(g) liver disease, liver damage, or a liver injury;

optionally, wherein the liver disease is chronic liver disease.

20. The use of any one of claims 1-19, wherein pirfenidone is formulated in extended-release pills or sustained-release pills, wherein each of the extended-release pills or sustained-release pills comprises pirfenidone and one or more excipients; the coronavirus is severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) and/or a SARS-CoV-2 variant thereof; and the subject has coronavirus disease 2019 (COVID-19) and/or a disease caused by a SARS-CoV-2 variant thereof.

21. The use of any one of claims 1-20, wherein the subject has one or more contraindications for:

(a) immediate-release pirfenidone; or

(b) standard-release pirfenidone.

22. The use of any one of claims 1-21, wherein a daily dose of pirfenidone comprises:

(a) approximately 400 mg to approximately 4800 mg of pirfenidone per day;

(b) approximately 800 mg to approximately 3000 mg of pirfenidone per day; or

(c) approximately 1000 mg to approximately 2400 mg of pirfenidone per day.

23. The use of any one of claims 7-22, wherein the sustained-release tablets or extended-release tablets are to be administered orally:

(a) 1 to 8 times per day; or

(b) two times per day.

24. The use of any one of claims 7-23, wherein the extended-release pills are to be administered for approximately:

(a) ten days or more or

(b) fourteen days or more; or

(c) twenty-eight days or more.

25 The use of any one of claims 7-23, wherein the extended-release pills or sustained-release pills are to be administered for approximately:

(a) thirty days or more; or

(b) ten to approximately thirty days.

26. The use of any one of claims 1-25, comprising a formulation of pirfenidone that provides release of pirfenidone over 12 hours.

27. A kit comprising a pharmaceutical composition comprising pirfenidone and one or more excipients, for use in treating or preventing viremia caused by a virus, viremia-induced disease, COVID-19, a disease caused by a SARS-CoV-2 variant thereof, an infection with a virus, and/or ARDS caused by infection with an infectious agent; and

instructions for administering to a subject with the pharmaceutical composition.