

CLAIMS

1. A method of treating coronavirus infection or a disease or condition caused by or associated with coronavirus infection, the method comprising:
 - 5 - providing an individual who is suspected of having or of having had a coronavirus infection,
 - administering to the individual, a therapeutically effective amount of pentosan polysulfate (PPS) or a pharmaceutically acceptable salt thereofthereby treating or preventing coronavirus infection or a disease or condition caused by or associated with coronavirus infection in the individual.
- 10 2. The method of claim 1, wherein the disease or condition caused by or associated with coronavirus infection is a respiratory disease or condition, an inflammatory disease or condition, a cardiovascular disease or condition or a gastrointestinal disease or condition.
- 15 3. The method of claim 1, wherein the disease or condition caused by or associated with coronavirus infection is cytokine-associated toxicity, including hypercytokinemia.
4. The method of claim 1 or claim 2, wherein the disease or condition is characterised as a mild condition that does not require hospitalisation.
5. The method of claim 1 or claim 2, wherein the disease or condition is
20 characterised as severe and requiring hospitalisation.
6. The method of claim 1, wherein the individual does not display symptoms of coronavirus infection.
7. A method of preventing cytokine-associated toxicity induced by coronavirus infection, the method comprising:
 - 25 - providing an individual who been exposed to or has or is recovering from a coronavirus infection,

- administering to the individual, a therapeutically effective amount of pentosan polysulfate (PPS) or a pharmaceutically acceptable salt thereof; thereby preventing cytokine-associated toxicity in the individual.
8. The method according to claims 6 or 7, wherein the cytokine associated toxicity is characterised by one or more of fever, hypotension, tachycardia, myalgia, headache and elevated levels of one or more cytokines selected from the group consisting of: IL-1B, IL-2, IL-4, IL-5, IL-6, IL-7, IL-10, IL-12, IL-13, IL-17 INF γ , TNF- α , granulocyte macrophage colony-stimulating factor.
9. A method of treating one or more of fever, hypotension, tachycardia, myalgia, headache or inappropriate cytokine release induced by coronavirus infection, comprising:
- providing an individual who has or is suspected of having fever, hypotension, tachycardia, myalgia, headache or inappropriate cytokine release induced by coronavirus or pneumonia severe acute respiratory syndrome (SARS), or immunotherapy;
 - administering to the individual, an amount of pentosan polysulfate (PPS) or pharmaceutically acceptable salt thereof, effective to treat the one or more of fever, hypotension, tachycardia, myalgia, headache or inappropriate cytokine release ,
- thereby treating fever, hypotension, tachycardia, myalgia, headache or inappropriate cytokine release induced by coronavirus, pneumonia severe acute respiratory syndrome (SARS), or immunotherapy.
10. The method according to any one of claims 1 to 6, wherein the pentosan polysulfate (PPS) is administered prior to or after the onset of coronavirus infection.
11. The method according to any one of the preceding claims, wherein the PPS is administered prophylactically once the individual has recovered from an initial infection with coronavirus.

12. A method of preventing or reducing the likelihood of coronavirus infection in an individual, the method comprising:
- providing an individual who is at risk of infection with a coronavirus;
 - administering to the individual, a prophylactically effective amount of pentosane polysulfate (PPS), or a pharmaceutically acceptable salt thereof,
- 5 thereby preventing or reducing the likelihood of coronavirus infection in an individual.
13. The method of claim 12, wherein the method reduces the likelihood of serious coronavirus infection.
- 10 14. The method of claim 12 or 13, wherein the individual at risk is selected from: immunocompromised individuals (including an individual who has primary or secondary immunodeficiency), an adult more than 60 years of age, a child younger than 2 years of age, healthcare workers, adults or children in close contact with a person(s) with confirmed or suspected coronavirus infection, and
- 15 people with underlying medical conditions such as pulmonary infection, heart disease, obesity or diabetes.
15. The method according to any one of the preceding claims, wherein the pentosan polysulfate (PPS) is administered to the individual intravenously, subcutaneously, orally, intramuscularly, via gastric tube, intranasally or by inhalation.
- 20 16. The method according to any one of the previous claims, wherein the pentosan polysulfate is provided as a salt selected from the group consisting of sodium pentosan polysulfate, calcium pentosan polysulfate or magnesium pentosan polysulfate.
- 25 17. The method according to any one of the preceding claims, wherein the coronavirus infection is an infection with SARS-CoV or SARS-CoV-2, or a mutated form or variant thereof, including but not limited to mutants D614G, S477N, 20A.EU1, the Danish COVID-19 mink variant, the "UK" variant B.1.1.7, the "South African" variant B.1.351, the "Brazil" variant P.1 or the "Russian" variant B.1.1.317.

18. The method according to any one of the preceding claims, wherein the coronavirus infection is an infection with SARS-CoV-2 or variant or mutated form thereof.
20. The method according to any one of the preceding claims wherein the method
5 includes further administering to the individual one or more of: a corticosteroid, an IL-6 inhibitor, a TNF- α inhibitor or a vasopressor.
21. The method according to claim 20 wherein the corticosteroid is dexamethasone, prednisolone or methylprednisolone.
22. The method according to claim 20 wherein the IL-6 inhibitor is tocilizumab.
- 10 23. The method according to claim 20 wherein the vasopressor is any one or more of noradrenaline, adrenaline, dopamine or phenylephrine.
24. The method according to claim 20 wherein the TNF- α inhibitor is etanercept or infliximab.
- 15 25. Use of pentosan polysulfate, or a pharmaceutically acceptable salt thereof, in the manufacture of a medicament for the prevention or treatment of coronavirus infection, or a disease or condition caused by or associated with coronavirus infection.
26. The use of claim 25, wherein the disease or condition caused by or associated with coronavirus infection is a respiratory disease or condition, an inflammatory
20 disease or condition, a cardiovascular disease or condition or a gastrointestinal disease or condition.
27. The use according to claim 25, wherein the disease or condition caused by or associated with coronavirus infection is cytokine-associated toxicity.
28. The use according to claim 27, wherein the cytokine-associated toxicity is
25 hypercytokinemia.
29. The use according to 27 or 28, wherein the cytokine-associated toxicity is characterised by one or more of fever, hypotension, tachycardia, myalgia, headache and elevated levels of one or more cytokines selected from the group

consisting of: IL-1B, IL-2, IL-4, IL-5, IL-6, IL-7, IL-10, IL-12, IL-13, IL-17 INF γ , TNF- α , granulocyte macrophage colony-stimulating factor.

30. Use of pentosan polysulfate, or a pharmaceutically acceptable salt thereof, in the manufacture of a medicament for the prevention or treatment of fever,
5 hypotension, tachycardia, myalgia, headache, respiratory or inappropriate cytokine release induced by a coronavirus infection.
31. The use according to any one of claims 25 to 30, wherein the coronavirus infection is an infection with SARS-CoV or SARS-CoV-2, or a mutated form or variant thereof, including but not limited to mutants D614G, S477N, 20A.EU1, the
10 Danish COVID-19 mink variant, the "UK" variant B.1.1.7, the "South African" variant B.1.351, the "Brazil" variant P.1 or the "Russian" variant B.1.1.317.
32. Pentosan polysulfate or a pharmaceutically acceptable salt thereof, for use in the prevention or treatment of a coronavirus infection, or a disease or condition associated with coronavirus infection, such as cytokine-associated toxicity.
- 15 33. Pentosan polysulfate or a pharmaceutically acceptable salt thereof, for use in the prevention or treatment of fever, hypotension, tachycardia, myalgia, headache or inappropriate cytokine release associated with cytokine associated toxicity induced by an infection with a coronavirus.
- 20 34. Pentosan polysulfate or a pharmaceutically acceptable salt thereof, for the use of claims 26 or 27, wherein the coronavirus infection is an infection with SARS-CoV or SARS-CoV-2, or a mutated form or variant thereof, including but not limited to mutants D614G, S477N, 20A.EU1, the Danish COVID-19 mink variant, the "UK" variant B.1.1.7, the "South African" variant B.1.351, the "Brazil" variant P.1 or the "Russian" variant B.1.1.317.

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