CLAIMS:

1. A method of treating or preventing inflammatory lung disease in a human subject in need thereof, the method comprising administering to the subject a composition comprising mesenchymal lineage precursor or stem cells (MLPSCs), wherein the subject has an elevated circulating C-reactive protein (CRP).

2. The method of claim 1, wherein the subject has an initial circulating CRP level of at least 2mg/ml.

3. The method of claim 1, wherein the subject has an initial circulating CRP level of at least 3mg/ml or at least 4mg/ml.

4. The method according to any one of claims 1 to 3, wherein the inflammatory lung disease is selected from the group consisting of Acute Respiratory Distress Syndrome (ARDS), Chronic Obstructive Pulmonary Disease (COPD), Idiopathic Pulmonary Fibrosis (IPF), Pulmonary Arterial Hypertension (PAH), asthma, cystic fibrosis, pneumonia and interstitial lung diseases.

5. The method according to any one of claims 1 to 4, wherein the inflammatory lung disease is caused by a viral infection.

6. The method of claim 5 wherein the viral infection is caused by a rhinovirus, an influenza virus, a respiratory syncytial virus (RSV) or a coronavirus.

7. The method of claim 6 wherein the viral infection is caused by a coronavirus.

8. The method of claim 7 wherein the coronavirus is Severe Acute Respiratory Syndrome coronavirus (SARS-CoV), Middle East Respiratory Syndrome coronavirus (MERS-CoV) or COVID-19.

9. The method of any one of claims 1 to 8, wherein the MLPSCs have been cryopreserved and thawed.

10. The method of any one of claims 1 to 9, wherein the MLPSCs are culture expanded from an intermediate cryopreserved MLPSCs population.

11. The method according to any one of claims 1 to 10, wherein the MLPSCs are culture expanded for at least about 5 passages.

12. The method of any one of claims 1 to 11, wherein the MLPSCs express at least 13 pg TNFR1 per million MLPSCs.

13. The method of any one of claims 1 to 12, wherein the MLPSCs express about 13 pg to about 44 pg TNFR1 per million MLPSCs.

14. The method of any one of claims 10 to 13, wherein said culture expansion comprises at least 20 population doublings.

15. The method of any one of claims 10 to 13, wherein said culture expansion comprises at least 30 population doublings.

16. The method according to any one of claims 1 to 15, wherein the composition is administered intravenously.

17. The method according to any one of claims 1 to 16, wherein the MLPSCs are mesenchymal stem cells (MSCs).

18. The method according to any one of claims 1 to 17, wherein the MLPSCs are allogeneic.

19. The method according to any one of claims 1 to 18 which comprises administering between 1 x 10^7 and 2 x 10^8 cells per dose.

20. The method according to any one of claims 1 to 19 which comprises administering about 1 x 10^8 cells per dose.

21. The method according to claim 19 or claim 20 wherein a dose is administered at baseline followed by 3 subsequent doses monthly over 90 days.

22. The method according to any one of claims 1 to 21, wherein the subject has an improvement in FEV1 after treatment.

23. The method according to claim 22, wherein the subject has an FEV1 change from baseline of at least 0.02, or at least 0.05, within 120 days of receiving the first dose of cells.

24. The method according to any one of claims 1 to 23, wherein the subject has an improvement in FVC after treatment.

25. The method according to claim 24, wherein the subject has an FVC change from baseline of at least 0.05, or at least 0.1, within 120 days of receiving the first dose of cells.

26. The method according to any one of claims 1 to 25, wherein the subject has an improvement in FEV1/FVC after treatment.

27. The method according to claim 26, wherein the subject has an FEV1/FVC change from baseline of at least 0.01, or at least 0.015, within 120 days of receiving the first dose of cells.

28. The method according to any one of claims 1 to 27, wherein the subject shows an improvement in a 6 minute walk test after treatment.

29. The method according to claim 28, wherein the subject shows an improvement in the 6 minute walk test of at least 40 meters, or at least 50 meters, within 60 days or within 120 days of receiving the first dose of cells.

30. The method according to any one of claims 1 to 29, wherein the composition further comprises Plasma-Lyte A, dimethyl sulfoxide (DMSO), human serum albumin (HSA).

31. The method according to any one of claims 1 to 30, wherein the composition further comprises Plasma-Lyte A (70%), DMSO (10%), HSA (25%) solution, the HSA solution comprising 5% HSA and 15% buffer.

32. The method according to any one of claims 1 to 31, wherein the composition comprises greater than $6.68x10^6$ viable cells/mL.

CLAIMS

1. Use of a composition comprising a population of culture expanded, cryopreserved and thawed mesenchymal lineage precursor or stem cells (MLPSCs) in the manufacture of a medicament for treating Acute Respiratory Distress Syndrome (ARDS) in a human subject in need thereof, in which the subject has an elevated circulating C-reactive protein (CRP), in which the ARDS is caused by COVID-19, and in which the subject has an improvement in one or more of the following after administration of the medicament:

- Forced expiratory volume in one second (FEV1);
- Forced vital capacity (FVC);
- FEV1/FVC; and
- 6 minute walk test.

2. Use according to Claim 1, in which the subject has an initial circulating CRP level of at least 2mg/ml.

3. Use according to Claim 1, in which the subject has an initial circulating CRP level of at least 3mg/ml, preferably at least 4mg/ml.

4. Use according to Claim 1, 2 or 3, in which the MLPSCs are culture expanded, from an intermediate cryopreserved MLPSCs population.

5. Use according to any preceding claim, in which the MLPSCs are culture expanded for at least about 5 passages.

6. Use according to any preceding claim, in which the composition is to be administered intravenously.

7. Use according to any preceding claim, in which the MLPSCs are mesenchymal stem cells (MSCs).

8. Use according to any preceding claim, in which the MLPSCs are allogeneic.

9. Use according to any preceding claim, in which between 1×10^7 and 2×10^8 cells per dose are to be administered.

10. Use according to any preceding claim, in which about 1 x 10^8 cells per dose are to be administered.

11. Use according to Claim 9 or 10, in which a dose is to be administered at baseline followed by 3 subsequent doses monthly over 90 days.

12. Use according to any preceding claim, in which the subject has an FEV1 change from baseline of at least 0.02, or at least 0.05, within 120 days of administration of the medicament.

13. Use according to any preceding claim, in which the subject has an FVC change from baseline of at least 0.05, or at least 0.1, within 120 days of administration of the medicament.

14. Use according to any preceding claim, in which the subject has an FEV1/FVC change from baseline of at least 0.01, or at least 0.015, within 120 days of administration of the medicament.

15. Use according to any preceding claim, in which the subject shows an improvement in the 6 minute walk test of at least 40 meters, or at least 50 meters, within 60 days or within 120 days of administration of the medicament.

16. Use according to any preceding claim, in which the composition further comprises Plasma-Lyte A, dimethyl sulfoxide (DMSO), human serum albumin (HSA).

17. Use according to any of Claims 1 to 15, in which the composition further comprises Plasma-Lyte A (70%), DMSO (10%), HSA (25%) solution, the HSA solution comprising 5% HSA and 15% buffer.

18. Use according to any preceding claim, in which the composition comprises greater than 6.68x10^6 viable cells/mL.