

CLAIMS

1. A composition comprising a population of culture expanded mesenchymal lineage precursor or stem cells (MLPSC), in which the population of MLPSCs are culture expanded from a cryopreserved intermediate MLPSC preparation and the culture expanded MLPSCs
5 express a receptor which, upon activation via an inflammatory stimulus, phosphorylates NF- κ B, in which the MLPSCs express a level of the receptor that is sufficient to increase phosphorylation of NF- κ B upon activation via the inflammatory stimulus at least 3.5 fold greater than unstimulated MLPSCs.
2. A composition according to Claim 1, in which the receptor is one or both of TNF-R1 or
10 IL-1R.
3. A composition according to Claim 1 or 2, in which activation of the MLPSCs via the inflammatory stimulus increases secretion of one or more of MCP-1, M-CSF and PGE2 under culture conditions.
4. A composition according to Claim 1, 2 or 3, in which the receptor which, upon
15 activation via an inflammatory stimulus, phosphorylates NF- κ B is TNF-R1 and the MLPSCs express at least 100 pg/ml to 225 pg/ml TNF-R1 under culture conditions.
5. A composition comprising a population of culture expanded mesenchymal lineage precursor or stem cells, in which the composition comprises at least 25×10^6 cells and, in which the population of culture expanded cells has been selected for use in treatment of an
20 inflammatory disease by determining expression of least about 200 pg/ml TNF-R1 under culture conditions.
6. A composition according to any preceding claim, in which the population of culture expanded cells express at least 100 pg/ml TNF-R1 to at least 270 pg/ml TNF-R1 under culture conditions.
- 25 7. A composition according to any preceding claim, in which the population of culture expanded cells are culture expanded in 3D culture.
8. A composition according Claim 5, 6 or 7, in which the inflammatory disease is graft versus host disease (GvHD).

9. A method for determining the therapeutic efficacy of mesenchymal lineage precursor or stem cells comprising:

- (i) obtaining a population comprising mesenchymal lineage precursor or stem cells;
- (ii) culturing the cells in a culture medium; and

5 (iii) determining the amount of TNF-R1 expressed by the cells into the culture medium under culture conditions, in which an amount of at least about 100 pg/ml TNF-R1 is indicative of therapeutic efficacy.

10. Use of a composition comprising mesenchymal lineage precursor or stem cells in the preparation of a medicament for the treatment of an inflammatory disease, in which the cells
10 express at least about 100 pg/ml TNF-R1 under culture conditions.

11. Use according to Claim 10, in which the inflammatory disease is a T cell mediated inflammatory disease.

12. Use according to Claim 10 or 11, in which the inflammatory disease is GvHD.

13. Use according to Claim 12, in which the GvHD is chronic GvHD.

15 14. Use according to any of Claims 10 to 13, in which a subject following the treatment has improved 100 day survival.

15. Use according to any of Claims 10 to 14, in which the treatment is for a subject that is refractory to steroid immunosuppressant and/or a biologic therapy.

20 16. Use according to any of Claims 10 to 15, in which the mesenchymal precursor lineage or stem cells are culture expanded from a cryopreserved intermediate MLPSC preparation.

17. A composition according to any of Claims 1 to 8, a method according to Claim 9 or use according to any of Claims 10 to 16, in which the mesenchymal precursor lineage or stem cells are mesenchymal stem cells.

25 18. A composition according to any of Claims 1 to 8 or use according to any of Claims 10 to 17, in which the composition further comprises Plasma-Lyte A, dimethyl sulfoxide (DMSO), human serum albumin (HSA).

19. A composition according to any of Claims 1 to 8 or use according to any of Claims 10 to 17, in which the composition comprises greater than 6.68×10^6 viable cells/mL.
20. A composition or use according to Claim 19, in which each dose comprises at least 2×10^6 cells/kg body weight of subject.