

CLAIMS

1. A method of selecting a cell population for culture expansion, the method comprising:
(i) obtaining a population of mesenchymal precursor lineage or stem cells (MLPSCs); (ii)
culturing the MLPSC population in a culture medium; (iii) determining under culture
5 conditions the level of IL2-RA inhibition; and, (iv) selecting an MLPSC population for further
expansion that inhibits IL2-RA by at least 55% under culture conditions.
2. A method according to Claim 1, which comprises selecting an MLPSC population for
further expansion that inhibits IL2-RA by at least 60% under culture conditions.
3. A method according to Claim 1 or 2, in which the MLPSC population that is selected for
10 further expansion also expresses at least 80 pg/ml TNF-R1 under culture conditions.
4. A method according to Claim 1, 2 or 3, further comprising culture expanding a selected
MLPSC population to provide a pharmaceutical composition.
5. A method according to any preceding claim, in which culture expansion of the selected
MLPSC population provides a MLPSC population characterized by IL2-RA inhibition greater
15 than 60%, greater than 70% under culture conditions.
6. A method for determining therapeutic efficacy of an intermediate population of
mesenchymal precursor lineage or stem cells (MLPSCs): (i) obtaining a population of
MLPSCs; (ii) culturing the cells in a culture medium; and (iii) determining under culture
conditions the level of IL2-RA inhibition, in which at least 55% IL2-RA inhibition under
20 culture conditions is indicative of therapeutic efficacy.
7. A method according to Claim 6, in which IL2-RA inhibition greater than 60%, greater
than 70% under culture conditions is indicative of therapeutic efficacy.
8. A method according to Claim 6 or 7, in which upon determining therapeutic efficacy,
the intermediate population of MLPSCs is culture expanded to provide a pharmaceutical
25 composition.
9. A method according to Claim 8, in which the pharmaceutical composition comprises a
MLPSC population characterized by IL2-RA inhibition between 60% and 80% under culture
conditions.

10. Use of a composition comprising a culture expanded population of mesenchymal lineage precursor or stem cells (MLPSCs) in the preparation of a medicament for treating an inflammatory disease in a subject, in which the MLPSCs are culture expanded from a population of MLPSCs which inhibit IL2-RA by at least 55% under culture conditions.
- 5 11. Use according to Claim 10, in which the culture expanded MLPSCs which comprise the medicament inhibit IL2-RA by at least 60% under culture conditions.
12. A cryopreserved cellular intermediate comprising a population of culture expanded mesenchymal lineage precursor or stem cells (MLPSC), in which the population of MLPSCs are culture expanded between 2 and 5 passages and the culture expanded MLPSCs: a) inhibit
 - 10 IL2-RA by at least 55% under culture conditions.
 13. A method according to any of Claims 1 to 9, use according to Claim 10 or 11, or a cellular intermediate according to Claim 12, in which the MLPSCs are culture expanded in 2D culture and 5% +/- 2% CO₂.
 14. Use according to Claim 10, 11 or 13, in which the inflammatory disease is graft versus
 - 15 host disease (GvHD).
 15. Use according to Claim 14, in which the GvHD is Grade D.
 16. Use according to Claim 14, in which the GvHD is chronic GvHD.
 17. Use according to any of Claims 10, 11 or 14 to 16, in which the medicament increases 100 day survival to greater than 60%, greater than 70%.
 - 20 18. Use according to any of Claims 10, 11 or 14 to 17, in which the subject is refractory to steroid immunosuppressant and/or a biologic therapy.
 19. A method according to any of Claims 1 to 9, use according to any of Claims 10, 11, or 14 to 18, or a cellular intermediate according to Claim 12, in which the MLPSCs are mesenchymal stem cells.
 - 25 20. A method of manufacturing drug product which comprises a population of mesenchymal lineage precursor or stem cells (MLPSCs), the method comprising: acquiring a determination of whether a test population of MLPSCs have a predetermined level of IL2-RA inhibition under culture conditions, and culture expanding at least a portion of the test

population of MLPSCs to a drug product if the test population of MLPSCs have at least the predetermined level of IL2-RA inhibition under culture conditions, thereby manufacturing the drug product; or discarding at least a portion of the test population of MLPSCs if the population of MLPSCs has less than the predetermined level of IL2-RA inhibition under culture conditions.

21. A method according to Claim 20, in which the predetermined level of IL2-RA inhibition is at least 55% under culture conditions.

22. A method according to Claim 20, in which the predetermined level of IL2-RA inhibition is at least 60% under culture conditions.

23. A method according to Claim 20, 21 or 22, in which culture expanding at least a portion of the test population of MLPSCs to a drug product provides a MLPSC population characterized by IL2-RA inhibition greater than 60%, greater than 70% under culture conditions.