

CLAIMS

1. Use of a composition comprising culture expanded mesenchymal lineage precursor or stem cells (MLPSCs) in the preparation of a medicament for treatment of chronic Graft versus Host Disease (cGvHD) in a human subject, in which the composition is to be intravenously administered at a dose of 1×10^6 MLPSCs/kg to 3×10^6 MLPSCs/kg, in which the cGvHD subject is refractory to steroid therapy, and the MLPSCs inhibit IL2-R α expression on T cells by at least 60%.
2. Use according to Claim 1, in which the MLPSCs are culture expanded from an intermediate cryopreserved MLPSC population.
3. Use according to Claim 1 or 2, in which the MLPSCs are culture expanded for at least 5 passages.
4. Use according to any preceding claim, in which a partial response is characterized by one or more or all of:
 - reduction in Skin % BSA score of at least one point;
 - reduction in mouth score of at least one point;
 - reduction in eye score of at least one point;
 - reduction in skin features score of at least one point;
 - reduction in gastrointestinal tract score of at least one point;
 - reduction in liver score of at least one point;
 - reduction in lung symptom score of at least one point;
 - reduction in lung FEV1 score of at least one point;
 - reduction in joints and fascia score of at least one point; and
 - reduction in genital tract score of at least one point.
5. Use according to Claim 4, in which a partial response is characterized by one or more or all of:
 - reduction in Skin % BSA score of at least one point;
 - reduction in mouth score of at least one point; and

reduction in eye score of at least one point.

6. Use according to any preceding claim, in which the MLPSCs are mesenchymal stem cells (MSCs).
7. Use according to any preceding claim, in which the composition further comprises
- 5 Plasma-Lyte A, dimethyl sulfoxide (DMSO), human serum albumin (HSA), preferably Plasma-Lyte A (70%), DMSO (10%), HSA (25%) solution, the HSA solution comprising 5% HSA and 15% buffer.
8. Use according to any preceding claim, in which the composition comprises greater than 6.68×10^6 viable cells/mL.
- 10 9. Use according to any preceding claim, in which the human MLPSCs were culture expanded in a single type of serum.
10. Use according to any preceding claim, in which the medicament is cryopreserved.
11. Use according to Claim 10, in which, prior to the cryopreservation, the culture expanded human MLPSCs were cultured in culture medium comprising at least 5% serum.
- 15 12. Use according to Claim 11, in which the serum is bovine serum.