CLAIMS

1. A method of manufacturing drug product which comprises a population of mesenchymal lineage precursor or stem cells (MLPSCs), the method comprising:

(i) acquiring a determination of whether a test population of MLPSCs inhibits IL-2RA at a predetermined level under culture conditions, in which step (i) comprises co-culturing the test population of MLPSCs with CD3/CD28 activated PBMCs; and determining the level of IL-2RA inhibition relative to a control population of CD3/CD28 activated PBMCs in the absence of MLPSCs; in which the predetermined level of IL-2RA inhibition is at least 56%; and in which the control population of CD3/CD28 activated PBMCs express at least 12,000 pg/ml IL-2RA.

2. A method according to Claim 1, in which CD3/CD28 activation of PBMCs comprises stimulating PBMCs with an anti- CD3 antibody and an anti-CD28 antibody.

3. A method according to Claim 1 or 2, in which the PBMCs are co-cultured with MLPSCs at a ratio of 5 PBMC:1 MPLSC.

4. A method according to Claim 3, in which $1x10^6$ PBMCs are co-cultured with $2x10^5$ MLPSCs.

5. A method according to any preceding claim, in which the PBMCs and MLPSCs are co-cultured for a period of about 72 hours.

6. A method according to any preceding claim, in which the level of IL-2RA inhibition is determined by:

(i) measuring IL-2RA levels in a test population of MLPSCs co-cultured with CD3/CD28-activated PBMCs, a positive control population of CD3/CD28-activated PBMCs in the absence of MLPSCs, and a negative control population of un-activated PBMCs in the absence of MLPSCs;

(ii) constructing a standard curve to determine IL-2RA levels in the positive control population, negative control population, and test population; and

(iii) calculating % inhibition of IL-2RA levels on the positive control population by the test population of MLPSCs co-cultured with CD3/CD28-activated PBMCs, relative to the positive control CD3/CD28-activated PBMC population.

7. A method according to Claim 6, in which the IL-2RA levels are measured by enzyme-linked immunosorbent assay (ELISA).

8. A method according to Claim 6 or 7, in which the standard curve is generated using a four-parameter logistic (4-PL) curve fit.

9. A method according to any preceding claim, in which the MLPSCs are mesenchymal stem cells.

10. A method according to any of Claims 1 to 8, in which the predetermined level of IL-2RA inhibition is ≥ 60%.

11. A method according to any of Claims 1 to 8, in which the predetermined level of IL-2RA inhibition is ≥ 65%.

12. Use of a composition comprising a culture expanded population of mesenchymal lineage precursor or stem cells (MLPSCs) in the manufacture of a medicament for treating a subject with graft versus host disease (GvHD), in which the MLPSCs in the composition inhibit IL-2RA by at least 56% under culture conditions , in which the level of IL-2RA inhibition is determined by co-culturing the MLPSCs with CD3/CD28 activated PBMCs; and determining the level of IL-2RA inhibition relative to a control population of CD3/CD28 activated PBMCs in the absence of MLPSCs, in which the control population of CD3/CD28 activated PBMCs express at least 12,000 pg/ml IL-2RA.

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

14. Use according to Claim 12 or 13, in which the GvHD is refractory to steroid therapy.

15. Use according to Claim 12, 13 or 14, in which the GvHD is Grade D GvHD.

16. Use according to any of Claims 12 to 15, in which treatment increases 100 day survival to greater than 60%, preferably greater than 70%.