Claims

1. A method for predicting clinical response to the administration of a pharmaceutical composition comprising of stem cells, stromal cells, regulatory T-cells, fibroblasts and combinations in a patient suffering from tissue damage, an ischemic, an inflammatory and/or an immune disorder thereof by evaluating one or more lymphocytes markers.

2. A method for treating a human subject having tissue damage, an ischemic, an inflammatory and/or an immune disorder with a pharmaceutical composition comprising of stem cells (preferably mesenchymal stem cells), stromal cells, regulatory T-cells, fibroblasts and combinations thereof comprising

i) determining whether the patient is a responder or a non-responder to said pharmaceutical composition by evaluating a lymphocyte marker in a blood sample obtained from said human subject and
ii) administering said pharmaceutical composition only if the human subject is determined to be a responder.

3. A method according to claims 1 or 2 wherein said lymphocyte marker is selected from the group comprising CD4+ lymphocyte level, CD8+ lymphocyte level, lymphocyte HLA-II level and combinations thereof.

4. A method according to any of claims 1 to 3 wherein a subject having a CD4+ level equal to or less than a value in the range of 35% to 55% of the total T-lymphocytes is classified as a responder.

5. A method according to any of claims 1 to 3 wherein a subject having a CD8+ level equal to or greater than a value in the range of 45% to 65% of the total T-lymphocytes is classified as a responder.

6. A method according to any of claims 1 to 3 wherein a subject having a CD4:CD8+ ratio equal to or lower than 1.5 is classified as a responder.

7. A method according to any of claims 1 to 3 wherein a subject having a reduction in lymphocyte HLA-II level after contact thereof with allogeneic mesenchymal stem cells is classified as a responder.

8. A method according to any of claims 1 to 7 wherein the stem cells are mesenchymal stem cells.

9. A method according to any of claims 1 to 8 wherein the stem cells are multipotent stromal or stromal stem cells.

10. A method according to claims 8 or 9 wherein the mesenchymal stem cells are adipose tissue derived mesenchymal stem cells.

11. A method according to either of claims 1 to 10 wherein the stem cells are allogeneic stem cells.

12. A pharmaceutical composition comprising of stem cells, stromal cells, regulatory T-cells, fibroblasts and combinations thereof for use in the treatment, modulation, prophylaxis, and/or amelioration of one or more symptoms associated with tissue damage, an ischemic, an inflammatory and/or an immune disorder in a human subject wherein said human subject has a CD4+ level equal to or less than a value in the range of 35% to 55% of T-lymphocytes.

13. A pharmaceutical composition comprising of stem cells, stromal cells, regulatory T-cells, fibroblasts and combinations thereof for use in the treatment, modulation, prophylaxis, and/or amelioration of one or more symptoms associated with tissue damage, an ischemic, an inflammatory and/or an immune disorder in a human subject wherein said human subject has a CD8+ level equal to or greater than a value in the range of 45% to 65% of T-lymphocytes.

14. A pharmaceutical composition comprising of stem cells, stromal cells, regulatory T-cells, fibroblasts and combinations thereof

for use in the treatment, modulation, prophylaxis, and/or amelioration of one or more symptoms associated with tissue damage, an ischemic, an inflammatory and/or an immune disorder in a human subject wherein said human subject has a CD4:CD8 ratio equal to or lower than 1.5.

15. A pharmaceutical composition comprising of stem cells, stromal cells, regulatory T-cells, fibroblasts and combinations thereof for use in the treatment, modulation, prophylaxis, and/or amelioration of one or more symptoms associated with tissue damage, an ischemic, an inflammatory and/or an immune disorders in a human subject wherein said human subject has a reduction in lymphocyte HLA-II level after contact thereof with allogeneic mesenchymal stem cells.

16. Use of stem cells, stromal cells, regulatory T-cells, fibroblasts and combinations thereof for the preparation of a pharmaceutical composition for the treatment, modulation, prophylaxis, and/or amelioration of one or more symptoms associated with tissue damage, an ischemic, an inflammatory and/or an immune disorder in a human subject wherein said human subject has a CD4+ level equal to or less than a value in the range of 35% to 55% of T-lymphocytes.

17. Use of stem cells, stromal cells, regulatory T-cells, fibroblasts and combinations thereof for the preparation of a pharmaceutical composition for the treatment, modulation, prophylaxis, and/or amelioration of one or more symptoms associated with tissue damage, an ischemic, an inflammatory and/or an immune disorder in a human subject wherein said human subject has a CD8+ level equal to or greater than a value in the range of 45% to 65% of T-lymphocytes.

18. Use of stem cells, stromal cells, regulatory T-cells, fibroblasts and combinations thereof for the preparation of a pharmaceutical composition for the treatment, modulation, prophylaxis, and/or amelioration of one or more symptoms associated with tissue damage, an ischemic, an inflammatory and/or an immune disorder in a human subject wherein said human subject has a CD4:CD8 ratio equal to or lower than 1.5.

19. Use of stem cells, stromal cells, regulatory T-cells, fibroblasts and combinations thereof for the preparation of a pharmaceutical composition for the treatment, modulation, prophylaxis, and/or amelioration of one or more symptoms associated with tissue damage, ischemic, inflammatory and/or an immune disorders in a human subject wherein said human subject has a reduction in lymphocyte HLA-II level after contact thereof with allogeneic mesenchymal stem cells.

Claims

1. A method for predicting clinical response to the administration of a pharmaceutical composition comprising stromal and/or mesenchymal stem cells in a patient suffering from tissue damage, an inflammatory and/or an immune disorder by evaluating one or more lymphocyte markers, wherein said lymphocyte marker is the CD4+ and/or the CD8+ lymphocyte level.

2. A method according to claim 1 wherein a subject having a CD4+ level equal to or less than a value in the range of 35% to 55% of the total T-lymphocytes is classified as a responder.

3. A method according to claim 1 wherein a subject having a CD8+ level equal to or greater than a value in the range of 45% to 65% of the total T-lymphocytes is classified as a responder.

4. A method according to claim 1 wherein a subject having a CD4:CD8+ ratio equal to or lower than 1.5 is classified as a responder.

5. A method according to any one of claims 1 to 4 wherein the mesenchymal stem cells are adipose tissue derived mesenchymal stem cells.

6. A method according to any one of claims 1 to 5 wherein the stem cells are allogeneic stem cells.

7. Use of stromal and/or mesenchymal stem cells for the preparation of a pharmaceutical composition for the treatment, modulation, prophylaxis, and/or amelioration of one or more symptoms associated with tissue damage, an inflammatory and/or an immune disorder in a human subject wherein said human subject has a CD4+ level equal to or less than a value in the range of 35% to 55% of T-lymphocytes.

8. Use of stromal and/or mesenchymal stem cells for the preparation of a pharmaceutical composition for the treatment, modulation, prophylaxis, and/or amelioration of one or more symptoms associated with tissue damage, an inflammatory and/or an immune disorder in a human subject wherein said human

subject has a CD8+ level equal to or greater than a value in the range of 45% to 65% of T-lymphocytes.

9. Use of stromal and/or mesenchymal stem cells for the preparation of a pharmaceutical composition for the treatment, modulation, prophylaxis, and/or amelioration of one or more symptoms associated with tissue damage, an inflammatory and/or an immune disorder in a human subject wherein said human subject has a CD4:CD8 ratio equal to or lower than 1.5.