CLAIMS

1. An *in vitro* 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 in a blood sample obtained from the patient, wherein said lymphocyte marker is the CD4+ and/or the CD8+ lymphocyte level, and wherein the patient is classified as a responder if:

(a) the patient has a $CD4^+$ level in the range of 35% to 55% of the total T-lymphocytes;

(b) the patient has a $CD8^+$ level in the range of 45% to 65% of the total T-lymphocytes; or if

(c) the patient has a $CD4^+$:$CD8^+$ ratio equal to or lower than 1.2.

2. The method according to claim 1 wherein the mesenchymal stem cells are adipose tissue derived mesenchymal stem cells.

3. The method according to any one of claims 1 or 2 wherein the stem cells are allogeneic stem cells.

4. 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 having a $CD4^+$ level in the range of 35% to 55% of T-lymphocytes has been determined by the method of claim 1.

5. 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 having a $CD8^+$ level in the range of 45% to 65% of T-lymphocytes has been determined by the method of claim 1.

6. 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 having a $CD4^+$:$CD8^+$ ratio equal to or lower than 1.2 has been determined by the method of claim 1.