CLAIMS

1. Use of a cell suspension comprising from 4 x 10^8 to 1.2 x 10^9 autologous or allogeneic white blood cells derived from the bone marrow of a human subject, wherein of the total number of from 4 x 10^8 to 1.2 x 10^9 white blood cells:

    i. 20% to 51% are lymphocytes, and 3.9% to 22.3% are monocytes;
    ii. 1.4% to 10% are hematopoietic stem cells that express CD34;
    iii. 25.3% to 83.3% of the total number of white blood cells are mononuclear cells;
    iv. 16.7% to 74.7% are granulocytes;
    v. 5.4% to 38.8% of the total number of white blood cells express CXCR4;
    vi. 0.07% to 24.7% of total number of white blood cells express VEGFR2;
    vii. Of the total number of hematopoietic stem cells that express CD34, 7.7% to 55.5% are early, non-committed hematopoietic stem cells that do not express CD38 and 0.7% to 10.3% are stem cells that express CD34 and CXCR4; and
    viii. The maximum ratio of red blood cells to leucocyte cells is 6.7 and the maximum ratio of platelets to leucocyte cells is 32

in the manufacture of a medicament for the treatment or amelioration of lower extremity peripheral artery disease.

2. The use according to claim 1, wherein of the total number of white blood cells 32.3% to 80.0% are mononuclear cells selected from the list consisting of lymphocytes, monocytes and hematopoietic stem cells that express CD34 cells and 20.0% to 67.7%, are granulocytes.

3. The use according to claims 1 or 2, wherein the cell suspension comprises 5 x 10^8 to 1.2 x 10^9.

4. The use according to claims 1 or 2, wherein the cell suspension comprises 8 x 10^8 to 1.2 x 10^9.

5. The use according to claims 1 or 2, wherein the cell suspension comprises 9 x 10^8 to 1.1 x 10^9.

6. The use according to claims 1 or 2, wherein the cell suspension comprises 9.5×10^8 to 1.05×10^9.

7. The use according to claims 1 or 2, wherein the cell suspension comprises 9.8×10^8 to 1.02×10^9.

8. The use according to any of claims 1 to 7, wherein the lower extremity peripheral artery disease is critical limb ischemia.

9. The use according to any of claims 1 to 8, wherein the cells of such cell suspension are suspended in a volume of from 5 to 30 ml of a heparinized saline solution or lactated Ringer solution, preferably comprising about 1% HSA and about 2.5% glucose.

10. The use as defined in any of claims 1 to 7, for treatment of lower extremity peripheral artery disease, preferably critical limb ischemia, via intra-arterial administration, wherein a low pressure blood flow of up to 4 atmospheres is obtained by positioning an inflatable balloon proximal to the occlusive vascular lesion at the distal femoral or popliteal artery and infusing said cell suspension intra-arterially.

11. A syringe or a plurality of syringes comprising a cell suspension as defined in any of claims 1 to 7.

12. The syringe(s) according to claim 11 for use in the treatment or amelioration of lower extremity peripheral artery disease, preferably critical limb ischemia.

13. The syringe(s) according to claim 11, for use in a method of treatment of lower extremity peripheral artery disease, preferably critical limb ischemia, via intra-arterial administration, wherein a low pressure blood flow of up to 4 atmospheres is obtained by positioning an inflatable balloon proximal to the occlusive vascular lesion at the distal femoral or popliteal artery and infusing said cell suspension intra-arterially.

14. The use according to any one of claims 1-7 or the syringe(s) for use according to any one of claims 12 to 13, wherein said suspension is provided as a single dose.

15. The use according to claim 10, or the syringe(s) for use according to claims 11 to 13, wherein the induction of low pressure flow is produced between 1 and 6 minutes and wherein the infusion of said cell suspension is carry-out between 2 and 10 minutes.

16. A manufacturing process of a cell suspension, which comprises:

    a. A Bone Marrow (BM) sample collected from a human subject is filtered, preferably by gravity, to remove any small bone fragments and to prevent clogging during later steps;

    b. The initial BM volume is reduced, preferably to about 50-100 mL, by using the SmartRedux program on the Sepax 2.0 device and associated sterile disposable SmartRedux kit (CS-490.1);

    c. The volume-reduced BM as obtained in step c), then goes through an automated density gradient centrifugation by performing a *NeatCell* density gradient centrifugation followed by two washes of the mononuclear cell (MNC) suspension using a washing solution, preferably composed of 2-4% HSA in saline solution (both pharmaceutical grade);

    d. Collect the product of step d) and filter it, preferably through a 50 µm filter, into a sterile falcon tube;

    e. The BM product is then rinsed with wash solution and filtered to improve MNC (mononuclear cells) recovery; and

    f. Optionally, the final volume of the BM product is adjusted to 40-60 mL.