CLAIMS

1. A composition comprising Th1/killer cells wherein:

(1) the Th1/killer cells have Th1 characteristics and cytolytic activity; or

(2) the Th1/killer cells are CD4+ cells having cytolytic activity against a tumor cell line; wherein the Th1/killer cells of the (1) are formulated with cross-linking agent for CD3 and CD28, and the Th1/killer cells of the (1) are derived from normal donor peripheral blood.

2. The composition of claim 1 wherein the cytolytic activity of (1) comprises NK characteristics.

3. The composition of claim 1 wherein the Th1/killer cells express: granzyme B and perforin; or IFN-gamma.

4. The composition of claim 1 wherein the Th1/killer cells of (1):

a) have substantially reduced or no expression of IL-4;

b) are CD4+ cells.

5. The composition of claim 1 wherein the composition of (1) comprises:

a) clinically-relevant number of the Th1/killer cells;

b) at least about 1×10^7 cells; or

c) at least about 1×10^8 cells.

6. The composition of claim 1 wherein the cytolytic activity of (1) of the Th1/killer cells inactivates diseased cells, and wherein the diseased cells preferably comprise cancerous cells, infected cells or combinations thereof.

7. The composition of claim 1 wherein the Th1/killer cells of (2):

a) comprise Th1 characteristics; or

b) do not inactivate normal cells.

8. The composition of claim 1 wherein the tumor cell line of (2) is ARH77.

9. Use of a composition in the manufacture of a medicament for destroying diseased cells in a patient with cancer or infection, wherein the composition comprises allogeneic Th1/killer cells expressing granzyme B and perforin wherein the interaction of the diseased cells with the Th1/killer cells leads to destruction of the diseased cells.

10. The use according to claim 9 wherein the Th1/killer cells express Th1 characteristics and cytolytic activity.

11. The use according to claim 10 wherein:

a) the cytolytic activity of the Th1/killer cells comprises expressing granzyme B-perforin;

b) the Th1 characteristics comprise expression of IFN-gamma; or

c) the Th1/killer cells lack expression of IL-4.

12. The use according to claim 9 wherein:

a) the Th1/killer cells are obtained by activation of CD4+ T-cells with cross-linked anti-CD3/anti-CD28 monoclonal antibodies;

b) the diseased cells comprise cancerous cells, infected cells or a combination thereof.

13. Use of a composition in the manufacture of a medicament for treatment of a patient with cancer or infection, wherein the composition comprises a clinically-relevant number of Th1/killer cells expressing granzyme B and perforin and cytolytic activity.

14. The use according to claim 9 or claim 13 wherein the Th1/killer cells are CD4+ cells.

15. The use according to claim 13 wherein:

a) the Th1/killer cells express Th1 characteristics and cytolytic activity, wherein preferably the Th1/killer cells are activated with beads attached to anti-CD3/anti-CD28 monoclonal antibodies and crosslinked;

b) the Th1/killer cells are obtained from the peripheral blood of a normal donor;

c) the Th1/killer cells are allogeneic to the patient; or

d) the clinically-relevant number of cells is at least 1×10^8.

CLAIMS

1. A composition comprising Th1/killer cells expressing granzyme B and perforin wherein:
   (1) the Th1/killer cells have Th1 characteristics and cytolytic activity; or
   (2) the Th1/killer cells are CD4+ cells having cytolytic activity against a tumor cell line.

2. The composition of claim 1 wherein the cytolytic activity of (1) comprises NK characteristics.

3. The composition of claim 1 wherein the Th1/killer cells express IFN-gamma.

4. The composition of claim 1 wherein the Th1/killer cells of (1):
   a) have substantially reduced or no expression of IL-4;
   b) are CD4+ cells;
   c) are formulated with cross-linking agent for CD3 and CD28; or
   d) are derived from normal donor peripheral blood.

5. The composition of claim 1 wherein the composition of (1) comprises:
   a) clinically-relevant number of the Th1/killer cells;
   b) at least about 1×10^7 cells; or
   c) at least about 1×10^8 cells.

6. The composition of claim 1 wherein the cytolytic activity of (1) of the Th1/killer cells specifically inactivates diseased cells and not normal cells, and wherein the diseased cells preferably comprise cancerous cells, infected cells or combinations thereof.

7. The composition of claim 1 wherein the Th1/killer cells of (2):
   a) comprise Th1 characteristics; or
   b) do not inactivate normal cells.

8. The composition of claim 1 wherein the tumor cell line of (2) is ARH77.

9. A composition for use in destroying diseased cells, wherein the composition comprises allogeneic Th1/killer cells expressing granzyme B and perforin wherein the interaction of the diseased cells with the Th1/killer cells leads to destruction of the diseased cells.

10. The composition for use according to claim 9 wherein the Th1/killer cells express Th1 characteristics and cytolytic activity.

~~11. The composition for use according to claim 10 wherein:~~

a) the Th1 characteristics comprise expression of IFN-gamma; or

b) the Th1/killer cells lack expression of IL-4.

12. The composition for use according to claim 9 wherein:

a) the Th1/killer cells are obtained by activation of CD4+ T-cells with cross-linked anti-CD3/anti-CD28 monoclonal antibodies;

b) the diseased cells comprise cancerous cells, infected cells or a combination thereof.

13. A composition for use in therapy, wherein the composition comprises a clinically-relevant number of Th1/killer cells.

14. The composition for use according to claim 9 or claim 13 wherein the Th1/killer cells are CD4+ cells.

15. The composition for use according to claim 13 wherein:

a) the Th1/killer cells express Th1 characteristics and cytolytic activity, wherein preferably the Th1/killer cells are activated with beads attached to anti-CD3/anti-CD28 monoclonal antibodies and crosslinked;

b) the Th1/killer cells are obtained from the peripheral blood of a normal donor;

c) the Th1/killer cells are allogeneic to the patient; or

d) the clinically-relevant number of cells is at least 1×10^8.