WHAT IS CLAIMED IS

1. A biologic drug composition comprising living cells formulated in non-nutritive buffer, wherein the living cells are CD4+ activated Th1 cells, maintain their identity and at least one functional characteristic that defined the living cells prior to formulation in the non-nutritive buffer after storage for greater than 24 hours in the non-nutritive buffer, the living cells useful in immunotherapy in the non-nutritive buffer and wherein the one functional characteristic is the level of secretion of IFN-γ after storage is recovered to at least 80% compared to the level at the time of formulation.

2. The composition of claim 1 wherein the living cells are in a flexible container or syringe, wherein the flexible container or syringe is in a package with a temperature controlled device that maintains the living cells within refrigeration temperatures, the preferred temperature range being between 0°C and 10°C.

3. The composition of claim 1 wherein the Th1 cells are activated by immobilized monoclonal antibodies specific for T-cell surface molecules or are activated by immobilized anti-CD3 and anti-CD28 monoclonal antibodies.

4. The composition of claim 3 wherein the monoclonal antibodies are cross-linked.

5. The composition of claim 1 wherein the at least one functional characteristic is expression of CD40L, FasL, perforin and granzyme B, expression of costimulatory molecules, expression of adhesion molecules, secretion of cytokines, chemokines or combinations thereof.

6. The composition of claim 1 wherein the live cells in the non-nutritive buffer maintain their identity and at least one functional characteristic that defined the living cells prior to formulation in the non-nutritive buffer for at least 72 hours.

7. A method of handling a biological drug composition with living cells comprising:

formulating the living cells in a non-nutritive buffer, wherein the living cells are CD4+ cells that are activated Th1 cells; and

maintaining the living cells in the non-nutritive buffer at a storage temperature below 20°C, wherein the living cells maintain their identity and at least one of the functional characteristics of the cells that defined the living cells prior to formulation in the non-nutritive buffer, the living cells

useful for immunotherapy after being stored for greater than 24 hours in the non-nutritive buffer and wherein the one functional characteristic is the level of secretion of IFN-γ after storage is recovered to at least 80% compared to the level at the time of formulation.

8. The method of claim 7 wherein the storage temperature is in a range between 0°C and 10°C.

9. The method of claim 7 wherein the concentration of the cells in the non-nutritive buffer is 10^6 cells/ml or greater and/or the living cells are placed in a flexible container or syringe, wherein the flexible container or syringe is packaged in a temperature controlled device that maintains the living cells at the storage temperature.

10. The method of claim 7 wherein the Th1 cells are activated by immobilized monoclonal antibodies that are cross-linked or the Th1 cells are activated by immobilized anti-CD3 and anti-CD28 monoclonal antibodies.

11. The method of claim 7 wherein the functional characteristic is expression of CD40L, FasL, perforin and granzyme B, expression of costimulatory molecules, expression of adhesion molecules, secretion of cytokines, chemokines or combinations thereof.

12. The method of claim 7 wherein the living cells in the composition express CD40L after storage in an amount of at least 80% relative to the expression of CD40L at the time of formulation.

13. The method of claim 7 wherein the secretion of IFN-γ after storage is recovered after incubation at 37°C for at least 24 hours.

14. The method of claim 7 wherein the living cells in the non-nutritive buffer maintain their identity and at least one functional characteristic that defined the living cells prior to formulation in the non-nutritive buffer for at least 72 hours.

15. A method of providing living cell compositions to a point of care facility comprising:

formulating the living cells in a non-nutritive buffer at a processing facility, wherein the living cells are CD4+ cells that are activated Th1 cells; and

transporting the cells to a point of care facility in a package equipped to maintain a storage temperature below 20°C, wherein the living cells are at the storage temperature for greater than 24 hours while maintaining their identity and at least one of the functional characteristics of the living cells useful in immunotherapy and wherein the one functional characteristic is the level of secretion of IFN-γ after storage is recovered to at least 80% compared to the level at the time of formulation.

16. The method of claim 15 further comprising placing the formulated cells in a flexible container or syringe prior to transporting.

17. The method of claim 15 wherein the Th1 cells are activated by immobilized monoclonal antibodies, wherein the monoclonal antibodies are cross-linked.

18. The method of claim 15 wherein the live cells in the composition express CD40L after transportation and removal from storage temperature in an amount of at least 80% relative to the expression of CD40L at the time of formulation.

19. The method of claim 15 wherein the secretion of IFN-γ after transportation and storage is recovered after incubation at 37°C for at least 24 hours.

20. The method of claim 15 wherein the live cells in the non-nutritive buffer are at the storage temperature for at least 72 hours.

WHAT IS CLAIMED IS

1. A biologic drug composition comprising living cells formulated in non-nutritive buffer, wherein the living cells, maintain their identity and at least one functional characteristic that defined the living cells prior to formulation in the non-nutritive buffer after storage for greater than 24 hours in the non-nutritive buffer, the living cells useful in immunotherapy in the non-nutritive buffer.

2. The composition of claim 1 wherein the living cells are in a flexible container or syringe, wherein the flexible container or syringe is in a package with a temperature controlled device that maintains the living cells within refrigeration temperatures, the preferred temperature range being between 0°C and 10°C.

3. The composition of claim 1 wherein the live cells are CD4+ cells and are activated Th1 cells.

4. The composition of claim 3 wherein the Th1 cells are activated by immobilized monoclonal antibodies specific for T-cell surface molecules or are activated by immobilized anti-CD3 and anti-CD28 monoclonal antibodies.

5. The composition of claim 4 wherein the monoclonal antibodies are cross-linked.

6. The composition of claim 1 wherein the at least one functional characteristic is expression of CD40L, FasL, perforin and granzyme B, expression of costimulatory molecules, expression of adhesion molecules, secretion of cytokines, chemokines or combinations thereof.

7. The composition of claim 6 wherein the cytokine secreted is IFN-γ and the level of secretion of IFN-γ after storage is recovered to at least 80% compared to the level at the time of formulation.

8. The composition of claim 1 wherein the live cells in the non-nutritive buffer maintain their identity and at least one functional characteristic that defined the living cells prior to formulation in the non-nutritive buffer for at least 72 hours.

9. A method of handling a biological drug composition with living cells comprising:

formulating the living cells in a non-nutritive buffer; and

maintaining the living cells in the non-nutritive buffer at a storage temperature below 20°C, wherein the living cells maintain their identity and at least one of the functional characteristics of the cells that defined the living cells prior to formulation in the non-nutritive buffer, the living cells

useful for immunotherapy after being stored for greater than 24 hours in the non-nutritive buffer.

10. The method of claim 9 wherein the storage temperature is in a range between 0°C and 10°C.

11. The method of claim 9 wherein the concentration of the cells in the non-nutritive buffer is 10^6 cells/ml or greater and/or the living cells are placed in a flexible container or syringe, wherein the flexible container or syringe is packaged in a temperature controlled device that maintains the living cells at the storage temperature.

12. The method of claim 9 wherein the living cells are CD4+ cells and when activated are Th1 cells.

13. The method of claim 12 wherein the Th1 cells are activated by immobilized monoclonal antibodies that are cross-linked or the Th1 cells are activated by immobilized anti-CD3 and anti-CD28 monoclonal antibodies.

14. The method of claim 9 wherein the functional characteristic is expression of CD40L, FasL, perforin and granzyme B, expression of costimulatory molecules, expression of adhesion molecules, secretion of cytokines, chemokines or combinations thereof.

15. The method of claim 9 wherein the living cells in the composition express CD40L after storage in an amount of at least 80% relative to the expression of CD40L at the time of formulation.

16. The method of claim 14 wherein the inflammatory cytokine secreted is IFN-γ and the level of secretion is in an amount of at least 80% compared to the levels at the time of formulation.

17. The method of claim 16 wherein the secretion of IFN-γ after storage is recovered after incubation at 37°C for at least 24 hours.

18. The method of claim 9 wherein the living cells in the non-nutritive buffer maintain their identity and at least one functional characteristic that defined the living cells prior to formulation in the non-nutritive buffer for at least 72 hours.

19. A method of providing living cell compositions to a point of care facility comprising:

formulating the living cells in a non-nutritive buffer at a processing facility; and

transporting the cells to a point of care facility in a package equipped to maintain a storage temperature below 20°C, wherein the living cells are at the storage temperature for greater than 24 hours while maintaining their

identity and at least one of the functional characteristics of the living cells useful in immunotherapy.

20. The method of claim 19 further comprising placing the formulated cells in a flexible container or syringe prior to transporting.

21. The method of claim 19 wherein the live cells are CD4+ cells and when activated are Th1 cells.

22. The method of claim 21 wherein the Th1 cells are activated by immobilized monoclonal antibodies, wherein the monoclonal antibodies are cross-linked.

23. The method of claim 19 wherein the live cells in the composition express CD40L after transportation and removal from storage temperature in an amount of at least 80% relative to the expression of CD40L at the time of formulation.

24. The method of claim 19 wherein the cells in the composition secrete IFN-γ after transportation and removal from storage temperature in an amount of at least 80% compared to the levels at the time of formulation.

25. The method of claim 24 wherein the secretion of IFN-γ after transportation and storage is recovered after incubation at 37°C for at least 24 hours.

26. The method of claim 19 wherein the live cells in the non-nutritive buffer are at the storage temperature for at least 72 hours.