

WHAT IS CLAIMED IS:

1. ~~A population of CD4⁺ T cells that have been genetically modified to comprise an exogenous polynucleotide encoding IL-10, wherein the CD4⁺ T cells were obtained from at least three different T cell donors (poly-donor CD4^{HL-10} cells).~~
2. ~~The population of CD4⁺ T cells of claim 1, wherein the CD4⁺ T cells were obtained from three, four, five, six, seven, eight, nine, or ten different T cell donors.~~
3. ~~The population of CD4⁺ T cells of claim 1 or claim 2, wherein the CD4⁺ T cells in the population collectively have six, seven, eight, nine, ten, eleven, twelve, or more different HLA haplotypes.~~
4. ~~The population of CD4⁺ T cells of any one of the above claims, wherein all the CD4⁺ T cells in the population have at least 5/10, 6/10, 7/10, 8/10, or 9/10 match at the HLA-A, HLA-B, HLA-C, HLA-DRB1, and HLA-DQB1 loci to each other.~~
5. ~~The population of CD4⁺ T cells of any one of the above claims, wherein all the CD4⁺ T cells in the population have at least 4/8, 5/8, 6/8, 7/8, or 8/8 match at the HLA-A, HLA-B, HLA-C, and HLA-DRB1 loci to each other.~~
6. ~~The population of CD4⁺ T cells of any one of the above claims, wherein all the CD4⁺ T cells in the population have 2/2 match at the HLA-A locus to each other.~~
7. ~~The population of CD4⁺ T cells of any one of the above claims, wherein all the CD4⁺ T cell in the population have 2/2 match at the HLA-B locus to each other.~~
8. ~~The population of CD4⁺ T cells of any one of the above claims, wherein all the CD4⁺ T cell in the population have 2/2 match at the HLA-C locus to each other.~~
9. ~~The population of CD4⁺ T cells of any one of the above claims, wherein all the CD4⁺ T cells in the population have at least 3/4 or 4/4 match at the HLA-DRB1 and HLA-DQB1 loci with each other.~~
10. ~~The population of CD4⁺ T cells of any one of the above claims, wherein all the CD4⁺ T cells in the population have an A*02 allele.~~

- ~~11. The population of CD4⁺ T cells of any one of the above claims, wherein none of the CD4⁺ T cells is immortalized.~~
- ~~12. The population of CD4⁺ T cells of any one of the above claims, wherein the exogenous polynucleotide comprises an IL-10 encoding polynucleotide segment operably linked to expression control elements.~~
- ~~13. The population of CD4⁺ T cells of any one of the above claims, wherein the IL-10 is a human IL-10.~~
- ~~14. The population of CD4⁺ T cells of any one of claims 1-13, wherein the IL-10 is a viral IL-10.~~
- ~~15. The population of CD4⁺ T cells of any one of the above claims, wherein the IL-10 encoding polynucleotide segment encodes a protein having the sequence of SEQ ID NO:1.~~
- ~~16. The population of CD4⁺ T cells of claim 15, wherein the IL-10 encoding polynucleotide segment has the sequence of SEQ ID NO:2.~~
- ~~17. The population of CD4⁺ T cells of any one of claims 12-16, wherein the expression control elements drive constitutive expression of the encoded IL-10.~~
- ~~18. The population of CD4⁺ T cells of any one of the above claims, wherein the exogenous polynucleotide further comprises a sequence encoding a selection marker.~~
- ~~19. The population of CD4⁺ T cells of claim 18, wherein the selection marker is ΔNGFR.~~
- ~~20. The population of CD4⁺ T cells of claim 19, wherein the ΔNGFR has the sequence of SEQ ID NO: 3.~~
- ~~21. The population of CD4⁺ T cells of claim 19, wherein the exogenous polynucleotide comprises a sequence of SEQ ID NO:4.~~
- ~~22. The population of CD4⁺ T cells of claim 18, wherein the selection marker is a truncated form of EGFR polypeptide.~~
- ~~23. The population of CD4⁺ T cells of any one of the above claims, wherein the exogenous polynucleotide having a sequence of SEQ ID NO: 5.~~

24. The population of CD4⁺ T cells of any one of claims 1-23, wherein the exogenous polynucleotide is integrated into the T cell nuclear genome.
25. The population of CD4⁺ T cells of any one of claims 1-23, wherein the exogenous polynucleotide is not integrated into the T cell nuclear genome.
26. The population of CD4⁺ T cells of claim 24 or 25, wherein the exogenous polynucleotide further comprises lentiviral vector sequences.
27. The population of CD4⁺ T cells of any one of claims 1-26, wherein the exogenous polynucleotide is not integrated into the T cell nuclear genome.
28. The population of CD4⁺ T cells of any one of the above claims, wherein at least 90% of the CD4⁺ T cells within the population express IL-10.
29. The population of CD4⁺ T cells of claim 28, wherein at least 95% of the CD4⁺ T cells within the population express IL-10.
30. The population of CD4⁺ T cells of claim 29, wherein at least 98% of the CD4⁺ T cells within the population express IL-10.
31. The population of CD4⁺ T cells of any one of the above claims, wherein the genetically modified CD4⁺ T cells constitutively express at least 100pg IL-10 per 10⁶ of the CD4⁺ T cells/ml of culture medium.
32. The population of CD4⁺ T cells of claim 31, wherein the genetically modified CD4⁺ T cells constitutively express at least 100 pg, 200 pg, 500pg, 1ng, 5ng, 10ng, or 50ng IL-10 per 10⁶ of the CD4⁺ T cells/ml.
33. The population of CD4⁺ T cells of any one of the above claims, wherein the genetically modified CD4⁺ T cells express at least 1ng IL-10 per 10⁶ of the CD4⁺ T cells/ml after activation with anti-CD3 and anti-CD28 antibodies.
34. The population of CD4⁺ T cells of claim 33, wherein the genetically modified CD4⁺ T cells express at least 2ng, 5ng, 10ng, 100ng, 200ng, or 500ng IL-10 per 10⁶ of the CD4⁺ T cells/ml after activation with anti-CD3 and anti-CD28 antibodies.

35. The population of CD4⁺ T cells of any one of the above claims, wherein the genetically modified CD4⁺ T cells express IL-10 at a level at least 5-fold higher than unmodified CD4⁺ T cells.
36. The population of CD4⁺ T cells of claim 35, wherein the genetically modified CD4⁺ T cells express IL-10 at a level at least 10-fold higher than unmodified CD4⁺ T cells.
37. The population of CD4⁺ T cells of any one of the above claims, wherein at least 90% of the CD4⁺ T cells within the population express the selection marker from the exogenous polynucleotide.
38. The population of CD4⁺ T cells of claim 37, wherein at least 95% of the CD4⁺ T cells within the population express the selection marker from the exogenous polynucleotide.
39. The population of CD4⁺ T cells of claim 38, wherein at least 98% of the CD4⁺ T cells within the population express the selection marker from the exogenous polynucleotide.
40. The population of CD4⁺ T cells of any one of the above claims, wherein the genetically modified CD4⁺ T cells express CD49b.
41. The population of CD4⁺ T cells of any one of the above claims, wherein the genetically modified CD4⁺ T cells express LAG-3.
42. The population of CD4⁺ T cells of any one of the above claims, wherein the genetically modified CD4⁺ T cells express TGF- β .
43. The population of CD4⁺ T cells of any one of the above claims, wherein the genetically modified CD4⁺ T cells express IFN γ .
44. The population of CD4⁺ T cells of any one of the above claims, wherein the genetically modified CD4⁺ T cells express GzB.
45. The population of CD4⁺ T cells of any one of the above claims, wherein the genetically modified CD4⁺ T cells express perforin.
46. The population of CD4⁺ T cells of any one of the above claims, wherein the genetically modified CD4⁺ T cells express CD18.

47. ~~The population of CD4⁺ T cells of any one of the above claims, wherein the genetically modified CD4⁺ T cells express CD2.~~
48. ~~The population of CD4⁺ T cells of any one of the above claims, wherein the genetically modified CD4⁺ T cells express CD226.~~
49. ~~The population of CD4⁺ T cells of any one of the above claims, wherein the genetically modified CD4⁺ T cells express IL-22.~~
50. ~~The population of CD4⁺ T cells of any one of the above claims, wherein the CD4⁺ T cells have not been anergized in the presence of peripheral blood mononuclear cells (PBMCs) from a host.~~
51. ~~The population of CD4⁺ T cells of any one of the above claims, wherein the CD4⁺ T cells have not been anergized in the presence of recombinant IL-10 protein, wherein the recombinant IL-10 protein is not expressed from the CD4⁺ T cells.~~
52. ~~The population of CD4⁺ T cells of any one of the above claims, wherein the CD4⁺ T cells have not been anergized in the presence of DC10 cells from a host.~~
53. ~~The population of CD4⁺ T cells of any one of claims 1-52, wherein the CD4⁺ T cells are in a frozen suspension.~~
54. ~~The population of CD4⁺ T cells of any one of claims 1-52, wherein the CD4⁺ T cells are in a liquid suspension.~~
55. ~~The population of CD4⁺ T cells of claim 54, wherein the liquid suspension has previously been frozen.~~
56. ~~A pharmaceutical composition comprising:~~
- ~~(i) the population of CD4⁺ T cells of any one of the above claims; suspended in~~
 - ~~(ii) a pharmaceutically acceptable carrier.~~
57. ~~A method of making poly-donor CD4^{HL-10} cells, comprising the steps of:~~
- ~~(i) pooling primary CD4⁺ T cells obtained from at least three different T cell donors; and~~
 - ~~(ii) modifying the pooled CD4⁺ T cells by introducing an exogenous polynucleotide encoding IL-10,~~

thereby obtaining the poly donor CD4^{IL-10} cells.

58. A method of making poly donor CD4^{IL-10} cells, comprising the steps of:

- (i) obtaining primary CD4⁺ T cells from at least three different T cell donors; and
 - (ii) separately modifying each donor's CD4⁺ T cells by introducing an exogenous polynucleotide encoding IL-10, and then
 - (iii) pooling the genetically modified CD4⁺ T cells,
- thereby obtaining the poly donor CD4^{IL-10} cells.

59. The method of claim 57 or claim 58, further comprising the step, after step (i) and before step (ii), after step (ii), after step (ii) and before step (iii), or after step (iii) of:

incubating the primary CD4⁺ T cells in the presence of an anti-CD3 antibody, and anti-CD28 antibody or anti-CD3 antibody and CD28 antibody coated beads.

60. The method of claim 59, incubating the primary CD4⁺ T cells further in the presence of IL-2.

61. The method of any one of claims 57-60, wherein the exogenous polynucleotide is introduced into the primary CD4⁺ T cells using a viral vector.

62. The method of claim 61, wherein the viral vector is a lentiviral vector.

63. The method of any one of claims 57-62, wherein the exogenous polynucleotide comprises a segment encoding IL-10 having the sequence of SEQ ID NO:1.

64. The method of any one of claims 53-58, wherein the IL-10 encoding polynucleotide segment has the sequence of SEQ ID NO:2.

65. The method of any one of claims 57-64, wherein the exogenous polynucleotide further comprises a segment encoding a selection marker.

66. The method of claim 65, wherein the encoded selection marker is ANGFR.

67. The method of claim 66, wherein the encoded selection marker has the sequence of SEQ ID NO:3.

- ~~68. The method of any one of claims 65-67, further comprising the step, after step (ii), of:
isolating the genetically modified CD4⁺ T cells expressing the selection marker, thereby
generating an enriched population of genetically modified CD4⁺ T cells.~~
- ~~69. The method of claim 67, wherein at least 90% or at least 95% of the genetically modified
CD4⁺ T cells in the enriched population express IL-10.~~
- ~~70. The method of claim 68, wherein at least 98% of the genetically modified CD4⁺ T cells in
the enriched population express IL-10.~~
- ~~71. The method of any one of claims 68-69, wherein at least 90% or at least 95% of the
genetically modified CD4⁺ T cells in the enriched population express the selection marker.~~
- ~~72. The method of claim 70, wherein at least 98% of the genetically modified CD4⁺ T cells in
the enriched population express the selection marker.~~
- ~~73. The method of any one of claims 68-72, further comprising the step of incubating the
enriched population of genetically modified CD4⁺ T cells.~~
- ~~74. The method of claim 73, wherein the step of incubating the enriched population of
genetically modified CD4⁺ T cells is performed in the presence of anti-CD3 antibody and
anti-CD28 antibody or CD3 antibody and CD28 antibody coated beads in the presence of IL-
2.~~
- ~~75. The method of any one of claims 57-74, further comprising the later step of freezing the
genetically modified CD4⁺ T cells.~~
- ~~76. The method of any one of claims 57-75, wherein in step (i), the primary CD4⁺ T cells are
obtained from three, four, five, six, seven, eight, nine, or ten different T cell donors.~~
- ~~77. The method of any one of claim 76, wherein the at least three T cell donors have at least
5/10, 6/10, 7/10, 8/10, or 9/10 match at the HLA-A, HLA-B, HLA-C, HLA-DRB1, and
HLA-DQB1 loci to each other.~~
- ~~78. The method of any one of claims 57-77, wherein the at least three T cell donors have at least
4/8, 5/8, 6/8, 7/8, or 8/8 match at the HLA-A, HLA-B, HLA-C, and HLA-DRB1 loci to each
other.~~

- ~~79. The method of any one of claims 57-78, wherein the at least three T cell donors have 2/2 match at the HLA-A locus to each other.~~
- ~~80. The method of any one of claims 57-79, wherein the at least three T cell donors have 2/2 match at the HLA-B locus to each other.~~
- ~~81. The method of any one of claims 57-80, wherein the at least three T cell donors have 2/2 match at the HLA-C locus to each other.~~
- ~~82. The method of any one of claims 57-81, wherein the at least three T cell donors have at least 3/4 or 4/4 match at the HLA-DRB1 and HLA-DQB1 loci to each other.~~
- ~~83. The method of any one of claims 57-82, wherein each of the at least three T cell donors has an A*02 allele.~~
- ~~84. The method of any one of claims 57-83, wherein in step (i), the primary CD4⁺T cells are obtained from one or more frozen stocks.~~
- ~~85. The method of any one of claims 57-83, wherein in step (i), the primary CD4⁺T cells are obtained from unfrozen peripheral blood mononuclear cells of the at least three different T cell donors.~~
- ~~86. The method of claim 85, further comprising the step of isolating CD4⁺T cells from the peripheral blood mononuclear cells.~~
- ~~87. A method of treating a patient, comprising the step of:
administering the poly-donor CD4^{H⁻I⁰}-cells of any one of claims 1-55, or the pharmaceutical composition of claim 56, to a patient in need of immune tolerization.~~
- ~~88. The method of claim 87, further comprising the preceding step of thawing a frozen suspension of poly-donor CD4^{H⁻I⁰}-cells.~~
- ~~89. The method of claim 87 or 88, wherein the poly-donor CD4^{H⁻I⁰}-cells or the pharmaceutical composition prevents or reduces severity of pathogenic T cell response in the patient.~~
- ~~90. The method of any one of claims 87-89, further comprising the step of administering mononuclear cells to the patient.~~

91. ~~The method of claim 90, wherein the poly-donor CD4^{H-10}-cells or the pharmaceutical composition and the mononuclear cells are administered concurrently.~~
92. ~~The method of claim 90, wherein the mononuclear cells are administered either prior to or subsequent to administration of the poly-donor CD4^{H-10}-cells or the pharmaceutical composition.~~
93. ~~The method of any one of claims 87-92, further comprising the step of:~~
~~administering hematopoietic stem cells (HSC) of an HSC donor to the patient~~
~~either prior to or subsequent to administration of the pooled donor CD4^{H-10}-cells or~~
~~pharmaceutical composition.~~
94. ~~The method of claim 93, wherein the HSC donor is partially HLA-mismatched to the patient.~~
95. ~~The method of claim 94, wherein the HSC donor has less than 5/10, 6/10, 7/10, 8/10, 9/10 or 10/10 match at the HLA-A, HLA-B, HLA-C, HLA-DRB1, and HLA-DQB1 loci to the patient.~~
96. ~~The method of claim 94, wherein the HSC donor has less than 4/8, 5/8, 6/8, 7/8, or 8/8 match at the HLA-A, HLA-B, HLA-C, and HLA-DRB1 loci to the patient.~~
97. ~~The method of claim 94, wherein the HSC donor has less than 2/2 match at the HLA-A, HLA-B, or HLA-C locus to the patient.~~
98. ~~The method of claim 94, wherein the HSC donor has less than 3/4 or 4/4 match at the HLA-DRB1 and HLA-DQB1 loci to the patient.~~
99. ~~The method of any one of claims 87-98, wherein one or more of the T cell donors are HLA-mismatched or partially HLA-mismatched to the patient.~~
100. ~~—The method of claim 99, wherein one or more of the T cell donors have less than 5/10, 6/10, 7/10, 8/10, 9/10 or 10/10 match at the HLA-A, HLA-B, HLA-C, HLA-DRB1, and HLA-DQB1 loci to the patient.~~
101. ~~—The method of claim 99, wherein one or more of the T cell donors have less than 4/8, 5/8, 6/8, 7/8, or 8/8 match at the HLA-A, HLA-B, HLA-C, and HLA-DRB1 loci to the patient.~~

102. — The method of claim 99, wherein one or more of the T cell donors have less than 2/2 match at the HLA-A, HLA-B, or HLA-C locus to the patient.
103. — The method of claim 99, wherein one or more of the T cell donors have less than 2/4, 3/4 or 4/4 match at the HLA-DRB1 and HLA-DQB1 loci to the patient.
104. — The method of any one of claims 87-103, wherein one or more of the T cell donors are HLA-mismatched or partially HLA-mismatched with the HSC donor.
105. — The method of claim 104, wherein one or more of the T cell donors have less than 5/10, 6/10, 7/10, 8/10, 9/10 or 10/10 match at the HLA-A, HLA-B, HLA-C, HLA-DRB1, and HLA-DQB1 loci to the HSC donor.
106. — The method of claim 104, wherein one or more of the T cell donors have less than 4/8, 5/8, 6/8, 7/8, or 8/8 match at the HLA-A, HLA-B, HLA-C, and HLA-DRB1 loci to the HSC donor.
107. — The method of claim 104, wherein one or more of the T cell donors have less than 2/2 match at the HLA-A, HLA-B, or HLA-C locus to the HSC donor.
108. — The method of claim 104, wherein one or more of the T cell donors have less than 3/4 or 4/4 match at the HLA-DRB1 and HLA-DQB1 loci to the HSC donor.
109. — The method of any one of claims 79-108, wherein the poly-donor CD4^{HL-10}-cells or the pharmaceutical composition prevents or reduces severity of GvHD by the transplanted-hematopoietic stem cells.
110. — The method of any one of claims 93-109, wherein the poly-donor CD4^{HL-10}-cells or the pharmaceutical composition prevents or reduces severity of pathogenic response of lymphoid cells from the transplanted hematopoietic cells.
111. — The method of any one of claims 87-110, wherein the patient has neoplastic cells.
112. — The method of claim 111, wherein the neoplastic cells expresses CD13, HLA-class I and CD54.
113. — The method of any one of claims 111-112, wherein the neoplastic cells expresses CD112, CD58, or CD155.

114. — The method of any one of claims 111–113, wherein the patient has a cancer, optionally wherein the cancer is a solid or hematological neoplasm.
115. — The method of any one of claims 87–114, wherein the patient has a cancer selected from the group consisting of: Adrenal Cancer, Anal Cancer, Bile Duct Cancer, Bladder Cancer, Bone Cancer, Brain/CNS Tumors In Adults, Brain/CNS Tumors In Children, Breast Cancer, Breast Cancer In Men, Cancer of Unknown Primary, Castleman Disease, Cervical Cancer, Colon/Rectum Cancer, Endometrial Cancer, Esophagus Cancer, Ewing Family Of Tumors, Eye Cancer, Gallbladder Cancer, Gastrointestinal Carcinoid Tumors, Gastrointestinal Stromal Tumor (GIST), Gestational Trophoblastic Disease, Hodgkin Disease, Kaposi Sarcoma, Kidney Cancer, Laryngeal and Hypopharyngeal Cancer, Leukemia, Acute Lymphocytic (ALL), Acute Myeloid (AML, including myeloid sarcoma and leukemia cutis), Chronic Lymphocytic (CLL), Chronic Myeloid (CML) Leukemia, Chronic Myelomonocytic (CMML), Leukemia in Children, Liver Cancer, Lung Cancer, Lung Cancer with Non-Small-Cell, Lung Cancer with Small-Cell, Lung Carcinoid Tumor, Lymphoma, Lymphoma of the Skin, Malignant Mesothelioma, Multiple Myeloma, Myelodysplastic Syndrome, Nasal Cavity and Paranasal Sinus Cancer, Nasopharyngeal Cancer, Neuroblastoma, Non-Hodgkin Lymphoma, Non-Hodgkin Lymphoma In Children, Oral Cavity and Oropharyngeal Cancer, Osteosarcoma, Ovarian Cancer, Pancreatic Cancer, Penile Cancer, Pituitary Tumors, Prostate Cancer, Retinoblastoma, Rhabdomyosarcoma, Salivary Gland Cancer, Sarcoma—Adult Soft-Tissue Cancer, Skin Cancer, Skin Cancer—Basal and Squamous Cell, Skin Cancer—Melanoma, Skin Cancer—Merkel Cell, Small Intestine Cancer, Stomach Cancer, Testicular Cancer, Thymus Cancer, Thyroid Cancer, Uterine Sarcoma, Vaginal Cancer, Vulvar Cancer, Waldenstrom Macroglobulinemia, and Wilms Tumor.
116. — The method of claim 115, wherein the patient has a myeloid cancer.
117. — The method of claim 115, wherein the patient has AML or CML.
118. — The method of any one of claims 87, wherein the patient has an inflammatory or autoimmune disease.
119. — The method of claim 118, wherein the inflammatory or autoimmune disease is selected from the group consisting of: type 1 diabetes, autoimmune uveitis, rheumatoid arthritis, psoriasis, psoriatic arthritis, multiple sclerosis, systemic lupus, inflammatory bowel disease,

Addison's disease, Graves' disease, Sjögren's syndrome, Hashimoto's thyroiditis, myasthenia gravis, autoimmune vasculitis, pernicious anemia, ulcerative colitis, bullous diseases, scleroderma, and celiac disease.

120. — The method of claim 119, wherein the inflammatory or autoimmune disease is Crohn's disease, ulcerative colitis, celiac disease, type 1 diabetes, lupus, psoriasis, psoriatic arthritis, or rheumatoid arthritis.

121. — The method of any one of claims 87-113 or 118-120, wherein the patient has a disease or disorder involving hyperactivity of NLRP3 inflammasome.

122. — The method of any one of claims 87-113 or 118-121, wherein the patient has type 2 diabetes, neurodegenerative diseases, cardiovascular diseases or inflammatory bowel disease.

123. — The method of any one of claims 87-113 or 118-121, wherein the patient has a disease or disorder involving increased IL-1 β production by activated monocytes, macrophages or dendritic cells.

124. — The method of any one of claims 87-113 or 118-121, wherein the patient has a disease or disorder involving increased IL-18 production by activated monocytes, macrophages or dendritic cells.

125. — The method of any one of claims 87-113 or 118-121, wherein the patient has a disease or disorder involving increased mature caspase-1 production by activated monocytes, macrophages or dendritic cells.

126. — The method of any one of claims 87-113, wherein the patient has an allergic or atopic disease.

127. — The method of claim 126, wherein the allergic or atopic disease is selected from the group consisting of: asthma, atopic dermatitis, and rhinitis.

128. — The method of any one of claims 87-113, wherein the patient has a food allergy.

129. — The method of any one of claims 87-113, further comprising the step of organ transplantation to the patient, either prior to or subsequent to administration of the population of CD4⁺ T cells or the pharmaceutical composition.

130. — The method of claim 129, wherein the poly-donor CD4^{HL-10}-cells or the pharmaceutical composition prevents or reduces severity of host rejection of the organ transplantation.
131. — The method of any one of claims 87-113, further comprising the step of transplanting iPS cell-derived cells or tissues to the patient, either prior to or subsequent to administration of the population of CD4⁺-T cells or the pharmaceutical composition.
132. — The method of claim 131, wherein poly-donor CD4^{HL-10}-cells or the pharmaceutical composition prevents or reduces severity of host rejection of the cell transplantation.
133. — The method of any one of claims 87-113, further comprising the step of administering a recombinant AAV to the patient, either prior to or subsequent to administration of the poly-donor CD4^{HL-10}-cells or the pharmaceutical composition.
134. — The method of claim 133, wherein the poly-donor CD4^{HL-10}-cells or the pharmaceutical composition reduces immune responses against the recombinant AAV.
135. — The method of any one of claims 87-113, wherein the patient has an excessive immune response against viral or bacterial infection.
136. — The method of claim 135, wherein the patient has a coronavirus infection.
137. — The method of any one of claims 87-136, further comprising the step of detecting the selection marker in a biological sample obtained from the patient, thereby detecting presence or absence of poly-donor CD4^{HL-10}-T cells.
138. — The method of claim 137, wherein the biological sample is a biopsy or blood from the patient.
139. — A method of treating a patient with a malignancy, comprising:
administering an allo-HSCT graft to the patient, and
administering a therapeutically effective amount of poly-donor CD4^{HL-10}-cells.
140. — The method of claim 139, wherein none of the donors of the CD4^{HL-10}-cells in the poly-donor CD4^{HL-10}-cells is the donor of the HSCT graft.
141. — A method of treating a hematological cancer, comprising:

administering to a hematological cancer patient an amount of poly donor CD4^{IL-10} cells sufficient induce anti cancer effect,

wherein the poly donor CD4^{IL-10} cells comprise CD4⁺ T cells obtained from at least three different T cell donors and genetically modified by vector mediated gene transfer of the coding sequence of human IL-10 under control of a constitutive promoter.

142. — The method of claim 141, further comprising the step of administering allo HSCT graft to the patient prior to or subsequent to administration of the poly donor CD4^{IL-10} cells.

143. — The method of claim 142, wherein the amount of poly donor CD4^{IL-10} cells is further sufficient to suppress graft versus host disease (GvHD) without suppressing graft versus leukemia (GvL) or graft versus tumor (GvT) efficacy of the allo HSCT.

144. — The method of any one of claims 141-143, wherein the hematological cancer is a myeloid leukemia.

145. — The method of any one of claims 141-142, wherein the poly donor CD4^{IL-10} cells target and kill cancer cells that express CD13.

146. — The method of any one of claims 141-145, wherein the poly donor CD4^{IL-10} cells target and kill cancer cells that express HLA class I.

147. — The method of any one of claims 141-146, wherein the myeloid leukemia is acute myeloid leukemia (AML).

148. — The method of any one of claims 141-147, wherein the allo HSCT graft is obtained from a related or unrelated donor with respect to the recipient.

149. — The method of any one of claims 141-148, wherein the poly donor CD4^{IL-10} cells are non-autologous to the recipient.

150. — The method of any one of claims 141-148, wherein the poly donor CD4^{IL-10} cells are allogeneic to the recipient.

151. — The method of any one of claims 141-148, wherein the poly donor CD4^{IL-10} cells are not anergized to host allo antigens prior to administration to the host.

152. — The method of any one of claims 141–148, wherein the poly-donor CD4^{HL-10}-cells are Tr1-like cells.
153. — The method of any one of claims 141–148, wherein the poly-donor CD4^{HL-10}-cells are polyclonal.
154. — The method of any one of claims 141–148, wherein the poly-donor CD4^{HL-10}-cells are polyclonal and non-autologous to the recipient.
155. — The method of any one of claims 141–148, wherein the poly-donor CD4^{HL-10}-cells are isolated from at least three donors prior to being genetically modified.
156. — The method of claim 155, wherein none of the at least three donors is the same donor as the allo-HSCT donor.
157. — The method of any one of claims 141–156, wherein the allo-HSCT graft is obtained from a matched or mismatched donor with respect to the recipient.
158. — The method of any one of claims 141–157, wherein the poly-donor CD4^{HL-10}-cells target and kill cells that express CD54.
159. — The method of any one of claims 141–158, wherein the poly-donor CD4^{HL-10}-cells target and kill cancer cells that express HLA class I and CD54.
160. — The method of any one of claims 141–159, wherein the poly-donor CD4^{HL-10}-cells target and kill cancer cells that express CD112.
161. — The method of any one of claims 141–160, wherein the poly-donor CD4^{HL-10}-cells target and kill cancer cells that express CD58.
162. — The method of any one of claims 141–161, wherein the poly-donor CD4^{HL-10}-cells target and kill cancer cells in the host.
163. — A method of treating a hematological cancer by allogeneic hematopoietic stem cell transplant (allo-HSCT), comprising:
- administering allo-HSCT graft to a subject (host);

~~administering to the allo-HSCT recipient (host) an amount of poly-donor CD4^{IL-10}-cells sufficient to suppress graft versus host disease (GvHD) without suppressing graft versus-leukemia (GvL) or graft versus-tumor (GvT) efficacy of the allo-HSCT graft,~~

~~wherein the poly-donor CD4^{IL-10}-cells comprise CD4⁺-T cells obtained from at least three different T cell donors and genetically modified by vector-mediated gene transfer of the coding sequence of human IL-10 under control of a constitutive promoter;~~

~~wherein the poly-donor CD4^{IL-10}-cells are non-autologous to the recipient and non-autologous to the allo-HSCT donor;~~

~~wherein the poly-donor CD4^{IL-10}-cells are not anergized to host allo-antigens prior to administration to the host; and~~

~~wherein the poly-donor CD4^{IL-10}-cells are polyclonal and Tr1-like.~~

164. — A method of treating a hematological cancer by allogeneic hematopoietic stem cell transplant (allo-HSCT), comprising:

~~administering allo-HSCT graft to a subject (host);~~

~~administering to the allo-HSCT recipient (host) an amount of poly-donor CD4^{IL-10}-cells sufficient to suppress graft versus host disease (GvHD) without suppressing graft versus-leukemia (GvL) or graft versus-tumor (GvT) efficacy of the allo-HSCT graft,~~

~~wherein the poly-donor CD4^{IL-10}-cells comprise CD4⁺-T cells obtained from at least three different T cell donors and genetically modified by vector-mediated gene transfer of the coding sequence of human IL-10 under control of a constitutive promoter;~~

~~wherein the poly-donor CD4^{IL-10}-cells target and kill cancer cells in the host;~~

~~wherein the wherein the poly-donor CD4^{IL-10}-cells are not anergized to host allo-antigens prior to administration to the host; and~~

~~wherein the poly-donor CD4^{IL-10}-cells are non-autologous to the recipient, and polyclonal, and are Tr1-like.~~