CLAIMS

1. A method of mobilizing a population of hematopoietic stem cells from the bone marrow of a mammalian donor into peripheral blood, the method comprising (i) a CXCR2 agonist selected from the group consisting of Gro-β, Gro-β T, and variants thereof at a dose of from about 50 μg/kg to about 300 mg/kg and (ii) a CXCR4 antagonist to be administered to the donor.

2. The method of claim 1, wherein the CXCR2 agonist is Gro-β T.

3. The method of claim 1 or 2, wherein the CXCR2 agonist is to be administered to the donor at a dose of from about 100 μg/kg to about 250 μg/kg.

4. The method of claim 3, wherein the CXCR2 agonist is to be administered to the donor at a dose of from about 125 μg/kg to about 225 μg/kg.

5. The method of claim 4, wherein the CXCR2 agonist is to be administered to the donor at a dose of about 150 μg/kg.

6. The method of any one of claims 1-5, wherein the CXCR2 agonist is to be administered intravenously to the donor.

7. The method of any one of claims 1-6, wherein the CXCR4 antagonist is to be administered subcutaneously to the donor.

8. The method of any one of claims 1-7, wherein the CXCR4 antagonist is plerixafor or a pharmaceutically acceptable salt thereof.

9. The method of claim 8, wherein the plerixafor or pharmaceutically acceptable salt thereof is to be administered to the donor at a dose of from about 50 μg/kg to about 500 μg/kg.

10. The method of claim 9, wherein the plerixafor or pharmaceutically acceptable salt thereof is to be administered to the donor at a dose of from about 200 μg/kg to about 300 μg/kg.

11. The method of claim 10, wherein the plerixafor or pharmaceutically acceptable salt thereof is to be administered to the donor at a dose of about 240 μg/kg.

12. A method of mobilizing a population of hematopoietic stem cells from the bone marrow of a mammalian donor into peripheral blood, the method comprising:

a. mobilizing amounts of a CXCR2 agonist and a CXCR4 antagonist to be administered to the donor;

b. acquiring an input value for each of one or more parameters listed in **TABLE 2** characterizing a sample of peripheral blood of the donor; and

c. releasing the sample for *ex vivo* expansion of the hematopoietic stem cells for use in the treatment of one or more stem cell disorders in a mammalian patient if the input value for each of the one or more parameters meets the corresponding reference criterion for each of the one or more parameters.

13. The method of claim 12, wherein the one or more reference parameters are a set of parameters listed in any one of **TABLES 3-6**.

14. The method of claim 12 or 13, further comprising expanding the hematopoietic stem cells *ex vivo* if the sample is released for *ex vivo* expansion.

15. The method of any one of claims 12-14, further comprising infusing the hematopoietic stem cells, or progeny thereof, into a mammalian patient suffering from one or more stem cell disorders if the sample is released for use in the treatment thereof.

16. The method of any one of claims 12-15, wherein the CXCR2 agonist is Gro-β T or a variant thereof and wherein the CXCR2 agonist is to be administered to the donor at a dose of from about 50 μg/kg to about 1mg/kg, from about 50 μg/kg to about 300 μg/kg, or from about 100 μg/kg to about 250 μg/kg.

17. A pharmaceutical composition comprising a population of hematopoietic stem cells or progeny thereof isolated from a mammalian donor, wherein the ratio of CD34+ cells to leukocytes in the population is from about 0.0008 to about 0.0021 or is from about 0.0010 to about 0.0018.

18. A pharmaceutical composition comprising a population of hematopoietic stem cells or progeny thereof isolated from a mammalian donor, wherein the ratio of CD34+ cells to neutrophils in the population is from about 0.0018 to about 0.0058 or is from about 0.0026 to about 0.0046.

19. A pharmaceutical composition comprising a population of hematopoietic stem cells or progeny thereof isolated from a mammalian donor, wherein the ratio of CD34+ cells to lymphocytes in the population is from about 0.0021 to about 0.0094 or is from about 0.0025 to about 0.0035.

20. A pharmaceutical composition comprising a population of hematopoietic stem cells or progeny thereof isolated from a mammalian donor, wherein the ratio of CD34+ cells to monocytes in the population is from about 0.0071 to about 0.0174 or is from about 0.0100 to about 0.0140.

21. A pharmaceutical composition comprising a population of hematopoietic stem cells or progeny thereof isolated from a mammalian donor, wherein the frequency of CD34+ cells in the population is from about 0.051% to about 0.140% or is from about 0.080% to about 0.120%.

22. A pharmaceutical composition comprising a population of hematopoietic stem cells or progeny thereof isolated from a mammalian donor, wherein the ratio of CD34+ CD90+ CD45RA- cells to leukocytes in the population is from about 0.0003 to about 0.0016 or is from about 0.0006 to about 0.0012.

23. A pharmaceutical composition comprising a population of hematopoietic stem cells or progeny thereof isolated from a mammalian donor, wherein the ratio of CD34+ CD90+ CD45RA- cells to neutrophils in the population is from about 0.0007 to about 0.0043 or is from about 0.0014 to about 0.0034.

24. A pharmaceutical composition comprising a population of hematopoietic stem cells or progeny thereof isolated from a mammalian donor, wherein the ratio of CD34+ CD90+ CD45RA- cells to lymphocytes in the population is from about 0.0008 to about 0.0069 or is from about 0.0011 to about 0.0031.

25. A pharmaceutical composition comprising a population of hematopoietic stem cells or progeny thereof isolated from a mammalian donor, wherein the ratio of CD34+ CD90+ CD45RA- cells to monocytes in the population is from about 0.0028 to about 0.0130 or is from about 0.0063 to about 0.0083.

26. A pharmaceutical composition comprising a population of hematopoietic stem cells or progeny thereof isolated from a mammalian donor, wherein the ratio of CD34+ CD90+ CD45RA- cells to CD34+ cells in the population is from about 0.393 to about 0.745 or is from about 0.625 to about 0.725.

27. A pharmaceutical composition comprising a population of hematopoietic stem cells or progeny thereof isolated from a mammalian donor, wherein the frequency of CD34+ CD90+ CD45RA- cells in the population is from about 0.020% to about 0.110% or is from about 0.046% to about 0.086%.

28. The pharmaceutical composition of any one of claims 17-27 for use in the treatment of a stem cell disorder in a mammalian patient.

29. Use of the pharmaceutical composition of any one of claims 17-27 in the manufacture of a medicament for the treatment of a stem cell disorder in a mammalian patient.

30. The use of claim 28 or 29, wherein the stem cell disorder is any one of:

a hemoglobinopathy disorder selected from the group consisting of sickle cell anemia, thalassemia, Fanconi anemia, aplastic anemia, and Wiskott-Aldrich syndrome,

a myelodysplastic disorder,

a congenital immunodeficiency disorder,

an acquired immunodeficiency disorder selected from the group consisting of human immunodeficiency virus or acquired immune deficiency syndrome,

a metabolic disorder selected from the group consisting of glycogen storage diseases, mucopolysaccharidoses, Gaucher's Disease, Hurlers Disease, sphingolipidoses, and metachromatic leukodystrophy,

a cancer selected from the group consisting of leukemia, lymphoma, multiple myeloma, neuroblastoma, acute myeloid leukemia, acute lymphoid leukemia, chronic myeloid leukemia, chronic lymphoid leukemia, multiple myeloma, diffuse large B-cell lymphoma, or non-Hodgkin’s lymphoma,

a disorder selected from the group consisting of adenosine deaminase deficiency and severe combined immunodeficiency, hyper immunoglobulin M syndrome, Chediak-Higashi disease, hereditary lymphohistiocytosis, osteopetrosis, osteogenesis imperfecta, storage diseases, thalassemia major, systemic sclerosis, systemic lupus erythematosus, multiple sclerosis, and juvenile rheumatoid arthritis, or

an autoimmune disorder selected from the group consisting of multiple sclerosis, human systemic lupus, rheumatoid arthritis, inflammatory bowel disease, treating psoriasis, Type 1 diabetes mellitus, acute disseminated encephalomyelitis, Addison's disease, alopecia universalis, ankylosing spondylitis, antiphospholipid antibody syndrome, aplastic anemia, autoimmune hemolytic anemia, autoimmune hepatitis, autoimmune inner ear disease, autoimmune lymphoproliferative syndrome, autoimmune oophoritis, Balo disease, Behcet's disease, bullous

pemphigoid, cardiomyopathy, Chagas' disease, chronic fatigue immune dysfunction syndrome, chronic inflammatory demyelinating polyneuropathy, Crohn's disease, cicatricial pemphigoid, coeliac sprue-dermatitis herpetiformis, cold agglutinin disease, CREST syndrome, Degos disease, discoid lupus, dysautonomia, endometriosis, essential mixed cryoglobulinemia, fibromyalgia-fibromyositis, Goodpasture' s syndrome, Grave's disease, Guillain-Barre syndrome, Hashimoto' s thyroiditis, Hidradenitis suppurativa, idiopathic and/or acute thrombocytopenic purpura, idiopathic pulmonary fibrosis, IgA neuropathy, interstitial cystitis, juvenile arthritis, Kawasaki's disease, lichen planus, Lyme disease, Meniere disease, mixed connective tissue disease, myasthenia gravis, neuromyotonia, opsoclonus myoclonus syndrome, optic neuritis, Ord's thyroiditis, pemphigus vulgaris, pernicious anemia, polychondritis, polymyositis and dermatomyositis, primary biliary cirrhosis, polyarteritis nodosa, polyglandular syndromes, polymyalgia rheumatica, primary agammaglobulinemia, Raynaud phenomenon, Reiter' s syndrome, rheumatic fever, sarcoidosis, scleroderma, Sjögren's syndrome, stiff person syndrome, Takayasu's arteritis, temporal arteritis, ulcerative colitis, uveitis, vasculitis, vitiligo, vulvodynia, and Wegener's granulomatosis.

31. The use of claim 29 or 30, wherein the hematopoietic stem cells are autologous with respect to the patient.

32. The use of any one of claims 29-31, wherein the hematopoietic stem cells are allogeneic with respect to the patient.

33. The use of claim 32, wherein the hematopoietic stem cells are HLA-matched with respect to the patient.

34. The use of any one of claims 29-33, wherein the hematopoietic stem cells have been genetically modified to disrupt an endogenous gene.

35. The use of claim 34, wherein the endogenous gene encodes a major histocompatibility complex protein.

36. A method of mobilizing $CD34^{dim}$ cells from the bone marrow of a human donor into peripheral blood, the method comprising (i) a CXCR2 agonist selected from the group consisting

of Gro-β, Gro-β T, and variants thereof and (ii) a CXCR4 antagonist to be administered to the donor.

37. A method of performing an allogeneic hematopoietic stem cell transplant in a patient in need thereof, the method comprising a therapeutically effective amount of allogeneic hematopoietic stem cells to be infused into the patient, wherein the hematopoietic stem cells were mobilized from bone marrow of a human donor into peripheral blood of the human donor by a method comprising administering to the donor (i) a CXCR2 agonist selected from the group consisting of Gro-β, Gro-β T, and variants thereof and (ii) a CXCR4 antagonist to be administered to the donor.

38. Use of a therapeutically effective amount of hematopoietic stem cells in the manufacture of a medicament for preventing, reducing the risk of developing, or reducing the severity of a post-transplant infection in a patient in need thereof, wherein the hematopoietic stem cells were mobilized from bone marrow of a human donor into peripheral blood of the human donor by a method comprising (i) a CXCR2 agonist selected from the group consisting of Gro-β, Gro-β T, and variants thereof and (ii) a CXCR4 antagonist to be administered to the human donor, and wherein the medicament is to be infused into the patient.

39. Use of a therapeutically effective amount of hematopoietic stem cells in the manufacture of a medicament for preventing, reducing the risk of developing, or reducing the severity of graft versus host disease (GVHD) in a patient in need thereof, wherein the hematopoietic stem cells were mobilized from bone marrow of a human donor into peripheral blood of the human donor by a method comprising (i) a CXCR2 agonist selected from the group consisting of Gro-β, Gro-β T, and variants thereof and (ii) a CXCR4 antagonist to be administered to the human donor, and wherein the medicament is to be infused into the patient.

40. The method of any one of claims 36-37, or the use of any one of claims 38-39, wherein the $CD34^{dim}$ cells are present in the peripheral blood in an amount that is at least two- to ten-fold higher than if the hematopoietic stem cells were mobilized using the CXCR4 antagonist alone.

41. The method of any one of claims 36-37, or the use of any one of claims 38-39, wherein the $CD34^{dim}$ cells are capable of suppressing alloreactive T lymphocyte proliferation when it is to be administered to a recipient.

42. The method of any one of claims 36, 37, 40 and 41, or the use of any one of claims 38-41, wherein the CXCR2 agonist is Gro-β T.

43. The method of any one of claims 36, 37 and 40-42, or the use of any one of claims 38-42, wherein the CXCR2 agonist is to be administered to the donor at a dose of from about 50 µg/kg to about 1000 µg/kg.

44. The method of any one of claims 36, 37 and 40-42, or the use of any one of claims 38-42, wherein the CXCR2 agonist is to be administered to the donor at a dose of from about 100 µg/kg to about 250 µg/kg.

45. The method or use of claim 44, wherein the CXCR2 agonist is to be administered to the donor at a dose of from about 125 µg/kg to about 225 µg/kg.

46. The method or use of claim 45, wherein the CXCR2 agonist is to be administered to the donor at a dose of about 150 µg/kg.

47. The method of any one of claims 36, 37 and 40-46, or the use of any one of claims 38-46, wherein the CXCR2 agonist is to be administered intravenously or subcutaneously to the donor.

48. The method of any one of claims 36, 37 and 40-47, or the use of any one of claims 38-47, wherein the CXCR4 antagonist is plerixafor or a pharmaceutically acceptable salt thereof.

49. The method or use of claim 48, wherein the plerixafor or pharmaceutically acceptable salt thereof is to be administered to the donor at a dose of from about 50 µg/kg to about 500 µg/kg.

50. The method or use of claim 48, wherein the plerixafor or pharmaceutically acceptable salt thereof is to be administered to the donor at a dose of from about 200 µg/kg to about 300 µg/kg.

51. The method or use of claim 48, wherein the plerixafor or pharmaceutically acceptable salt thereof is to be administered to the donor at a dose of about 240 µg/kg.

52. A population of $CD34^{dim}$ cells derived from the method of any one of claims 36, 37 and 40-51, or the use of any one of claims 38-51.