## CLAIMS

What is claimed is:

1. A pharmaceutical composition suitable for diagnostic in vivo use comprising a pharmaceutically acceptable salt of a ShK polypeptide having the sequence Arg-Ser-Cys-Ile-Asp-Thr-Ile-Pro-Lys-Ser-Arg-Cys-Thr-Ala-Phe-Gln-Cys-Lys-His-Ser-Xaa-Lys-Tyr-Arg-Leu-Ser-Phe-Cys-Arg-Lys-Thr-Cys-Gly-Thr-Cys (SEQ ID NO:1) wherein the ShK polypeptide is attached to a detectable label and an organic or inorganic chemical entity that has an anionic charge, and wherein the C-terminus is an acid or an amide.

2. The composition of claim 1 wherein said detectable label is a chelate of Indium-111 ($In^{111}$).

3. The composition of claim 2 wherein said detectable label is a 1,4,7,10-tetraazacyclododecane-1,4,7,10-tetraacetic acid (DOTA)-chelate of Indium-111 ($In^{111}$).

4. The composition of claim 1 wherein said detectable label is a chelate of gadolinium (Gd).

5. The composition of claim 4 wherein said detectable label is a DOTA-chelate of gadolinium (Gd).

6. The composition of claim 1 wherein said ShK polypeptide has the sequenceTyr-AEEA-Arg-Ser-Cys-Ile-Asp-Thr-Ile-Pro-Lys-Ser-Arg-Cys-Thr-Ala-Phe-Gln-Cys-Lys-His-Ser-Met-Lys-Tyr-Arg-Leu-Ser-Phe-Cys-Arg-Lys-Thr-Cys-Gly-Thr-Cys-$NH_2$ (ShK-198) and the detectable label is at the amino terminus.

7. The composition of claim 6 wherein the detectable label is a 1,4,7,10-tetraazacyclododecane-1,4,7,10-tetraacetic acid (DOTA)-chelate of Indium-111 ($In^{111}$).

8. A pharmaceutical composition comprising a pharmaceutically acceptable salt of a ShK polypeptide having the sequence Arg-Ser-Cys-Ile-Asp-Thr-Ile-Pro-Lys-Ser-Arg-Cys-Thr-Ala-Phe-Gln-Cys-Lys-His-Ser-Xaa-Lys-Tyr-Arg-Leu-Ser-Phe-Cys-Arg-Lys-Thr-Cys-Gly-Thr-Cys (SEQ ID NO:1) wherein the ShK polypeptide is attached to an organic or inorganic chemical entity that has an anionic charge, and wherein the C-terminus is an acid or an amide.

9. The pharmaceutical composition of claim 8 in an aqueous carrier.

10. The pharmaceutical composition of claim 9 with a pH between 5 and 7.

11. The pharmaceutical composition of claim 9 further comprising a surfactant in an amount effective to dissolve the ShK polypeptide in the aqueous carrier.

12. The pharmaceutical composition of claim 9 wherein the ShK polypeptide is present at an amount from 0.01 mg/ml to 500 mg/ml.

13. The pharmaceutical composition of claim 11 wherein the surfactant is polysorbate 20.

14. The pharmaceutical composition of claim 13, wherein the surfactant is polysorbate 20 at 0.05 w/v%.

15. The pharmaceutical composition of claim 10, wherein the pH is 6.0.

16. The pharmaceutical composition of claim 12, comprising 0.01, 0.1, 0.5, 0.75, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50 or 500 mg/ml of the ShK polypeptide.

17. The pharmaceutical composition of claim 8 wherein the ShK polypeptide is obtained from a natural source.

18. The pharmaceutical composition of claim 8 wherein the ShK polypeptide is synthetic.

19. The pharmaceutical composition of claim 8 wherein the chemical entity is attached to the N terminus of the ShK polypeptide.

20. The pharmaceutical composition of claim 19 wherein the chemical entity is attached to the N-terminus of the ShK polypeptide through a linking molecule or linking group.

21. The pharmaceutical composition of claim 20, wherein the chemical entity is attached to the N-terminus of the ShK polypeptide by an aminoethyloxyethyloxy-acetyl linker.

22. The pharmaceutical composition of claim 11, wherein the chemical entity

is selected from the group consisting of AEEAc-L-Pmp($OH_2$); AEEAc-D-Pmp($OH_2$); AEEAc-D-Pmp(OH, Et); AEEAc-L-Pmp($Et_2$); AEEAc-D-Pmp($Et_2$); AEEAc-L-Tyr; AEEAc-L-Tyr($PO_3H_2$); AEEAc-L-Phe(p-$NH_2$); AEEAc-L-Phe(p-$CO_2H$); AEEAc-L-Aspartate; AEEAc-D-Aspartate; AEEAc-L-Glutamate; and AEEAc-D-Glutamate.

23. A pharmaceutical composition comprising a pharmaceutically acceptable salt of a ShK polypeptide having the formula p-phospho-Tyr-AEEA-Arg-Ser-Cys-Ile-Asp-Thr-Ile-Pro-Lys-Ser-Arg-Cys-Thr-Ala-Phe-Gln-Cys-Lys-His-Ser-Met-Lys-Tyr-Arg-Leu-Ser-Phe-Cys-Arg-Lys-Thr-Cys-Gly-Thr-Cys-$NH_2$.

24. The pharmaceutical composition of claim 23 in an aqueous carrier and further comprising polysorbate 20 at 0.05 w/v% wherein the composition has a pH between 5 and 7.

25. The pharmaceutical composition of claim 24 further comprising 10 mM sodium phosphate; 150 mM NaCl; and 0.5 mg/ml to 50 mg/ml of ShK-186 wherein the composition has a pH of 6.0.

26. A pharmaceutical composition comprising a pharmaceutically acceptable salt of a ShK polypeptide having the formula Tyr-AEEA-Arg-Ser-Cys-Ile-Asp-Thr-Ile-Pro-Lys-Ser-Arg-Cys-Thr-Ala-Phe-Gln-Cys-Lys-His-Ser-Met-Lys-Tyr-Arg-Leu-Ser-Phe-Cys-Arg-Lys-Thr-Cys-Gly-Thr-Cys-$NH_2$.

27. The pharmaceutical composition of claim 26 in an aqueous carrier further comprising polysorbate 20 at 0.05 w/v% and ShK-198 in a range from 0.5 mg/ml to 50 mg/ml wherein the composition has a pH between 5 and 7.

28. The pharmaceutical composition of claim 27 further comprising 10 mM sodium phosphate; 150 mM NaCl; and 0.5 mg/ml to 50 mg/ml of ShK-198 wherein the composition has a pH of 6.0.

29. A pharmaceutical composition comprising 10 mM sodium phosphate; 150 mM NaCl; 0.5 mg/ml to 50 mg/ml of a pharmaceutically acceptable acetate salt of a polypeptide having the formula Arg-Ser-Cys-Ile-Asp-Thr-Ile-Pro-Lys-Ser-Arg-Cys-Thr-Ala-Phe-Gln-Cys-Lys-His-Ser-Met-Lys-Tyr-Arg-Leu-Ser-Phe-Cys-Arg-Lys-Thr-Cys-Gly-

Thr-Cys-$NH_2$ (SEQ ID NO:1 wherein Xaa is Met) attached to p-phospho-Tyr-AEEA; and Polysorbate 20 at 0.05 w/v%, wherein the composition has a pH of 6.0.

30. The pharmaceutical composition of claim 8 wherein the pharmaceutically acceptable salt is potassium acetate or sodium acetate.

31. A process for manufacturing a pharmaceutical composition comprising: (a) preparing a solution of 0.05% polysorbate 20 in an aqueous carrier at a predetermined concentration; (b) adding to the solution of step (a) a predetermined amount of a pharmaceutically acceptable salt of a polypeptide having SEQ ID NO:1, wherein the C terminus is an acid or an amide, and wherein the polypeptide is attached to an organic or inorganic chemical entity that has an anionic charge; (c) adjusting the pH of the solution of step (b) until the polypeptide dissolves in the solution; and (d) if necessary, adjusting the pH of the solution of step (c) to a pH of 5-7, thereby manufacturing the pharmaceutical composition.

32. A pharmaceutical composition prepared by the process of claim 31.

33. A lyophilized pharmaceutical composition comprising a pharmaceutically acceptable salt of a polypeptide of SEQ ID NO:1, wherein the C terminus is an acid or an amide, and wherein the polypeptide is attached to an organic or inorganic chemical entity that has an anionic charge.

34. The lyophilized pharmaceutical composition of claim 33, wherein the pharmaceutically acceptable salt is potassium acetate or sodium acetate.

35. The lyophilized pharmaceutical composition of claim 33 wherein the pharmaceutically acceptable salt is sodium acetate.

36. The lyophilized pharmaceutical composition of claim 33 comprising 8-12% acetate content by weight.

37. The lyophilized pharmaceutical composition of claim 36 comprising 10-11% acetate content by weight.

38. The lyophilized pharmaceutical composition of claim 33 provided in a packaging material.

39. The lyophilized pharmaceutical composition of claim 33, wherein the water content of the pharmaceutical composition is less than 5%.

40. The lyophilized pharmaceutical composition of claim 33, wherein the water content of the pharmaceutical composition is less than 4.0%.

41. The lyophilized pharmaceutical composition of claim 33, wherein the water content of the pharmaceutical composition is less than 3.5%.

42. The pharmaceutical composition of claim 1 formulated for long-term storage.

43. The pharmaceutical composition of claim 42 wherein the composition is contained in a sterile glass vial and is instructed to be stored at -70°C.

44. The pharmaceutical composition of claim 8 formulated for subcutaneous administration.

45. The pharmaceutical composition of claim 44 wherein the composition is contained in a sterile syringe.

46. A unit of manufacture for pharmaceutical use comprising at least one glass vial prepared under sterile conditions that contains a pharmaceutical composition of any one of claims 1, 16, 19 or 22, wherein the pharmaceutical composition within the glass vial is stable for at least six months at -70°C, and further comprising instructions for diluting and preparing the pharmaceutical composition for administration to a human.

47. A unit of manufacture for pharmaceutical use comprising at least one sterile syringe containing a pharmaceutical composition of any one of claims 1, 16, 19 or 22 wherein the unit of manufacture further comprises instructions for administering the pharmaceutical composition to a human.

48. A method of preventing, treating or alleviating the symptoms of an autoimmune disorder in a human in need of such treatment or symptom alleviation, the method comprising administering to the human the pharmaceutical composition of any of claims 8, 23, 26 or 29 in an amount that is effective to prevent or treat the disease or alleviate the symptoms.

49. The method of claim 48, wherein the disorder is selected from the group consisting of multiple sclerosis, type-1 diabetes mellitus, rheumatoid arthritis, psoriasis, inflammatory bowel disease, contact-mediated dermatitis, psoriatic arthritis, asthma, allergy, restinosis, systemic sclerosis, fibrosis, scleroderma, glomerulonephritis, Sjogren syndrome, inflammatory bone resorption, transplant rejection, graft-versus-host disease, and lupus erythematosis.

50. The method of claim 48, wherein the disorder is multiple sclerosis, and the method comprises administering a composition of claim 16.

51. The method of claim 48, wherein the pharmaceutical composition is administered daily, weekly, monthly, every two months, every three months, or every six months.

52. The method of claim 48, wherein the pharmaceutical composition is administered subcutaneously.

53. A method of preventing, treating or alleviating a metabolic disorder in a human subject, wherein the method comprises administering to the human subject a pharmaceutical composition of any one of claims 8, 23, 36 or 29 in an amount effective to prevent, treat, or alleviate one or more symptoms of the metabolic disorder in the human subject.

54. The method of claim 53, wherein the metabolic disorder is one or more of obesity, Type 2 diabetes, hypercholesterolemia, coronary artery disease, metabolic syndrome, metabolic syndrome X, insulin resistance, hyperlipidemia, lipodystrophy, dyslipidemia, hypertriglyceridemia, glucose intolerance, hypertension, overweightness, and disorders of energy metabolism.

55. The method of claim 53, wherein the pharmaceutical composition is administered daily, weekly, monthly, every two months, every three months, or every six months.

56. The method of claim 53, wherein the pharmaceutical composition is administered subcutaneously or intravenously.

57. A pharmaceutical composition comprising a pharmaceutically acceptable salt of an ShK polypeptide having the sequence Arg-Ser-Cys-Ile-Asp-Thr-Ile-Pro-Lys-Ser-Arg-Cys-Thr-Ala-Phe-Gln-Cys-Lys-His-Ser-Xaa-Lys-Tyr-Arg-Leu-Ser-Phe-Cys-Arg-Lys-Thr-

Cys-Gly-Thr-Cys (SEQ ID NO:1 wherein Xaa is Met or Ile), 10 mM sodium phosphate; 150 mM NaCl; and Polysorbate 20 at 0.05 w/v%, wherein the ShK polypeptide is attached to an organic or inorganic chemical entity that has an anionic charge, the C-terminus is an acid or an amide and the composition has a pH of 6.0.

58. A pharmaceutical composition comprising a pharmaceutically acceptable salt of an ShK polypeptide having the formula Arg-Ser-Cys-Ile-Asp-Thr-Ile-Pro-Lys-Ser-Arg-Cys-Thr-Ala-Phe-Gln-Cys-Lys-His-Ser-Met-Lys-Tyr-Arg-Leu-Ser-Phe-Cys-Arg-Lys-Thr-Cys-Gly-Thr-Cys-$NH_2$ (SEQ ID NO:1 wherein Xaa is Met) 10 mM sodium phosphate; 150 mM NaCl; and Polysorbate 20 at 0.05 w/v%, wherein the ShK polypeptide is attached to an organic or inorganic chemical entity that has an anionic charge, the C-terminus is an acid or an amide and the composition has a pH of 6.0.

59. A pharmaceutical composition comprising a pharmaceutically acceptable salt of an ShK polypeptide having the formula p-phospho-Tyr-AEEA-Arg-Ser-Cys-Ile-Asp-Thr-Ile-Pro-Lys-Ser-Arg-Cys-Thr-Ala-Phe-Gln-Cys-Lys-His-Ser-Met-Lys-Tyr-Arg-Leu-Ser-Phe-Cys-Arg-Lys-Thr-Cys-Gly-Thr-Cys-$NH_2$; 10 mM sodium phosphate; 150 mM NaCl; and Polysorbate 20 at 0.05 w/v% and wherein the composition has a pH of 6.0.

60. A pharmaceutical composition comprising an ShK polypeptide having the formula Tyr-AEEA-Arg-Ser-Cys-Ile-Asp-Thr-Ile-Pro-Lys-Ser-Arg-Cys-Thr-Ala-Phe-Gln-Cys-Lys-His-Ser-Met-Lys-Tyr-Arg-Leu-Ser-Phe-Cys-Arg-Lys-Thr-Cys-Gly-Thr-Cys-$NH_2$; 10 mM sodium phosphate; 150 mM NaCl; and Polysorbate 20 at 0.05 w/v% and wherein the composition has a pH of 6.0.

## CLAIMS

What is claimed is:

1. A pharmaceutical composition suitable for diagnostic in vivo use comprising a pharmaceutically acceptable salt of a ShK polypeptide having the sequence Arg-Ser-Cys-Ile-Asp-Thr-Ile-Pro-Lys-Ser-Arg-Cys-Thr-Ala-Phe-Gln-Cys-Lys-His-Ser-Xaa-Lys-Tyr-Arg-Leu-Ser-Phe-Cys-Arg-Lys-Thr-Cys-Gly-Thr-Cys (SEQ ID NO:1) wherein

   the ShK polypeptide is attached to a detectable label and an organic or inorganic chemical entity that has an anionic charge,

   the C-terminus of the ShK polypeptide is an acid or an amide; and

   Xaa is selected from the group consisting of Met and Nle.

2. The composition of claim 1 wherein said detectable label is a chelate of Indium-111 ($In^{111}$).

3. The composition of claim 2 wherein said detectable label is a 1,4,7,10-tetraazacyclododecane-1,4,7,10-tetraacetic acid (DOTA)-chelate of Indium-111 ($In^{111}$).

4. The composition of claim 1 wherein said detectable label is a chelate of gadolinium (Gd).

5. The composition of claim 4 wherein said detectable label is a DOTA-chelate of gadolinium (Gd).

6. A pharmaceutical composition suitable for diagnostic in vivo use comprising a pharmaceutically acceptable salt of a ShK polypeptide having the sequence Tyr-AEEA-Arg-Ser-Cys-Ile-Asp-Thr-Ile-Pro-Lys-Ser-Arg-Cys-Thr-Ala-Phe-Gln-Cys-Lys-His-Ser-Met-Lys-Tyr-Arg-Leu-Ser-Phe-Cys-Arg-Lys-Thr-Cys-Gly-Thr-Cys-$NH_2$ (ShK-198), wherein the Shk polypeptide is attached to a detectable label at the amino terminus.

7. The composition of claim 6 wherein the detectable label is a 1,4,7,10-tetraazacyclododecane-1,4,7,10-tetraacetic acid (DOTA)-chelate of Indium-111 ($In^{111}$).

8. The pharmaceutical composition of any one of claims 1-7 formulated for long-term storage.

9. The pharmaceutical composition of claim 8 wherein the composition is contained in a sterile glass vial and is instructed to be stored at -70°C.

10. A unit of manufacture for pharmaceutical use comprising at least one glass vial prepared under sterile conditions that contains a pharmaceutical composition of any one of claims 1-7, wherein the pharmaceutical composition within the glass vial is stable for at least six months at -70°C, and further comprising instructions for diluting and preparing the pharmaceutical composition for administration to a human.

11. A unit of manufacture for pharmaceutical use comprising at least one sterile syringe containing a pharmaceutical composition of any one of claims 1-7, wherein the unit of manufacture further comprises instructions for administering the pharmaceutical composition to a human.