CLAIMS

WHAT IS CLAIMED IS:

1. A composition comprising:

a polypeptide comprising the amino acid sequence of SEQ ID NO: 1 with zero to four conservative amino acid substitutions, or alterations, wherein the polypeptide possesses fusogenic properties of human saposin C (SapC);

a phosphatidylserine lipid;

a buffer at pH 5.0 to 8.0;

trehalose at 1.5 to 9 percent w/w;

t-butyl alcohol at 0 to 35 percent; and

water,

wherein the polypeptide is at a concentration of 0.4 to 5.0 mg/ml, and the molar ratio of the phosphatidylserine lipid to the polypeptide is in the range of 8:1 to 20:1.

2. The composition of claim 1, wherein the buffer is tris(hydroxymethyl)aminomethane (Tris) at a concentration of 10 to 50 mM, and the pH of the composition is pH 6.8 to 7.6.

3. The composition of claim 1, wherein the buffer is citrate buffer at a concentration of 10 to 50 mM.

4. The composition of claim 1, wherein the buffer is acetate buffer at a concentration of 10 to 50 mM.

5. The composition of claim 1, wherein the phosphatidylserine lipid is dioleoyl phosphatidylserine (DOPS).

6. The composition of claim 1, wherein the phosphatidylserine lipid comprises one or more of DOPS, dihexanoyl phosphatidylserine lipid, dioctanoyl phosphatidylserine lipid, didecanoyl phosphatidylserine lipid, dilauroyl phosphatidylserine lipid, dimyristoyl phosphatidylserine lipid, dipalmitoyl phosphatidylserine lipid, palmitoyl-oleoyl phosphatidylserine lipid, 1-stearoyl-2-oleoyl phosphatidylserine lipid, or diphytanoyl phosphatidylserine lipid.

7. The composition of claim 1, wherein the polypeptide's amino acid sequence comprises SEQ ID NO: 1 with one or two conservative amino acid substitutions, or alterations.

8. The composition of claim 1, wherein the polypeptide's amino acid sequence comprises SEQ ID NO: 1.

9. The composition of claim 1, wherein the polypeptide's amino acid sequence consists of SEQ ID NO: 1.

10. The composition of claim 1, wherein

the polypeptide comprises the sequence of SEQ ID NO: 1 and is at a concentration of 1.9 to 2.5 mg/ml;

the phosphatidylserine lipid is DOPS and is at a concentration of 2.0 to 2.8 mg/ml;

the buffer is Tris at a concentration of 23 to 27 mM;

the trehalose is at a concentration of 4 to 6 percent w/w;

the pH of the composition is in the range of pH 6.8 to 7.6; and

the composition further comprises t-butyl alcohol at a concentration of 15 to 25 percent w/w.

11. A composition in solid form comprising:

a polypeptide comprising the amino acid sequence of SEQ ID NO: 1 with zero to four conservative amino acid substitutions, or alterations, wherein the polypeptide possesses fusogenic properties of human saposin C (SapC);

a phosphatidylserine lipid;

a buffer; and

trehalose at 75 to 90 percent w/w,

wherein the polypeptide is at a concentration of 3.2 to 4.4 percent w/w, and the molar ratio of phosphatidylserine lipid to polypeptide is in the range of 8:1 to 20:1.

12. The composition of claim 11, wherein the buffer is Tris at 5.6 to 7.6 percent w/w.

13. The composition of claim 11, wherein the buffer is citrate buffer at 9 to 13 percent w/w.

14. The composition of claim 11, wherein the buffer is acetate buffer at 3 to 5 percent w/w.

15. The composition of claim 11, wherein the phosphatidylserine lipid is DOPS.

16. The composition of claim 11, wherein the phosphatidylserine lipid comprises one or more of DOPS, dihexanoyl phosphatidylserine lipid, dioctanoyl phosphatidylserine lipid, didecanoyl phosphatidylserine lipid, dilauroyl phosphatidylserine lipid, dimyristoyl phosphatidylserine lipid, dipalmitoyl phosphatidylserine lipid, palmitoyl-oleoyl phosphatidylserine lipid, 1-stearoyl-2-oleoyl phosphatidylserine lipid, or diphytanoyl phosphatidylserine lipid.

17. The composition of claim 11, wherein the polypeptide's amino acid sequence comprises SEQ ID NO: 1 with one or two conservative amino acid substitutions, or alterations.

18. The composition of claim 11, wherein the polypeptide's amino acid sequence comprises SEQ ID NO: 1.

19. The composition of claim 11, wherein the polypeptide's amino acid sequence consists of SEQ ID NO: 1.

20. The composition of claim 11, further comprising t-butyl alcohol in an amount less than 3 percent w/w.

21. The composition of claim 11, wherein

the polypeptide comprises the sequence of SEQ ID NO: 1 and is at a concentration of 3.3 to 4.3 percent w/w;

the phosphatidylserine lipid is DOPS and is at a concentration of 3.4 to 4.8 percent w/w;

the buffer is Tris and is at a concentration of 6.0 to 7.2 percent w/w;

the trehalose is at a concentration of 81 to 87.3 percent w/w; and

the composition further comprises t-butyl alcohol at a concentration of less than 3 percent w/w.

22. A pharmaceutical composition comprising:

a polypeptide comprising the amino acid sequence of SEQ ID NO: 1 with zero to four conservative amino acid substitutions, or alterations, wherein the polypeptide possesses fusogenic properties of human saposin C (SapC);

a phosphatidylserine lipid;

a buffer at pH 5.0 to 8;

trehalose at 1.5 to 9 percent w/v; and

water,

wherein the polypeptide is at a concentration of 0.4 to 5 mg/ml, and the molar ratio of phosphatidylserine lipid to polypeptide is in the range of 8:1 to 20:1.

23. The pharmaceutical composition of claim 22, wherein the buffer is Tris at a concentration of 10 to 50 mM, and the pH of the composition is pH 6.8 to 7.6.

24. The pharmaceutical composition of claim 22, wherein the buffer is citrate buffer at a concentration of 10 to 50 mM.

25. The pharmaceutical composition of claim 22, wherein the buffer is acetate buffer at a concentration of 10 to 50 mM.

26. The pharmaceutical composition of claim 22, wherein the phosphatidylserine lipid is dioleoyl phosphatidylserine (DOPS).

27. The pharmaceutical composition of claim 22, wherein the phosphatidylserine lipid comprises one or more of DOPS, dihexanoyl phosphatidylserine lipid, dioctanoyl phosphatidylserine lipid, didecanoyl phosphatidylserine lipid, dilauroyl phosphatidylserine lipid, dimyristoyl phosphatidylserine lipid, dipalmitoyl phosphatidylserine lipid, palmitoyl-oleoyl phosphatidylserine lipid, 1-stearoyl-2-oleoyl phosphatidylserine lipid, or diphytanoyl phosphatidylserine lipid.

28. The pharmaceutical composition of claim 22, wherein the polypeptide's amino acid sequence comprises SEQ ID NO: 1 with one or two conservative amino acid substitutions, or alterations.

29. The pharmaceutical composition of claim 22, wherein the polypeptide's amino acid sequence comprises SEQ ID NO: 1.

30. The pharmaceutical composition of claim 22, wherein the polypeptide's amino acid sequence consists of SEQ ID NO: 1.

31. The pharmaceutical composition of claim 22, further comprising t-butyl alcohol in an amount less than 3 percent.

32. The pharmaceutical composition of claim 22, wherein
the polypeptide comprises the amino acid sequence of SEQ ID NO: 1 and is at a concentration of 1.9 to 2.5 mg/ml;
the phosphatidylserine lipid is DOPS and is at a concentration of 2.0 to 2.8 mg/ml;
the buffer is Tris and is at a concentration of 23 to 27 mM;
the trehalose is at a concentration of 4 to 6 percent w/v;
the pH of the composition is in the range of pH 6.8 to 7.6; and
the composition further comprises t-butyl alcohol in an amount less than 0.5 percent w/w.

33. The composition of any one of claims 1-21 or the pharmaceutical composition of any one of claims 22-32 for use in therapy.

34. Use of the pharmaceutical composition of any one of claims 22-32 in the preparation of a medicament for the treatment of cancer in a human patient, wherein the medicament is to be administered to the patient.

35. The use of claim 34, wherein the patient has a solid tumor.

36. The use of claim 35, wherein the patient has a glioma or ependymoma.

37. The use of claim 35, wherein the patient has a gastrointestinal cancer.

38. The use of claim 34, wherein the medicament is to be delivered intravenously in a dose ranging from 0.4 mg/kg to 7 mg/kg polypeptide, and the ratio of polypeptide to phosphatidylserine lipid in the medicament is in the range of 1:8 to 1:20.

39. The use of claim 34, wherein the medicament is to be delivered intravenously in a dose of 2.3-2.5 mg/kg polypeptide, and the ratio of polypeptide to phosphatidylserine lipid in the medicament is in the range of 1:11 to 1:13.

40. The use of claim 38, wherein the medicament is to be administered repeatedly to the patient over at least two cycles, as follows:
Cycle 1:
week 1: one dose on each of days 1-5;
week 2: three doses every other day;
weeks 3 and 4: one dose each week (every 7 (+/- 3) days);
Cycle 2: one dose during week 5.

41. The use of claim 40, further comprising at least one subsequent cycle, wherein the at least one subsequent cycle comprises: one dose 28 (+/- 3) days after the most recent prior dose.

42. Use of the composition of claim 11 in the preparation of a medicament for the treatment of cancer in a human patient, wherein the composition is to be reconstituted in water or saline to produce a reconstituted medicament, and a dose of the reconstituted medicament is to be intravenously administered to the patient.