CLAIMS

1. A composition comprising a Keyhole Limpet Hemocyanin (KLH)-peptide conjugate, a buffer, a disacharide, and a surfactant, wherein the peptide conjugated to KLH in the KLH-peptide conjugate comprises an EGFRvIII amino acid sequence comprising at least the sequence Lys-Lys-Gly-Asn-Tyr.

2. The composition according to claim 1, wherein the buffer comprises a phosphate buffer.

3. The composition according to claim 2, wherein the buffer comprises a potassium phosphate buffer.

4. The composition according to any one of claims 1 to 3, wherein the buffer is present in a concentration ranging from 5 mM to 30 mM.

5. The composition according to any one of claims 1 to 3, wherein the buffer is present in a concentration such that after 12 weeks at 40°C, the concentration of the KLH-peptide conjugate in the composition, as measured in mg/mL, has changed by less than 15% when compared to the original concentration.

6. The composition according to any one of claims 1 to 5, wherein the disaccharide is trehalose, and is:

(a) present in a concentration ranging from 45 to 150 mg/mL;

(b) present in an amount ranging from 80 to 110 mg per mg of KLH-peptide conjugate; or

(c) present in a concentration such that after 12 weeks at 40°C, the concentration of the KLH-peptide conjugate in the composition, as measured in mg/mL, has changed by less than 15% when compared to the original concentration.

7. The composition according to any one of claims 1 to 6, wherein the surfactant is polysorbate, and is:

(a) present in a concentration ranging from 0.01 to 0.3 mg/mL;

(b) present in an amount ranging from 0.01 to 0.3 mg per mg of KLH-peptide conjugate; or

(c) present in a concentration such that after 12 weeks at 40°C, the concentration of the KLH-peptide conjugate in the composition, as measured in mg/mL, has changed by less than 15% when compared to the original concentration.

8. The composition according to any one of the preceding claims, wherein the peptide conjugated to KLH in the KLH-peptide conjugate consists of SEQ ID NO:1 or SEQ ID NO:2.

9. The composition according to any one of the preceding claims, wherein the peptide is conjugated to KLH with a sulfo-SMCC linker.

10. The composition according to any one of the preceding claims, wherein the epitope density ranges from 20 to 80.

11. The composition according to any one of the preceding claims, wherein

(a) the amount of KLH-peptide conjugate present in dimer form ranges from 45% to 65% by mass of the total mass of the composition, as determined by size exclusion chromatography;

(b) the amount of KLH-peptide conjugate present in monomer form ranges from 15% to 40% by mass of the total mass of the composition, as determined by size exclusion chromatography; or

(c) the amount of KLH-peptide conjugate present in monomer form ranges from 18% to 35% by mass of the total mass of the composition, and the amount of KLH-peptide conjugate present in dimer form ranges from 50% to 65% by mass of the total mass of the composition, as determined by size exclusion chromatography.

12. The composition according to any one of the preceding claims, wherein the composition is an aqueous pharmaceutical composition, and the pH of the composition ranges from 6 to 8.

13. The composition according to any one of the preceding claims, wherein the composition is an aqueous pharmaceutical composition, and after 12 weeks at 40°C, the concentration of the KLH-peptide conjugate in the composition, as measured in mg/mL, has changed by less than 15% when compared to the original concentration.

14. A liquid composition comprising a KLH-EGFRvIII peptide conjugate, potassium phosphate buffer, trehalose, and polysorbate 80, wherein: the peptide conjugated to KLH comprises SEQ ID NO:1; the KLH-EGFRvIII peptide conjugate has an epitope density ranging from 30 to 65; the buffer is present in a concentration ranging from 9 mM to 11 mM; the pH of the composition ranges from 7.3 to 7.5; the trehalose is present in a concentration ranging from 85 mg/mL to 95 mg/mL; the polysorbate 80 is present in a concentration ranging from 0.1 mg/mL to 0.3 mg/mL; and further wherein the amount of KLH-EGFRvIII peptide conjugate present in monomer form ranges from 18% to 35% by mass of the total mass of the

composition, and the amount of KLH-EGFRvIII peptide conjugate present in dimer form ranges from 50% to 65% by mass of the total mass of the composition, as determined by size exclusion chromatography.

15. The composition of claim 14, wherein the liquid composition is prepared by reconstituting a lyophilized composition with water.

16. The composition of claim 14 or claim 15, wherein the buffer is present in a concentration of 10 mM, the pH of the composition is 7.4, the trehalose is present in a concentration of 90 mg/mL, and the polysorbate 80 is present in a concentration of 0.2 mg/mL.

17. A composition comprising a KLH-EGFRvIII peptide conjugate wherein:

(a) the amount of KLH-EGFRvIII peptide conjugate present in monomer form ranges from 18% to 35% by mass of the total mass of the composition, and the amount of KLH-EGFRvIII peptide conjugate present in dimer form ranges from 50% to 65% by mass of the total mass of the composition, as determined by size exclusion chromatography;

(b) the composition is an aqueous pharmaceutical composition which has been stabilized such that after 12 weeks at 40°C, the concentration of the KLHEGFRvIII peptide conjugate in the composition, as measured in mg/mL, has changed by less than 15% when compared to the original concentration; or

(c) the mean epitope density of the conjugate is between about 20 and 80.

18. A composition comprising a KLH-EGFRvIII peptide conjugate wherein the composition has the following properties:

i) epitope density as measured by amino acid composition of 30-70 peptides/KLH;

ii) size distribution profile as measured by SEC HPLC as follows:

Peak 1 < 2%

Peak 2 8-17%

Peak 3 50-60%

Peak 4 20-30%

Peak 5 1-5%; and

iii) purity as measured by AEX RP-HPLC as follows:

Peptide dimer ≤ 5%

Linker or linker-related impurities ≤ 1%

Total peptide-linker impurities ≤ 10%.

19. The composition according to claim 17 or claim 18, which comprises a buffer.

20. The composition according to claim 19, wherein the buffer comprises a phosphate buffer.

21. The composition according to claim 20, wherein the buffer comprises a potassium phosphate buffer.

22. The composition according to any one of claims 17 to 21, which comprises a cryoprotectant or lyoprotectant.

23. The composition according to any one of claims 17 to 21, which comprises a disaccharide.

24. The composition according to claim 23, wherein the disaccharide is trehalose.

25. The composition according to any one of claims 17 to 24, which comprises a surfactant.

26. The composition according to claim 25, wherein the surfactant is a polysorbate, poloxamer or triton surfactant.

27. The composition according to claim 26, wherein the surfactant is polysorbate 80.

28. The composition according to any one of claims 17 to 27, wherein after 26 weeks at 5°C, the number of particulates greater than or equal to 25 µm, as measured by USP <788>, increases by less than 1000%.

29. A composition according to any one of the preceding claims, which is a liquid composition or a lyophilized composition.

30. A lyophilized composition obtained by subjecting a liquid composition according to any one of the preceding claims to a temperature of -20°C or less and to vacuum conditions.

31. A method of preparing a KLH-EGFRvIII conjugate comprising: a) combining KLH with a linker and allowing the KLH and linker to interact for a time ranging from 30 to 240 minutes; and b) adding a peptide comprising SEQ ID NO: 1 to the activated KLH product resulting from step a) to provide the KLH-EGFRvIII conjugate.

32. The method of claim 31, wherein the linker is combined with KLH in a linker:KLH molar ratio that ranges from 75:1 to 325:1.

33. The method of claim 31, wherein the linker is combined with KLH in a linker:KLH molar ratio that ranges from 150:1 to 250:1.

34. The method of claim 31, wherein the linker is combined with KLH in a linker:KLH molar ratio that ranges from 200:1.

35. The method of claim 31, wherein the linker is a sulfo-SMCC linker which is added in a non-aqueous solvent.

36. A method as claimed in claim 35 wherein the non-aqueous solvent comprises DMSO.

37. The method of any one of claims 31 to 36, further comprising the step of lyophilizing the conjugate.

38. A method for preparing a KLH-EGFRvIII conjugate comprising: a) combining KLH with a linker and allowing the KLH and linker to interact; and b) adding a peptide comprising SEQ ID NO: 1 to the activated KLH product resulting from step a) to provide the KLH-EGFRvIII conjugate, wherein the linker is a sulfo-SMCC linker which is added in a non-aqueous solvent.

39. The method of claim 38, wherein the non-aqueous solvent comprises DMSO.

40. A KLH-EGFRvIII conjugate produced by the method of any one of claims 31 to 39.