

CLAIMS

1. A pharmaceutical composition comprising:
 - a. a peptide having an amino acid sequence comprising or consisting of SEQ ID NO:70 at a concentration of from 1 to 10 mg/mL, and
 - b. a pharmaceutically acceptable carrier comprising:
 - i. Tris that is present in the range of 5 and 50 mM,
 - ii. trehalose that is present in the range of between 1 and 20% (w/v), and
 - iii. polysorbate-20 that is present in the range of from 0.001 to 0.1% (v/v).
2. The pharmaceutical composition of claim 1, wherein the peptide is fused with an immunoglobulin Fc region.
3. The pharmaceutical composition of claim 1 or 2, wherein the peptide has an amino acid sequence comprising SEQ ID NO:70.
4. The pharmaceutical composition of claim 1 or 2, wherein the peptide has an amino acid sequence consisting of SEQ ID NO:70.
5. The pharmaceutical composition of any one of claims 1 to 4, wherein the peptide is at a concentration of 1 mg/mL.
6. The pharmaceutical composition of any one of claims 1 to 4, wherein the peptide is at a concentration of 5 mg/mL.
7. The pharmaceutical composition of any one of claims 1 to 4, wherein the peptide is at a concentration of 10 mg/mL.
8. The pharmaceutical composition of any one of claims 1 to 7, wherein the Tris is present in the range of 15 and 40 mM.
9. The pharmaceutical composition of claim 8, wherein the Tris is present in the range of 20 and 35 mM.
10. The pharmaceutical composition of claim 9, wherein the Tris is present in the range of 20 and 30 mM.
11. The pharmaceutical composition of claim 10, wherein the Tris is present in the range of 20 and 25 mM.

12. The pharmaceutical composition of claim 11, wherein the Tris is present at 20 mM.
13. The pharmaceutical composition of any one of claims 1 to 12, wherein the trehalose is present in the range of 1 and 20%.
14. The pharmaceutical composition of any one of claims 1 to 12, wherein the trehalose is present in the range of 2 and 15%.
15. The pharmaceutical composition of any one of claims 1 to 12, wherein the trehalose is present in the range of 3 and 10%.
16. The pharmaceutical composition of any one of claims 1 to 12, wherein the trehalose is present in the range of 4 and 9.5%.
17. The pharmaceutical composition of any one of claims 1 to 12, wherein the trehalose is present in the range of 5 and 9.25%.
18. The pharmaceutical composition of any one of claims 1 to 12, wherein the trehalose is present in the range of 6 and 9%.
19. The pharmaceutical composition of any one of claims 1 to 12, wherein the trehalose is present in the range of 7 and 8.5%.
20. The pharmaceutical composition of any one of claims 1 to 12, wherein the trehalose is present in the range of 8 and 8.4%.
21. The pharmaceutical composition of any one of claims 1 to 12, wherein the trehalose is present at 8.2%.
22. The pharmaceutical composition of any one of claims 1 to 12, wherein the trehalose is present at 8.3%.
23. The pharmaceutical composition of any one of claims 1 to 12, wherein the trehalose is present at 8.4%.
24. The pharmaceutical composition of any one of claims 1 to 12, wherein the trehalose is present in the range of 9.2% and 9.3%.
25. The pharmaceutical composition of any one of claims 1 to 12, wherein the trehalose is present at 9.3%
26. The pharmaceutical composition of any one of claims 1 to 25, wherein the concentration of the polysorbate-20 is in the range of from 0.001 to 0.1% (v/v).

27. The pharmaceutical composition of any one of claims 1 to 25, wherein the concentration of the polysorbate-20 is in the range of from 0.0025 to 0.075% (v/v).
28. The pharmaceutical composition of any one of claims 1 to 25, wherein the concentration of the polysorbate-20 is in the range of from 0.005 to 0.05% (v/v).
29. The pharmaceutical composition of any one of claims 1 to 25, wherein the concentration of the polysorbate-20 is in the range of from 0.0075 to 0.025% (v/v).
30. The pharmaceutical composition of any one of claims 1 to 25, wherein the concentration of the polysorbate-20 is 0.01% (v/v).
31. The pharmaceutical composition of any one of claims 1 to 30, wherein the pharmaceutical composition has a pH in a range of 7.0 and 9.0 at 4°C or 25°C.
32. The pharmaceutical composition of any one of claims 1 to 30, wherein the pharmaceutical composition has a pH in a range of 7.5 and 8.5 at 4°C or 25°C.
33. The pharmaceutical composition of any one of claims 1 to 30, wherein the pharmaceutical composition has a pH of 8.0 at 4°C.
34. The pharmaceutical composition of any one of claims 1 to 30, wherein the pharmaceutical composition has a pH of 8.0 at 25°C.
35. A pharmaceutical composition comprising:
 - a. a peptide having an amino acid sequence consisting of SEQ ID NO:70 at a concentration of from 1 to 10 mg/mL, and
 - b. a pharmaceutically acceptable carrier comprising:
 - i. 20 mM Tris,
 - ii. from 8.2% to 8.4% (w/v) trehalose, and
 - iii. 0.01% (v/v) polysorbate-20;wherein the pharmaceutical composition has a pH of 8.0 at 25°C.
36. A pharmaceutical composition comprising:
 - a. a peptide having an amino acid sequence consisting of SEQ ID NO:70 at a concentration of from 1 to 10 mg/mL, and
 - b. a pharmaceutically acceptable carrier comprising:

- i. 20 mM Tris,
- ii. from 9.2% to 9.3% (w/v) trehalose, and
- iii. 0.01% (v/v) polysorbate-20;

wherein the pharmaceutical composition has a pH of 8.0 at 25°C.

- 37. The pharmaceutical composition of claim 35 or 36, wherein the peptide is present at a concentration of 1 mg/mL.
- 38. The pharmaceutical composition of claim 35 or 36, wherein the peptide is present at a concentration of 5 mg/mL.
- 39. The pharmaceutical composition of claim 35 or 36, wherein the peptide is present at a concentration of 10 mg/mL.
- 40. The pharmaceutical composition of any one of claims 35 to 39, wherein the peptide is fused with an immunoglobulin Fc region.
- 41. The pharmaceutical composition of any one of claims 1 to 40, wherein the pharmaceutical composition does not comprise a salt.
- 42. The pharmaceutical composition of any one of claims 1 to 41, wherein the pharmaceutical composition is in a liquid form.
- 43. The pharmaceutical composition of any one of claims 1 to 42, wherein less 10% of the peptide aggregates after a period of time when stored at 4°C or 37°C.
- 44. The pharmaceutical composition of any one of claims 1 to 42, wherein less 5% of the peptide aggregates after a period of time when stored at 4°C or 37°C.
- 45. The pharmaceutical composition of any one of claims 1 to 42, wherein less 2% of the peptide aggregates after a period of time when stored at 4°C or 37°C.
- 46. The pharmaceutical composition of any one of claims 43 to 45, wherein the period of time is 4 weeks at 4°C.
- 47. The pharmaceutical composition of any one of claims 43 to 45, wherein the period of time is 4 weeks at 37°C.
- 48. The pharmaceutical formulation of any one of claims 1 to 47, wherein the formulation is provided in a single-use container.

49. The pharmaceutical formulation of any one of claims 1 to 47, wherein the formulation is provided in a syringe or an autoinjector.
50. Use of the pharmaceutical composition of any one of claims 1 to 47 in the manufacture of a medicament for preventing, treating or managing a bile acid-related or associated disorder in a subject in need thereof, wherein the bile acid-related or associated disorder is selected from the group consisting of cholestasis, intrahepatic cholestasis, primary biliary cirrhosis (PBC), primary familial intrahepatic cholestasis (PFIC), progressive PFIC, primary sclerosing choangitis (PSC), pregnancy intrahepatic cholestasis (PIC), neonatal cholestasis, and drug induced cholestasis, diseases of extrahepatic cholestasis, bile acid malabsorption, bile acid diarrhea (BAD), bile acid synthesis abnormalities, non-alcoholic steatohepatitis (NASH), and cirrhosis.
51. The use of claim 50, wherein the bile acid-related or associated disorder is NASH.
52. Use of a pharmaceutical composition of any one of claims 1 to 47 in the manufacture of a medicament for preventing, treating or managing a glucose-related disorder in a subject in need thereof, wherein the glucose-related disorder is a hyperglycemic condition, insulin resistance, hyperinsulinemia, or glucose intolerance.
53. Use of a pharmaceutical composition of any one of claims 1 to 47 in the manufacture of a medicament for preventing, treating or managing an FGF19-dependent cancer or tumor in a subject in need thereof.
54. The use of claim 53, wherein the cancer or tumor is a hepatocellular carcinoma, colon cancer or tumor, prostate cancer or tumor, or lung cancer or tumor.