CLAIMS

1. A solid pharmaceutical composition comprising BT7480, or a pharmaceutically acceptable salt thereof, Tris base, mannitol, and sodium hydroxide.

2. The solid pharmaceutical composition of claim 1, comprising about 0.1 mg Tris base per mg of BT7480, or a pharmaceutically acceptable thereof.

3. The solid pharmaceutical composition of claim 1 or 2, comprising about 0.4 mg mannitol per mg of BT7480, or a pharmaceutically acceptable thereof.

4. The solid pharmaceutical composition of any one of claims 1-3, wherein the amount of sodium hydroxide provides a pH of about 7.0 to 7.5 when the solid pharmaceutical composition is reconstituted in water.

5. The solid pharmaceutical composition of any one of claims 1-4, comprising:
about 66 mg BT7480, or a pharmaceutically acceptable salt thereof;
about 6.6 mg Tris base;
about 26.4 mg mannitol; and
sodium hydroxide, wherein the amount of sodium hydroxide provides a pH of about 7.0 to 7.5 when the solid pharmaceutical composition is reconstituted in water.

6. An aqueous pharmaceutical composition comprising BT7480, or a pharmaceutically acceptable salt thereof, Tris base, mannitol, sodium hydroxide, and water.

7. The aqueous pharmaceutical composition of claim 6, comprising about 60 mg/mL BT7480, or a pharmaceutically acceptable salt thereof.

8. The aqueous pharmaceutical composition of claim 6 or 7, comprising about 6 mg/mL Tris base.

9. The aqueous pharmaceutical composition of any one of claims 6-8, comprising about 24 mg/mL mannitol.

10. The aqueous pharmaceutical composition of any one of claims 6-9, wherein the aqueous pharmaceutical composition is at a pH of about 7.0 to 7.5.

11 The aqueous pharmaceutical composition of any one of claims 6-10, which is at a volume of about 1.1 mL.

12. The aqueous pharmaceutical composition of any one of claims 6-11, comprising:
about 60 mg/mL BT7480, or a pharmaceutically acceptable salt thereof;
about 6 mg/mL Tris base;
about 24 mg/mL mannitol;
sodium hydroxide; and
water, wherein the aqueous pharmaceutical composition is at a pH of about 7.0 to 7.5.

13. The aqueous pharmaceutical composition of any one of claims 6-12, further comprising sodium chloride.

14. Use of the solid pharmaceutical composition of any one of claims 1-5 in the manufacture of a medicament for treating a Nectin-4 associated advanced malignancy in a patient, wherein the treatment to be administered is an aqueous pharmaceutical composition prepared by: (i) reconstituting the solid pharmaceutical composition in water, or (ii) dissolving the solid pharmaceutical composition in an injectable medium.

15. Use of the aqueous pharmaceutical composition of any one of claims 6-13 in the manufacture of a medicament for treating a Nectin-4 associated advanced malignancy in a patient, wherein the treatment to be administered is the aqueous pharmaceutical composition.

16. The use of claim 14 or 15, wherein the aqueous pharmaceutical composition is to be administered intravenously.

17. The use of claim 16, wherein the Nectin-4 associated advanced malignancy is selected from the group consisting of non-small-cell lung cancer (NSCLC), ovarian cancer, triple-negative breast cancer (TNBC), gastric/upper gastrointestinal (GI) cancer, pancreatic cancer, urothelial cancer, bladder cancer, head and neck cancer, esophageal cancer, and melanoma.

18. The use of any one of claims 14-17, wherein the aqueous pharmaceutical composition is to be administered once weekly or once every two weeks.

19. The use of any one of claims 14-18, wherein the BT7480, or a pharmaceutically acceptable salt thereof, is to be administered at a dose of:

(i) up to about 7.5 mg/kg;

(ii) about 0.02-6 mg/kg, about 0.05-6 mg/kg, about 0.15-6 mg/kg, about 0.3-6 mg/kg, about 0.6-6 mg/kg, about 1.3-6 mg/kg, or about 2.6-6 mg/kg; or

(iii) about 0.002 mg/kg, about 0.006 mg/kg, about 0.02 mg/kg, about 0.05 mg/kg, about 0.15 mg/kg, about 0.3 mg/kg, about 0.6 mg/kg, about 1.3 mg/kg, about 2.0 mg/kg, about 2.6 mg/kg, about 3.0 mg/kg, about 3.5 mg/kg, about 3.9 mg/kg, about 4.25 mg/kg, about 5.0 mg/kg, about 5.75 mg/kg, about 6.0 mg/kg, about 6.5 mg/kg, about 7.0 mg/kg, or about 7.5 mg/kg.

20. The use of any one of claims 14-19, wherein the aqueous pharmaceutical composition is to be administered via an IV infusion of about 60 minutes.

21. The use of any one of claims 14-20, wherein the aqueous pharmaceutical composition is to be administered with Nivolumab.

22. The use of claim 21, wherein Nivolumab:

(i) is to be administered via an IV infusion of about 30 minutes; and/or

(ii) is to be administered to the patient at a dosage level of 240 mg once every 2 weeks.