CLAIMS

1. A pharmaceutical composition comprising BT8009, or a pharmaceutically acceptable salt thereof, and a pharmaceutically acceptable excipient or carrier selected from a buffering agent, a stabilizer or cryoprotectant, and a surfactant.

2. The pharmaceutical composition of claim 1, wherein the buffering agent is histidine.

3. The pharmaceutical composition of claim 1 or 2, wherein the stabilizer or cryoprotectant is sucrose.

4. The pharmaceutical composition of any one of claims 1-3, wherein the surfactant is Polysorbate 20.

5. The pharmaceutical composition of any one of claims 1-4, further comprising a pH adjusting agent.

6. The pharmaceutical composition of claim 5, wherein the pH adjusting agent comprises hydrochloric acid.

7. The pharmaceutical composition of any one of claims 1-6, which is a solid pharmaceutical composition in lyophilized powder form.

8. The pharmaceutical composition of any one of claims 1-6, which is a liquid pharmaceutical composition further comprising water.

9. The pharmaceutical composition of any one of claims 1-8, comprising:

BT8009, or a pharmaceutically acceptable salt thereof;

about 1.31-2.62 mg histidine per mg of BT8009, or a pharmaceutically acceptable thereof;

about 15-30 mg sucrose per mg of BT8009, or a pharmaceutically acceptable thereof; and

about 0.05-0.1 mg Polysorbate 20 per mg of BT8009, or a pharmaceutically acceptable thereof.

10. The pharmaceutical composition of claim 9, comprising:
about 21.2 mg BT8009, or a pharmaceutically acceptable salt thereof;
about 27.8 mg histidine;
about 318 mg sucrose; and
about 1.06 mg Polysorbate 20.

11. The pharmaceutical composition of claim 8, comprising:
about 2-4 mg/mL BT8009, or a pharmaceutically acceptable salt thereof;
about 5.24 mg/mL histidine;
about 60 mg/mL sucrose; and
about 0.2 mg/mL Polysorbate 20.

12. A method for treating an advanced solid tumor malignancy associated with Nectin-4-expression in a patient comprising intravenously administering to the patient the pharmaceutical composition of any one of claims 1-11.

13. The method of claim 12, wherein the advanced solid tumor malignancy associated with Nectin-4-expression 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, and urothelial cancer.

14. The method of claim 12 or 13, wherein the pharmaceutical composition is administered once every 7 days.

15. The method of any one of claims 12-14, wherein the pharmaceutical composition is administered at a dose of about 2.5, 5.0, 7.5, 10.0, 13.0 or 17.0 mg/m^2.

16. The method of any one of claims 12-15, wherein the pharmaceutical composition is administered via an IV infusion of about 60 minutes.

17. The method of any one of claims 12-15, further comprising administering Nivolumab.

18. The method of claim 17, wherein the Nivolumab is administered via an IV infusion of about 30 minutes.