WHAT IS CLAIMED:

1. Use of a polypeptide comprising an amino acid sequence selected from the amino acid sequence of any one of SEQ ID NOs:1 to 5 in the manufacture of a medicament for treating cancer in a subject in need thereof, wherein the polypeptide is to be administered to the subject at a dose of about 400 to about 1600 mg.

2. The use of claim 1, wherein about 360 mg Q3W of nivolumab is to be administered to the subject.

3. The use of claim 1, wherein about 480 mg Q4W of nivolumab is to be administered to the subject.

4. The use of any one of claims 1 to 3, wherein the polypeptide is to be administered to the subject once per dosing cycle.

5. The use of claim 4, wherein the dosing cycle begins on day 1 and ends on day 21.

6. The use of any one of claims 1 to 3, wherein the polypeptide is to be administered to the subject twice per dosing cycle.

7. The use of claim 6, wherein the dosing cycle begins on day 1 and ends on day 28.

8. The use of any one of claims 4 to 7, wherein the polypeptide is to be administered to the subject on day 1 or day 15 of the dosing cycle.

9. The use of any one of claims 4 to 8, wherein the dosing cycle is repeated about 10 to about 20 times, about 15 to about 25 times, about 20 to about 30 times, about 25 to about 35 times, about 30 to about 40 times, or about 35 times.

10. The use of any one of claims 1 to 9, wherein the dose of the polypeptide is selected from the group consisting of: about 400 mg, about 800 mg, about 1200 mg, or about 1600 mg.

11. The use of any one of claims 1 to 10, wherein the polypeptide is to be administered Q3W.

12. The use of any one of claims 1 to 10, wherein the polypeptide is to be administered Q2W.

13. The use of any one of claims 2 to 12, wherein the nivolumab and the polypeptide are formulated together in a single pharmaceutical composition that further comprises an excipient.

14. The use of any one of claims 1 to 13, wherein the polypeptide comprises an amino acid sequence consisting of the amino acid sequence of SEQ ID 1.

15. The use of any one of claims 1 to 13, wherein the polypeptide comprises an amino acid sequence consisting of the amino acid sequence of SEQ ID 2.

16. The use of any one of claims 1 to 13, wherein the polypeptide comprises an amino acid sequence consisting of the amino acid sequence of SEQ ID 3.

17. The use of any one of claims 1 to 13, wherein the polypeptide comprises an amino acid sequence consisting of the amino acid sequence of SEQ ID 4.

18. The use of any one of claims 1 to 13, wherein the polypeptide comprises an amino acid sequence consisting of the amino acid sequence of SEQ ID 5.

19. The use of any one of claims 1 to 18, wherein the cancer comprises an advanced solid tumor.

20. The use of any one of claims 1 to 19, wherein the cancer is selected from the group consisting of non-small cell lung cancer (NSCLC), urothelial carcinoma (UC), squamous cell carcinoma of the head and neck (SCCHN), hepatocellular carcinoma (HCC), microsatellite-stable colorectal carcinoma (MSS CRC), renal cell carcinoma (RCC), and pancreatic ductal adenocarcinoma (PDAC).

21. The use of any one of claims 1 to 20, wherein the medicament is capable of resulting in a reduction in the size of a tumor or in the number of tumors associated with the cancer.

22. The use of any one of claims 1 to 21, wherein the subject is resistant or refractory to or intolerant of existing standard cancer therapies known to provide clinical benefit, or, wherein the subject is resistant or refractory to immunotherapy that inhibits PD-1 signaling, or wherein the subject is resistant or refractory to anti–PD-(L)1–based immunotherapy.

23. Use of nivolumab and a polypeptide comprising an amino acid sequence selected from any one of SEQ ID NO:1 to 5 in the manufacture of a medicament for treating cancer in a subject in need thereof; wherein

(i) about 360-480 mg, optionally about 360 mg, of nivolumab is to be administered to the subject on about day 1 of a dosing cycle; and

(ii) a dose of about 400-1600 mg of the polypeptide is to be administered to the subject on about day 1 of the dosing cycle.

24. The use of claim 23, wherein the polypeptide is to be administered to the subject a single time per dosing cycle.

25. Use of nivolumab and a polypeptide comprising an amino acid sequence selected from any one of SEQ ID NO:1 to 5 in the manufacture of a medicament for treating cancer in a subject in need thereof; wherein

(i) about 360-480 mg, optionally about 480 mg, of nivolumab is to be administered to the subject on about day 1 of a dosing cycle; and

(ii) a dose of about 400-1600 mg of the polypeptide is to be administered to the subject on about day 1 of the dosing cycle and a dose of about 400-1600 mg of the polypeptide is to be administered to the subject on about day 15 of the dosing cycle.

26. The use of claim 25, wherein the polypeptide is to be administered to the subject twice per dosing cycle.

27. Use of a TGF-β ligand trap and nivolumab in the manufacture of a medicament for preventing or treating a cancer in a subject, wherein an effective amount of the TGF-β ligand trap and nivolumab is to be administered to the subject in need thereof.

28. The use of claim 27, wherein the anti-PD-1 antibody is nivolumab.

29. The use of any one of claims 27 or 28, wherein the TGF-β ligand trap is a polypeptide comprising an amino acid sequence of any one of SEQ ID NO: 1 to 5.

30. The use of any one of claims 27 to 29, wherein a therapeutically effective amount of the TGF-β ligand trap is to be administered to the subject, optionally wherein the therapeutically effective amount comprises at least one dose selected from the group consisting of: about 400 mg, about 800 mg, about 1200 mg, and about 1600 mg.

31. The use of any one of claims 27 to 30, wherein the TGF-β ligand trap is to be administered every two weeks (Q2W).

32. The use of any one of claims 27 to 30, wherein the TGF-β ligand trap is to be administered every three weeks (Q3W).

33. The use of any one of claims 1 to 32, wherein the subject has:

(a) elevated levels of a biomarker as compared to levels of the biomarker in a reference population; or

(b) decreased levels of a biomarker as compared to levels of the biomarker in a reference population; and

wherein the level of the biomarker is predictive of responsiveness to nivolumab and/or the polypeptide,

optionally wherein the biomarker is collagen or CD8 tumor infiltrating lymphocytes, and

optionally wherein the level of the biomarker in the subject is to be monitored.

34. The use of claim 33, wherein the level of the biomarker is determined by:

(a) gene expression profiling for TGF-β epithelial-mesenchymal transition/cancer-associated fibroblasts (EMT/CAF), interferon gamma (IFNγ) signatures, cluster of differentiation 8 (CD8) tumor infiltrating lymphocytes (TIL), and/or T/NK cells;

(b) monitoring TGF-β signaling pathways;

(c) cytokine profiling in tumors and/or periphery;

(d) peptide or protein profiling in a tissue;

(e) profiling circulating micro ribonucleic acid;

(f) profiling circulating deoxyribonucleic acid (ctDNA);

(g) whole exome sequencing; and/or

(h) biomarker immunostaining,

optionally wherein the level of the biomarker is the protein or mRNA level of the biomarker, and

optionally wherein the mRNA level is determined by quantitative reverse transcription polymerase chain reaction (qRT-PCR).