In examples of the disclosure, the amount of anti-PD-1 antibody or antigen-binding fragment thereof administered to the patient is from about 350 mg to about 450 mg. In further examples, the amount of antibody or antigen-binding fragment is about 400 mg. In further examples, the amount of antibody or antigen-binding fragment is 400 mg.

In one aspect, there is provided use of an anti-PD-1 antibody, or antigen binding fragment thereof in the manufacture of a medicament for treating cancer in a human patient, wherein the anti-PD-1 antibody or antigen-binding fragment thereof comprises:

(a) light chain complementarity determining regions (CDRs) comprising a sequence of amino acids as set forth in SEQ ID NOs: 1, 2 and 3 and heavy chain CDRs comprising a sequence of amino acids as set forth in SEQ ID NOs: 6, 7 and 8; or

(b) light chain CDRs comprising a sequence of amino acids as set forth in SEQ ID NOs: 11, 12 and 13 and heavy chain CDRs comprising a sequence of amino acids as set forth in SEQ ID NOs: 14, 15 and 16, and

wherein about 400 mg of the anti-PD-1 antibody or antigen-binding fragment thereof is to be administered once to the patient every approximately six weeks.

In another aspect, there is provided a composition comprising about 400 mg of pembrolizumab and a pharmaceutically acceptable carrier.

In another aspect, there is provided a kit for use in treating a patient with cancer, the kit comprising:

(a) about 400 mg of an anti-PD-1 antibody or antigen binding fragment thereof as defined herein, and

(b) instructions for using the anti-PD-1 antibody or antigen binding fragment thereof, in the use as defined herein.

In another aspect, there is provided use of the composition as defined herein in the manufacture of a medicament for treating an individual suffering from cancer.

In all of the above treatment methods, compositions and uses herein, the PD-1 antibody or antigen-binding fragment inhibits the binding of PD-L1 to PD-1, and preferably also inhibits the binding of PD-L2 to PD-1. In some preferred examples of the treatment methods, compositions and uses of the disclosure, the PD-1 antibody or antigen-binding fragment is a monoclonal antibody, which specifically binds to PD-1 and blocks the binding of PD-L1 to PD-1. In one particular example, the anti-PD-1 antibody comprises a heavy chain and a light chain, and wherein the heavy and light chains comprise the amino acid sequences shown in Figure 1 (SEQ ID NO:5 and SEQ ID NO:10).

In some examples of any of the above treatment methods, compositions and uses, the cancer expresses one or both of PD-L1 and PD-L2. In some examples, PD-L1 expression is elevated in the cancer.

In certain examples of any of the methods described herein, the anti-PD-1 antibody or antigen binding fragment is administered to a patient subcutaneously.

WHAT IS CLAIMED IS:

1. Use of an anti-PD-1 antibody, or antigen binding fragment thereof in the manufacture of a medicament for treating cancer in a human patient, wherein the anti-PD-1 antibody or antigen-binding fragment thereof comprises:

(a) light chain complementarity determining regions (CDRs) comprising a sequence of amino acids as set forth in SEQ ID NOs: 1, 2 and 3 and heavy chain CDRs comprising a sequence of amino acids as set forth in SEQ ID NOs: 6, 7 and 8; or

(b) light chain CDRs comprising a sequence of amino acids as set forth in SEQ ID NOs: 11, 12 and 13 and heavy chain CDRs comprising a sequence of amino acids as set forth in SEQ ID NOs: 14, 15 and 16, and

wherein about 400 mg of the anti-PD-1 antibody or antigen-binding fragment thereof is to be administered once to the patient every approximately six weeks.

2. The use of claim 1, wherein the anti-PD-1 antibody or antigen-binding fragment thereof comprises:

(a) a heavy chain variable region comprising a sequence of amino acids as set forth in SEQ ID NO:9, or a variant of SEQ ID NO:9, and

(b) a light chain variable region comprising:

(i) a sequence of amino acids as set forth in SEQ ID NO:4, or a variant of SEQ ID NO:4,

(ii) a sequence of amino acids as set forth in SEQ ID NO:22, or a variant of SEQ ID NO:22, or

(iii) a sequence of amino acids as set forth in SEQ ID NO:23, or a variant of SEQ ID NO:23.

3. The use of claim 1 or 2, wherein the anti-PD-1 antibody or antigen-binding fragment thereof comprises a heavy chain variable region comprising a sequence of amino acids as set forth in SEQ ID NO:9 and a light chain variable region comprising a sequence of amino acids as set forth in SEQ ID NO:4.

4. The use of claim 1 or 2, wherein the anti-PD-1 antibody or antigen-binding fragment thereof is a monoclonal antibody comprising:

(a) a heavy chain comprising a sequence of amino acids as set forth in SEQ ID NO:10, or a variant of SEQ ID NO:10, and

(b) a light chain comprising a sequence of amino acids as set forth in SEQ ID NO:5, a variant of SEQ ID NO:5, SEQ ID NO:24, a variant of SEQ ID NO:24, SEQ ID NO:25, or a variant of SEQ ID NO:25.

5. The use of any of claims 1-4, wherein the anti-PD-1 antibody or antigen-binding fragment thereof is a monoclonal antibody comprising a heavy chain comprising a sequence of amino acids as set forth in SEQ ID NO:10 and a light chain comprising a sequence of amino acids as set forth in SEQ ID NO:5.

6. The use of any of claims 1-5, wherein the cancer is selected from the group consisting of: melanoma, non-small cell lung cancer, head and neck cancer, urothelial cancer, breast cancer, gastrointestinal cancer, multiple myeloma, hepatocellular cancer, non-Hodgkin lymphoma, renal cancer, Hodgkin lymphoma, mesothelioma, ovarian cancer, small cell lung cancer, esophageal cancer, anal cancer, biliary tract cancer, colorectal cancer, cervical cancer, thyroid cancer, endometrial cancer, squamous cell carcinoma, or salivary cancer.

7. The use of any of claims 1-6, wherein the patient has a tumor with a high mutational burden.

8. The use of any of claims 1-5, wherein the patient has a microsatellite instability-high (MSI-H) or mismatch repair deficient solid tumor.

9. The use of any of claims 1-5, wherein the cancer is unresectable or metastatic melanoma.

10. The use of any of claims 1-5, wherein the cancer is metastatic non-small cell lung cancer (NSCLC).

11. The use of any of claims 1-5, wherein the cancer is recurrent or metastatic head and neck squamous cell cancer (HNSCC).

12. The use of any of claims 1-5, wherein the cancer is (1) refractory classical Hodgkin lymphoma (cHL), or (2) cHL and the patient has relapsed after 3 or more lines of therapy for cHL.

13. The use of any of claims 1-5, wherein the cancer is locally advanced or metastatic urothelial carcinoma.

14. The use of any of claims 1-5, wherein the cancer is locally advanced or metastatic gastric cancer or gastroesophageal junction adenocarcinoma.

15. The use of any of claims 1-5, wherein the cancer is cervical cancer.

16. The use of any of claims 1-5, wherein the cancer is primary mediastinal large B-cell lymphoma (PMBCL).

17. The use of any of claims 1-5, wherein the cancer is resected high-risk stage III melanoma.

18. The use of any of claims 1-5, wherein the cancer is hepatocellular carcinoma.

19. The use of any of claims 1-5, wherein the cancer is renal cell carcinoma (RCC).

20. The use of any of claims 1-5, wherein the cancer is recurrent, locally advanced or metastatic Merkel cell carcinoma (MCC).

21. The use of any of claims 1-20, wherein the anti-PD-1 antibody or antigen-binding fragment thereof is pembrolizumab.

22. A composition comprising about 400 mg of pembrolizumab and a pharmaceutically acceptable carrier.

23. The composition of claim 22, further comprising 10 mM histidine, pH 5.5, 7% sucrose, and 0.02% polysorbate 80.

24. A kit for use in treating a patient with cancer, the kit comprising:

(a) about 400 mg of an anti-PD-1 antibody or antigen binding fragment thereof as defined in any of claims 1 to 21, and

(b) instructions for using the anti-PD-1 antibody or antigen binding fragment thereof, in the use of any of claims 1-~~20~~21.

25. The kit for use of claim 24, wherein the anti-PD-1 antibody is pembrolizumab.

26. Use of the composition of any of claims 22-23 in the manufacture of a medicament for treating an individual suffering from cancer.

27. The use of claim 26 or the kit of claim 24 or 25, wherein the cancer is melanoma, lung cancer, head and neck cancer, bladder cancer, breast cancer, gastrointestinal cancer, multiple myeloma, hepatocellular cancer, lymphoma, renal cancer, mesothelioma, ovarian cancer, esophageal cancer, anal cancer, biliary tract cancer, colorectal cancer, cervical cancer, thyroid cancer, endometrial cancer, squamous cell carcinoma, or salivary cancer.

28. The use of any of claims 1-5, wherein the cancer is endometrial cancer.