

WHAT IS CLAIMED IS:

1. A method of treating cancer in a patient, comprising administering to said patient:
 - (i) epacadostat, or a pharmaceutically acceptable salt thereof, at a dose from about 400 mg to about 700 mg on a free base basis BID; and
 - (ii) an antibody, or an antigen-binding fragment thereof, that binds to human PD-1, wherein the antibody comprises (ii-1) a variable heavy (VH) domain comprising VH complementarity determining region (CDR)1, VH CDR2, and VH CDR3; and (ii-2) a variable light (VL) domain comprising VL CDR1, VL CDR2, and VL CDR3; wherein:
 - (a) the VH CDR1 comprises the amino acid sequence SYWMN (**SEQ ID NO:6**);
 - (b) the VH CDR2 comprises the amino acid sequence VIHPDSETWLDQKFKD (**SEQ ID NO:7**);
 - (c) the VH CDR3 comprises the amino acid sequence EHYGTSPFAY (**SEQ ID NO:8**);
 - (d) the VL CDR1 comprises the amino acid sequence RASESVDNYGMSFMNW (**SEQ ID NO:9**);
 - (e) the VL CDR2 comprises the amino acid sequence AASNQGS (**SEQ ID NO:10**); and
 - (f) the VL CDR3 comprises the amino acid sequence QQSKEVPYT (**SEQ ID NO:11**).
2. The method of claim 1, wherein the epacadostat is administered as the free base.
3. The method of claim 2, wherein the epacadostat is administered at a dose of about 400 mg BID.
4. The method of claim 2, wherein the epacadostat is administered at a dose of about 425 mg BID.
5. The method of claim 2, wherein the epacadostat is administered at a dose of about 450 mg BID.
6. The method of claim 2, wherein the epacadostat is administered at a dose of about 475 mg BID.

7. The method of claim 2, wherein the epacadostat is administered at a dose of about 500 mg BID.
8. The method of claim 2, wherein the epacadostat is administered at a dose of about 525 mg BID.
9. The method of claim 2, wherein the epacadostat is administered at a dose of about 550 mg BID.
10. The method of claim 2, wherein the epacadostat is administered at a dose of about 575 mg BID.
11. The method of claim 2, wherein the epacadostat is administered at a dose of about 600 mg BID.
12. The method of any one of claims 1-11, wherein the antibody is administered at a dose of about 500 mg.
13. The method of any one of claims 1-11, wherein the antibody is administered at a fixed dose of about 500 mg once every four weeks.
14. The method of any one of claims 1-11, wherein the antibody is administered at a fixed dose of about 375 mg once every 3 weeks.
15. The method of any one of claims 1-14, wherein the antibody is administered via intravenous administration.
16. The method of any one of claims 1-15, wherein the VH domain comprises the amino acid sequence set forth in **SEQ ID NO:4**.
17. The method of any one of claims 1-16, wherein the antibody comprises a heavy chain and wherein the heavy chain comprises the amino acid sequence set forth in **SEQ ID NO:2**.

18. The method of any one of claims 1-17, wherein the VL domain comprises the amino acid sequence set forth in **SEQ ID NO:5**.
19. The method of any one of claims 1-18, wherein the antibody comprises a light chain and wherein the light chain comprises the amino acid sequence set forth in **SEQ ID NO:3**.
20. The method of any one of claims 1-19, wherein the VH domain comprises the amino acid sequence set forth in **SEQ ID NO:4** and the VL domain comprises the amino acid sequence set forth in **SEQ ID NO:5**.
21. The method of any one of claims 1-20, wherein the antibody comprises a heavy chain and a light chain, and wherein the heavy chain comprises the amino acid sequence set forth in **SEQ ID NO:2** and the light chain comprises the amino acid sequence set forth in **SEQ ID NO:3**.
22. The method of any one of claims 1-21, wherein the antibody comprises an Fc Region of the IgG4 isotype and an IgG4 Hinge Domain that comprises a stabilizing mutation.
23. The method of any one of claims 1-22, wherein the antibody is a humanized antibody.
24. The method of any one of claims 1-23, wherein the cancer is a solid tumor.
25. The method of any one of claims 1-24, wherein the cancer is skin cancer, lung cancer, lymphoma, sarcoma, bladder cancer, cancer of the ureter, urethra, and urachus, gastric cancer, cervical cancer, liver cancer, breast cancer, renal cancer, head and neck cancer, squamous cell carcinoma, colorectal cancer, endometrial cancer, anal cancer, and a tumor with microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or DNA polymerase ϵ exonuclease domain mutation positive disease.
26. The method of any one of claims 1-24, wherein the cancer is cholangiocarcinoma, melanoma, non-small cell lung cancer, small cell lung cancer, Hodgkin's lymphoma, urothelial carcinomagastric cancer, hepatocellular carcinoma, Merkel cell carcinoma, triple-negative breast cancer, renal cell carcinoma, squamous cell carcinoma of the head and neck, and colorectal cancer.

27. The method of any one of claims 1-24, wherein the cancer is squamous cell carcinoma of the anal canal.
28. The method of any one of claims 1-24, wherein the cancer is Merkel cell carcinoma.
29. The method of any one of claims 1-24, wherein the cancer is endometrial cancer.
30. The method of any one of claims 1-24, wherein the cancer is cervical cancer.
31. The method of any one of claims 1-24, wherein the cancer is renal cancer.
32. The method of claim 31, wherein the cancer is kidney renal clear cell carcinoma.
33. The method of any one of claims 1-24, wherein the cancer is lung cancer.
34. The method of claim 33, wherein the cancer is adenocarcinoma of the lung.
35. The method of claim 33, wherein the cancer is squamous cell carcinoma of the lung.
36. The method of claim 33, wherein the cancer is non-small cell lung cancer.
37. The method of any one of claims 1-24, wherein the cancer is head and neck cancer.
38. The method of claim 37, wherein the cancer is head and neck squamous cell carcinoma.
39. The method of any one of claims 1-24, wherein the cancer is bladder cancer.
40. The method of claim 39, wherein the bladder cancer is high risk BCG-unresponsive non-muscle invasive bladder cancer.
41. The method of any one of claims 1-40, wherein the cancer is microsatellite-stable (MSS).

42. The method of any one of claims 1-40, wherein the cancer is PD-L1 positive.
43. The method of any one of claims 1-41, wherein the cancer is microsatellite-stable (MSS) and PD-L1 positive.