

WHAT IS CLAIMED:

1. A method of treating a solid tumor in a human subject, the method comprising administering to the subject
(i) about 0.1 to about 20 mg/kg of an anti-B7-H4 antibody or antigen-binding fragment thereof that specifically binds to human B7-H4 and comprises a heavy chain variable region (VH) complementarity determining region (CDR) 1 comprising the amino acid sequence of SEQ ID NO:5, a VH CDR2 comprising the amino acid sequence of SEQ ID NO:6, a VH CDR3 comprising the amino acid sequence of SEQ ID NO:7, a light chain variable region (VL) CDR1 comprising the amino acid sequence of SEQ ID NO:8, a VL CDR2 comprising the amino acid sequence of SEQ ID NO:9, and a VL CDR3 comprising the amino acid sequence of SEQ ID NO:10; and (ii) about 200 mg of an anti-PD-1 antibody or antigen-binding fragment thereof comprising a VH CDR1 comprising the amino acid sequence of SEQ ID NO:34, a VH CDR2 comprising the amino acid sequence of SEQ ID NO:35, a VH CDR3 comprising the amino acid sequence of SEQ ID NO:36, a VL CDR1 comprising the amino acid sequence of SEQ ID NO:37, a VL CDR2 comprising the amino acid sequence of SEQ ID NO:38, and a VL CDR3 comprising the amino acid sequence of SEQ ID NO:39; or
2. ~~A method of treating a solid tumor in a human subject, the method comprising administering to the subject~~
(a) a pharmaceutical composition comprising (i) anti-B7-H4 antibodies or antigen-binding fragment thereof, wherein the anti-B7-H4 antibodies or antigen-binding fragments thereof specifically bind to human B7-H4 and comprise a VH CDR1 comprising the amino acid sequence of SEQ ID NO:5, a VH CDR2 comprising the amino acid sequence of SEQ ID NO:6, a VH CDR3 comprising the amino acid sequence of SEQ ID NO:7, a VL CDR1 comprising the amino acid sequence of SEQ ID NO:8, a VL CDR2 comprising the amino acid sequence of SEQ ID NO:9, and a VL CDR3 comprising the amino acid sequence of SEQ ID NO:10 and (ii) a pharmaceutically acceptable excipient,
wherein at least 95% of the anti-B7-H4 antibodies or antigen-binding fragments thereof in the composition are afucosylated, and

wherein about 0.1 to about 20 mg/kg of the antibodies or antigen-binding fragments thereof are administered; and

(b) a pharmaceutical composition comprising an anti-PD-1 antibody or antigen-binding fragment thereof comprising a VH CDR1 comprising the amino acid sequence of SEQ ID NO:34, a VH CDR2 comprising the amino acid sequence of SEQ ID NO:35, a VH CDR3 comprising the amino acid sequence of SEQ ID NO:36, a VL CDR1 comprising the amino acid sequence of SEQ ID NO:37, a VL CDR2 comprising the amino acid sequence of SEQ ID NO:38, and a VL CDR3 comprising the amino acid sequence of SEQ ID NO:39 and a pharmaceutically acceptable excipient, wherein about 200 mg of the antibody or antigen-binding fragment is administered;

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3. ~~The method of claim 1 or 2, wherein about 20 mg/kg of the anti-B7-H4 antibody or antigen-binding fragment thereof is administered to the subject.~~
 4. ~~The method of claim 1 or 2, wherein about 10 mg/kg of the anti-B7-H4 antibody or antigen-binding fragment thereof is administered to the subject.~~
 5. ~~The method of claim 1 or 2, wherein about 3 mg/kg of the anti-B7-H4 antibody or antigen-binding fragment thereof is administered to the subject.~~
 6. ~~The method of claim 1 or 2, wherein about 1 mg/kg of the anti-B7-H4 antibody or antigen-binding fragment thereof is administered to the subject.~~
 7. ~~The method of claim 1 or 2, wherein about 0.3 mg/kg of the anti-B7-H4 antibody or antigen-binding fragment thereof is administered to the subject.~~
 8. ~~The method of claim 1 or 2, wherein about 0.1 mg/kg of the anti-B7-H4 antibody or antigen-binding fragment thereof is administered to the subject.~~
 9. ~~The method of any one of claims 1-8, wherein the anti-B7-H4 antibody or antigen-binding fragment thereof and the anti-PD-1 antibody or antigen-binding fragment are administered~~

concurrently.

10. — ~~The method of claim 9, wherein the anti-B7-H4 antibody or antigen-binding fragment thereof and the anti-PD-1 antibody or antigen-binding fragment are administered as separate formulations on the same day.~~
11. — ~~The method of any one of claims 1-8, wherein the anti-B7-H4 antibody or antigen-binding fragment thereof and the anti-PD-1 antibody or antigen-binding fragment thereof are administered sequentially.~~
12. — ~~The method of claim 8, wherein the anti-PD-1 antibody or antigen-binding fragment thereof is administered after the anti-B7-H4 antibody or antigen-binding fragment thereof is administered.~~
13. — ~~The method of any one of claims 1-12, wherein the anti-B7-H4 antibody or antigen-binding fragment thereof is administered about once every three weeks.~~
14. — ~~The method of any one of claims 1-12, wherein the anti-PD-1 antibody or antigen-binding fragment thereof is administered about once every three weeks.~~
15. — ~~The method of any one of claims 1-12, wherein the anti-B7-H4 antibody or antigen-binding fragment thereof and the anti-PD-1 antibody or antigen-binding fragment thereof are each administered about once every three weeks.~~
16. — ~~The method of any one of claims 1-15, wherein the anti-B7-H4 antibody or antigen-binding fragment thereof is administered intravenously.~~
17. — ~~The method of any one of claims 1-16, wherein the anti-PD-1 antibody or antigen-binding fragment thereof is administered intravenously.~~
18. — ~~The method of any one of claims 1-17, wherein B7-H4 has been detected in the solid tumor~~

using immunohistochemistry (IHC) prior to the administration.

19. ~~The method of any one of claims 1-18, wherein the anti-B7-H4 antibody or antigen-binding fragment thereof comprises a VH comprising the amino acid sequence set forth in SEQ ID NO:11 and/or a VL comprising the amino acid sequence set forth in SEQ ID NO:12.~~
20. ~~The method of any one of claims 1-19, wherein the anti-B7-H4 antibody or antigen-binding fragment comprises a heavy chain constant region and/or a light chain constant region.~~
21. ~~The method of claim 20, wherein the heavy chain constant region is a human immunoglobulin IgG₁ heavy chain constant region and/or wherein the light chain constant region is a human immunoglobulin IgG_κ light chain constant region.~~
22. ~~The method of any one of claims 1-21, wherein the anti-B7-H4 antibody or antigen-binding fragment thereof comprises a heavy chain constant region comprising the amino acid sequence set forth in SEQ ID NO:25 and/or a light chain constant region comprising the amino acid sequence set forth in SEQ ID NO:23.~~
23. ~~The method of any one of claims 1-22, wherein the anti-B7-H4 antibody or antigen-binding fragment thereof comprises a heavy chain comprising the amino acid sequence set forth in SEQ ID NO:21 and/or a light chain comprising the amino acid sequence set forth in SEQ ID NO:22.~~
24. ~~The method of any one of claims 1-23, wherein the anti-B7-H4 antibody or antigen-binding fragment thereof is a human antibody or antigen-binding fragment thereof.~~
25. ~~The method of any one of claims 1 and 3-24, wherein the anti-B7-H4 antibody or antigen-binding fragment thereof is afucosylated.~~
26. ~~The method of any one of claims 1-25, wherein the anti-B7-H4 antibody or antigen-binding fragment thereof is a full length antibody.~~

- ~~27. The method of any one of claims 1-25, wherein the anti-B7-H4 antibody or antigen-binding fragment thereof is an antigen-binding fragment.~~
- ~~28. The method of claim 27, wherein the antigen-binding fragment comprises a Fab, Fab', F(ab')₂, single chain Fv (scFv), disulfide linked Fv, V-NAR domain, IgNar, intrabody, IgGΔCH2, minibody, F(ab')₃, tetrabody, triabody, diabody, single-domain antibody, DVD-Ig, Fcab, mAb², (scFv)₂, or scFv-Fc.~~
- ~~29. The method of any one of claims 2-29, wherein fucosylation of the anti-B7-H4 antibody or antigen-binding fragment thereof is undetectable in the composition.~~
- ~~30. The method of any one of claims 1-29, wherein the anti-PD-1 antibody or antigen-binding fragment comprises a VH comprising the amino acid sequence of SEQ ID NO:32 and a VL comprising the amino acid sequence SEQ ID NO:33.~~
- ~~31. The method of any one of claims 1-30, wherein the anti-PD-1 antibody or antigen-binding fragment is pembrolizumab.~~
- ~~32. The method of claim 31, wherein the method comprises administering 200 mg of pembrolizumab.~~
- ~~33. The method of any one of claims 1-32, wherein the method comprising administering to the subject (i) 3, 10 or 20 mg/kg of an anti-B7-H4 antibody or antigen-binding fragment thereof that specifically binds to human B7-H4 and comprises a VH comprising the amino acid sequence set forth in SEQ ID NO:11 and a VL comprising the amino acid sequence set forth in SEQ ID NO:12, wherein the anti-B7-H4 antibody or antigen-binding fragment is not detectably fucosylated; and (ii) 200 mg of pembrolizumab; wherein (i) and (ii) are administered intravenously as separate formulations on the same day.~~
- ~~34. The method of claim 33, wherein the anti-B7-H4 antibody comprises a heavy chain comprising the amino acid sequence set forth in SEQ ID NO:21 and a light chain~~

comprising the amino acid sequence set forth in SEQ ID NO:22.

35. — The method of any one of claims 1-34, wherein the solid tumor expresses B7-H4.
36. — The method of any of claims 1-35, wherein the solid tumor is unresectable, locally advanced, or metastatic.
37. — The method of any one of claims 1-36, wherein the solid tumor is selected from the group consisting of breast cancer, ductal carcinoma, endometrial carcinoma, ovarian cancer, urothelial cancer, non-small cell lung cancer, pancreatic cancer, thyroid cancer, kidney cancer and bladder cancer.
38. — The method of claim 37, wherein the solid tumor is breast cancer or ovarian cancer.
39. — The method of claim 38, wherein the solid tumor is breast cancer.
40. — The method of claim 39, wherein the breast cancer is advanced breast cancer.
41. — The method of any one of claims 38-40, wherein the breast cancer is triple negative breast cancer.
42. — The method of any one of claims 38-40, wherein the breast cancer is a hormone receptor (HR)-positive breast cancer.
43. — The method of claim 37, wherein the non-small cell lung cancer is squamous cell carcinoma.
44. — The method of any one of claims 1-43, wherein the patient has not received prior therapy with a PD-1/PD-L1 antagonist.
45. — The method of any one of claims 1-44, wherein the method further comprises monitoring

the number of immune cells in the tumor.

- ~~46. The method of any one of claims 1-44, wherein the method further comprises monitoring the number of natural killer (NK) cells, CD4+ cells, and/or CD8+ cells in the tumor.~~
- ~~47. The method of any one of claims 1-47, wherein method further comprises monitoring cytokine levels in the subject.~~
- ~~48. The method of any one of claims 1-47, wherein the method further comprises monitoring IL-2, IL-6, IL-10, TNF, and/or interferon gamma (IFN γ) levels in the subject.~~
- ~~49. A method of treating a solid tumor in a human subject, the method comprising administering to the subject (i) about 20 mg/kg of an anti-B7-H4 antibody that specifically binds to human B7-H4 and comprises a VH comprising the amino acid sequence of SEQ ID NO:11 and a VL comprising the amino acid sequence of SEQ ID NO:12; and (ii) about 200 mg of an anti-PD-1 antibody comprising a VH comprising the amino acid sequence of SEQ ID NO:32 and a VL comprising the amino acid sequence of SEQ ID NO:33, wherein the anti-B7-H4 antibody and the anti-PD-1 antibody are administered intravenously about once every three weeks.~~
- ~~50. A method of treating a solid tumor in a human subject, the method comprising administering to the subject~~
- ~~(a) a pharmaceutical composition comprising (i) anti-B7-H4 antibodies that specifically bind to human B7-H4 and comprise a VH comprising the amino acid sequence of SEQ ID NO:11 and a VL comprising the amino acid sequence of SEQ ID NO:12 and (ii) a pharmaceutically acceptable excipient,~~
- ~~wherein at least 95% of the anti-B7-H4 antibodies thereof in the composition are afucosylated, and~~
- ~~wherein about 20 mg/kg of the antibodies are administered; and~~
- ~~(b) a pharmaceutical composition comprising an anti-PD-1 antibody or antigen-binding~~

fragment thereof comprising a VH comprising the amino acid sequence of SEQ ID NO:32 and a VL comprising the amino acid sequence of SEQ ID NO:33 and a pharmaceutically acceptable excipient, wherein about 200 mg of the antibody or antigen-binding fragment is administered, wherein the anti-B7-H4 antibody and the anti-PD-1 antibody are administered intravenously about once every three weeks.

51. The method of claim 49 or 50, wherein the anti-B7-H4 antibody comprises a heavy chain comprising the amino acid sequence set forth in SEQ ID NO:21 and a light chain comprising the amino acid sequence set forth in SEQ ID NO:22.
52. The method of any one of claims 49-51, wherein the anti-PD-1 antibody comprises a heavy chain comprising the amino acid sequence set forth in SEQ ID NO:30 and a light chain comprising the amino acid sequence set forth in SEQ ID NO:31.
53. The method of any one of claims 49-53, wherein the solid tumor is breast cancer, optionally wherein the breast cancer is triple negative breast cancer, or ovarian cancer.