

WHAT IS CLAIMED:

1. ~~A method of treating a solid tumor in a human subject, the method comprising administering to the subject about 0.005 to about 20 mg/kg of an 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.~~
2. ~~A method of treating a solid tumor in a human subject, the method comprising administering to the subject a pharmaceutical composition comprising (i) antibodies or antigen-binding fragments thereof, wherein the 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 antibodies or antigen-binding fragments thereof in the composition are afucosylated, and
wherein about 0.005 to about 20 mg/kg of the antibodies or antigen-binding fragments thereof are administered.~~
3. ~~The method of claim 1 or 2, wherein about 20 mg/kg of the 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 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 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 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 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 antibody or antigen-binding fragment thereof is administered to the subject.~~
9. ~~The method of claim 1 or 2, wherein about 0.03 mg/kg of the antibody or antigen-binding fragment thereof is administered to the subject.~~
10. ~~The method of claim 1 or 2, wherein about 0.01 mg/kg of the antibody or antigen-binding fragment thereof is administered to the subject.~~
11. ~~The method of claim 1 or 2, wherein about 0.005 mg/kg of the antibody or antigen-binding fragment thereof is administered to the subject.~~
12. ~~The method of any one of claims 1-11, wherein the antibody or antigen-binding fragment thereof is administered about once every three weeks.~~
13. ~~The method of any one of claims 1-12, wherein the antibody or antigen-binding fragment thereof is administered intravenously.~~
14. ~~The method of any one of claims 1-13, wherein B7-H4 has been detected in the solid tumor using immunohistochemistry (IHC) prior to the administration.~~

15. ~~The method of any one of claims 1-14, wherein the 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.~~
16. ~~The method of any one of claims 1-15, wherein the antibody or antigen-binding fragment comprises a heavy chain constant region and/or a light chain constant region.~~
17. ~~The method of claim 16, 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.~~
18. ~~The method of any one of claims 1-17, wherein the 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.~~
19. ~~The method of any one of claims 1-18, wherein the 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.~~
20. ~~The method of any one of claims 1-19, wherein the antibody or antigen-binding fragment thereof is a human antibody or antigen-binding fragment thereof.~~
21. ~~The method of any one of claims 1 and 3-19, wherein the antibody or antigen-binding fragment thereof is afucosylated.~~
22. ~~The method of any one of claims 1-21, wherein the antibody or antigen-binding fragment thereof is a full-length antibody.~~

23. ~~The method of any one of claims 1-21, wherein the antibody or antigen-binding fragment thereof is an antigen-binding fragment.~~
24. ~~The method of claim 23, wherein the antigen-binding fragment comprises a Fab, Fab', F(ab')₂, single-chain Fv (scFv), disulfide-linked Fv, V-NAR domain, IgNar, intrabody, IgGACH2, minibody, F(ab')₃, tetrabody, triabody, diabody, single-domain antibody, DVD-Ig, Fcab, mAb², (scFv)₂, or scFv-Fc.~~
25. ~~The method of any one of claims 2-24, wherein fucosylation is undetectable in the composition.~~
26. ~~The method of any one of claims 1-25, wherein the solid tumor expresses B7-H4.~~
27. ~~The method of any of claims 1-26, wherein the solid tumor is unresectable, locally advanced, or metastatic.~~
28. ~~The method of any one of claims 1-27, 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.~~
29. ~~The method of claim 28, wherein the solid tumor is breast cancer, ovarian cancer, endometrial cancer, or urothelial cancer.~~
30. ~~The method of claim 28 or 29, wherein the breast cancer is advanced breast cancer.~~
31. ~~The method of any one of claims 28-30, wherein the breast cancer is HER2-negative.~~
32. ~~The method of any one of claims 28-31, wherein the breast cancer is triple-negative breast cancer.~~

- ~~33. The method of any one of claims 28-31, wherein the breast cancer is a hormone receptor (HR)-positive breast cancer.~~
- ~~34. The method of claim 28, wherein the non-small cell lung cancer is squamous cell carcinoma.~~
- ~~35. The method of any one of claims 1-34, wherein the subject has not received prior therapy with a PD-1/PD-L1 antagonist.~~
- ~~36. The method of any one of claims 1-35, wherein the method further comprises monitoring the number of immune cells in the tumor.~~
- ~~37. The method of any one of claims 1-35, wherein the method further comprises monitoring the number of natural killer (NK) cells, CD4⁺ cells, and/or CD8⁺ cells in the tumor.~~
- ~~38. The method of any one of claims 1-37, wherein method further comprises monitoring cytokine levels in the subject.~~
- ~~39. The method of any one of claims 1-37, wherein the method further comprises monitoring IL-2, IL-6, IL-10, TNF, and/or interferon gamma (IFN γ) levels in the subject.~~
- ~~40. A method of treating a solid tumor in a human subject, the method comprising intravenously administering to the subject about once every three weeks about 20 mg/kg of an antibody 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.~~
- ~~41. A method of treating a solid tumor in a human subject, the method comprising administering to the subject a pharmaceutical composition comprising (i) antibodies that specifically bind to human B7-H4 and comprise 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 and (ii) a pharmaceutically acceptable excipient,~~

~~wherein at least 95% of the antibodies or antigen-binding fragments thereof in the composition are afucosylated, and~~

~~wherein about 20 mg/kg of the antibodies or antigen-binding fragments thereof are administered intravenously about once every three weeks.~~

~~42. The method of claim 40 or 41, wherein the 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.~~

~~43. The method of any one of claims 40-42, wherein the solid tumor is breast cancer, ovarian cancer, endometrial cancer, or urothelial cancer.~~

Claims

1. An invention not claimed in any divisional application.