

on the surface of cancer cells, and which can thereby mediate T-cell activation, simulation of an immune response and killing of cancer cells that express B7-H3. It is an object of this invention to identify such compositions and treatment regimens.

Summary:

[0021] The present disclosure is directed to combination therapy involving the administration of a first molecule that specifically binds to human B7-H3 (*i.e.*, a B7-H3-binding molecule) and a second molecule that specifically binds to human PD-1 (*i.e.*, a PD-1-binding molecule) to a subject for the treatment of cancer and inflammation. The disclosure also concerns pharmaceutical compositions that comprise a first molecule that specifically binds to human B7-H3 and a second molecule that specifically binds to human PD-1 that are capable of mediating, and more preferably enhancing, the activation of the immune system against cancer cells that are associated with a variety of human cancers. The disclosure also relates to the use of such pharmaceutical compositions to treat cancer and other diseases.

[0021a] In one aspect, there is provided use of an anti-B7-H3 antibody or antigen-binding fragment thereof in the manufacture of a medicament for treating a B7-H3-expressing cancer in a subject in need thereof, wherein said anti-B7-H3 antibody or antigen-binding fragment thereof is to be administered: (a) at a dosage of 1-15 mg/kg body weight; and (b) in combination with an anti-PD-1 antibody or antigen-binding fragment thereof, wherein said anti-PD-1 antibody or antigen-binding fragment thereof is to be administered at: (1) a fixed dosage of between 50 mg and 500 mg; or (2) a dosage of 1-10 mg/kg body weight.

[0022] The disclosure also provides a method of treating a cancer comprising administering to a subject in need thereof, a molecule that specifically binds to B7-H3, and a molecule that specifically binds to PD-1.

[0023] The disclosure particularly concerns examples of such uses and methods, wherein the molecule that specifically binds to B7-H3 is an anti-B7-H3 antibody or antigen-binding fragment thereof, and the molecule that specifically binds to PD-1 is an anti-PD-1 antibody, or an antigen-binding fragment thereof.

[0024] The disclosure particularly concerns the example of such uses and methods wherein the anti-B7-H3 antibody, or antigen-binding fragment thereof:

- (a) competes for B7-H3 binding with BRCA84D, BRCA69D, PRCA157, or with an anti-B7-H3 antibody selected from **Table 5**; or
- (b) has the three heavy chain CDRs and the three light chain CDRs of BRCA84D, hBRCA84D (1.1), hBRCA84D (2.2), hBRCA84D-2, hBRCA69D (1.1), hBRCA (2.2), or the three heavy chain CDRs and the three light chain CDRs of an anti-B7-H3 selected from **Table 5**; or
- (c) has the heavy chain variable domain and the light chain variable domain of BRCA84D, hBRCA84D (1.1), hBRCA84D (2.2), hBRCA84D-2, hBRCA69D (1.1), hBRCA (2.2), or the heavy chain variable domain

4. Additional anti-B7-H3 Antibodies

[00112] Additional anti-B7-H3 antibodies which may be utilized in the methods and compositions of the instant invention are provided in **Table 5**.

Table 5: Anti-B7-H3 Antibodies	
B7-H3 Antibodies	Reference
LUCA1; BLA8; PA20; and SKIN2	US Patent No. 7,527,969; 8,779,098; and PCT Patent Publication WO 2004/001381
M30; cM30; M30-H1-L1; M30-H1-L2; M30-H1-L3; M30-H1-L4; M30-H1-L5; M30-H1-L6; M30-H1-L7; M30-H4-L1; M30-H4-L2; M30-H4-L3; and M30-H4-L4	US Patent Publication 2013/0078234; and PCT Patent Publication WO 2012/147713
8H9	US Patent No. 7,666,424; 7,737,258; 7,740,845; 8,148,154; 8,414,892; 8,501,471; 9,062,110; US Patent Publication 2010/0143245; and PCT Patent Publication WO 2008/116219

5. Exemplary Anti-B7-H3 Antibodies

[00113] In certain embodiments B7-H3 antibodies useful in the methods and compositions of the instant inventions comprise the VL and VH Domains of any of the antibodies provided above (*e.g.*, hBRCA84D, hBRCA69D, PRCA157, or the VL and VH Domains of any of the anti-B7-H3 antibodies in **Table 5**), a kappa CL Domain, and a variant IgG1 Fc Domain having enhanced ADCC (relative to a wild-type Fc Domain). In one embodiment, the CH2-CH3 Domains comprise the L235V, F243L, R292P, Y300L and P396L substitutions (wherein the numbering is according to the EU index as in Kabat). Such antibodies will preferably comprise an IgG1 CH1 Domain and Hinge Domain.

[00114] The amino acid sequence of a kappa CL Domain (**SEQ ID NO:13**) is shown below.

```
RTVAAPSVFI FPPSDEQLKS GTASVVCLLN NFYPREAKVQ WKVDNALQSG
NSQESVTEQD SKDSTYSLSS TLTLKADYE KHKVYACEVT HQGLSSPVTK
SFNRGEC
```

[00115] The amino acid sequence of an IgG1 CH1 Domain and Hinge (**SEQ ID NO:14**) is shown below.

```
ASTKGPSVFP LAPSSKSTSG GTAALGCLVK DYFPEPVTVS WNSGALTSGV
HTFPAVLQSS GLYSLSSVVT VPSSSLGTQT YICNVNHKPS NTKVDRVEP
KSCDKTHTCP PCP
```

What Is Claimed Is:

Claim 1. Use of an anti-B7-H3 antibody or antigen-binding fragment thereof in the manufacture of a medicament for treating a B7-H3-expressing cancer in a subject in need thereof, wherein said anti-B7-H3 antibody or antigen-binding fragment thereof is to be administered:

- (a) at a dosage of 1-15 mg/kg body weight; and
- (b) in combination with an anti-PD-1 antibody or antigen-binding fragment thereof, wherein said anti-PD-1 antibody or antigen-binding fragment thereof is to be administered at:
 - (1) a fixed dosage of between 50 mg and 500 mg; or
 - (2) a dosage of 1-10 mg/kg body weight.

Claim 2. The use of claim 1, wherein said anti-B7-H3 antibody, or antigen-binding fragment thereof:

- (a) competes for B7-H3 binding with an anti-B7-H3 antibody:
 - (1) comprising a heavy chain variable domain comprising the amino acid sequence of SEQ ID NO:20 and a light chain variable domain comprising the amino acid sequence of SEQ ID NO: 19; or
 - (2) comprising a heavy chain variable domain comprising the amino acid sequence of SEQ ID NO:32 and a light chain variable domain comprising the amino acid sequence of SEQ ID NO:31; or
 - (3) comprising a heavy chain variable domain comprising the amino acid sequence of SEQ ID NO:38 and a light chain variable domain comprising the amino acid sequence of SEQ ID NO:37; or
 - (4) selected from the group consisting of: BLA8; PA20; SKIN2; M30; and 8H9; or
- (b) comprises:
 - (1) the three heavy chain CDRs of a heavy chain variable domain comprising the amino acid sequence of SEQ ID NO:20, and the

- three light chain CDRs of a light chain variable domain comprising the amino acid sequence of SEQ ID NO:19; or
- (2) the three heavy chain CDRs of a heavy chain variable domain comprising the amino acid sequence of SEQ ID NO:32 or 36, and the three light chain CDRs of a light chain variable domain comprising the amino acid sequence of SEQ ID NO:31 or 34; or
- (3) the three heavy chain CDRs of a heavy chain variable domain comprising the amino acid sequence of SEQ ID NO:38, and the three light chain CDRs of a light chain variable domain comprising the amino acid sequence of SEQ ID NO:37; or
- (4) the three heavy chain CDRs and the three light chain CDRs of an anti-B7-H3 antibody selected from the group consisting of: BLA8; PA20; SKIN2; M30; and 8H9;

wherein the numbering of the CDRs is according to the Kabat numbering scheme; or

- (c) comprises:
 - (1) a heavy chain variable domain comprising an amino acid sequence selected from the group consisting of SEQ ID NOs:20, 27, 28, 29 and 30, and a light chain variable domain comprising an amino acid sequence selected from the group consisting of SEQ ID NOs:19, 21, 22, 23, 24, 25 and 26; or
 - (2) a heavy chain variable domain comprising an amino acid sequence selected from the group consisting of SEQ ID NO:32, 35 and 36, and a light chain variable domain comprising an amino acid sequence selected from the group consisting of SEQ ID NO:31, 33 and 34; or
 - (3) a heavy chain variable domain comprising the amino acid sequence of SEQ ID NO:38, and a light chain variable domain comprising the amino acid sequence of SEQ ID NO:37; or
 - (4) a heavy chain variable domain and a light chain variable domain of an anti-B7-H3 antibody selected from the group consisting of: BLA8; PA20; SKIN2; M30; and 8H9.

Claim 3. The use of any one of claims 1-2, wherein said anti-PD-1 antibody, or antigen-binding fragment thereof:

- (a) competes for PD-1 binding with an anti-PD-1 antibody:
 - (1) selected from the group consisting of: nivolumab, pembrolizumab, pidilizumab, PD1-17; PD1-28; PD1-33; PD1-35; PD1-F2; 17D8; 2D3; 4H1; 5C4; 4A11; 7D3; 5F4; hPD-1.08A; hPD-1.09A; h409A11; h409A16; h409A17; 1E3; 1E8; 1H3; 9A2; 10B11; 6E9; APE1922; APE1923; APE1924; APE1950; APE1963; APE2058; GA1; GA2; GB1; GB6; GH1; A2; C7; H7; SH-A4; SH-A9; RG1H10; RG1H11; RG2H7; RG2H10; RG3E12; RG4A6; RG5D9; RG1H10-H2A-22-15; RG1H10-H2A-27-25; RG1H10-3C; RG1H10-16C; RG1H10-17C; RG1H10-19C; RG1H10-21C; RG1H10-23C2; H1M7789N; H1M7799N; H1M7800N; H2M7780N; H2M7788N; H2M7790N; H2M7791N; H2M7794N; H2M7795N; H2M7796N; H2M7798N; H4H9019P; H4xH9034P2; H4xH9035P2; H4xH9037P2; H4xH9045P2; H4xH9048P2; H4H9057P2; H4H9068P2; H4xH9119P2; H4xH9120P2; H4xH9128P2; H4xH9135P2; H4xH9145P2; H4xH8992P; H4xH8999P; and H4xH9008P; or
 - (2) comprising a heavy chain variable domain comprising the amino acid sequence of SEQ ID NO:46, and a light chain variable domain comprising the amino acid sequence of SEQ ID NO:47; or
 - (3) comprising a heavy chain variable domain comprising the amino acid sequence of SEQ ID NO:50, and a light chain variable domain comprising the amino acid sequence of SEQ ID NO:51; or
 - (4) comprising a heavy chain variable domain comprising the amino acid sequence of SEQ ID NO:52, and a light chain variable domain comprising the amino acid sequence of SEQ ID NO:53; or
 - (5) comprising a heavy chain variable domain comprising the amino acid sequence of SEQ ID NO:54, and a light chain

- variable domain comprising the amino acid sequence of SEQ ID NO:55; or
- (6) comprising a heavy chain variable domain comprising the amino acid sequence of SEQ ID NO:56, and a light chain variable domain comprising the amino acid sequence of SEQ ID NO:57; or
- (b) comprises:
- (1) the three heavy chain CDRs and the three light chain CDRs of an anti-PD-1 antibody selected from the group consisting of: nivolumab, pembrolizumab, pidilizumab, PD1-17; PD1-28; PD1-33; PD1-35; PD1-F2; 17D8; 2D3; 4H1; 5C4; 4A11; 7D3; 5F4; hPD-1.08A; hPD-1.09A; h409A11; h409A16; h409A17; 1E3; 1E8; 1H3; 9A2; 10B11; 6E9; APE1922; APE1923; APE1924; APE1950; APE1963; APE2058; GA1; GA2; GB1; GB6; GH1; A2; C7; H7; SH-A4; SH-A9; RG1H10; RG1H11; RG2H7; RG2H10; RG3E12; RG4A6; RG5D9; RG1H10-H2A-22-15; RG1H10-H2A-27-25; RG1H10-3C; RG1H10-16C; RG1H10-17C; RG1H10-19C; RG1H10-21C; RG1H10-23C2; H1M7789N; H1M7799N; H1M7800N; H2M7780N; H2M7788N; H2M7790N; H2M7791N; H2M7794N; H2M7795N; H2M7796N; H2M7798N; H4H9019P; H4xH9034P2; H4xH9035P2; H4xH9037P2; H4xH9045P2; H4xH9048P2; H4H9057P2; H4H9068P2; H4xH9119P2; H4xH9120P2; H4xH9128P2; H4xH9135P2; H4xH9145P2; H4xH8992P; H4xH8999P; and H4xH9008P; or
 - (2) the three heavy chain CDRs of a heavy chain variable domain comprising the amino acid sequence of SEQ ID NO:46, and the three light chain CDRs of a light chain variable domain comprising the amino acid sequence of SEQ ID NO:47; or
 - (3) the three heavy chain CDRs of a heavy chain variable domain comprising the amino acid sequence of SEQ ID NO:50, and the three light chain CDRs of a light chain variable domain comprising the amino acid sequence of SEQ ID NO:51; or

- (4) the three heavy chain CDRs of a heavy chain variable domain comprising the amino acid sequence of SEQ ID NO:52, and the three light chain CDRs of a light chain variable domain comprising the amino acid sequence of SEQ ID NO:53; or
- (5) the three heavy chain CDRs of a heavy chain variable domain comprising the amino acid sequence of SEQ ID NO:54, and the three light chain CDRs of a light chain variable domain comprising the amino acid sequence of SEQ ID NO:55; or
- (6) the three heavy chain CDRs of a heavy chain variable domain comprising the amino acid sequence of SEQ ID NO:56, and the three light chain CDRs of a light chain variable domain comprising the amino acid sequence of SEQ ID NO:57;

wherein the numbering of the CDRs is according to the Kabat numbering scheme; or

(c) comprises:

- (1) the heavy chain variable domain and the light chain variable domain of an anti-PD-1 antibody selected from the group consisting of: nivolumab, pembrolizumab, pidilizumab, PD1-17; PD1-28; PD1-33; PD1-35; PD1-F2; 17D8; 2D3; 4H1; 5C4; 4A11; 7D3; 5F4; hPD-1.08A; hPD-1.09A; h409A11; h409A16; h409A17; 1E3; 1E8; 1H3; 9A2; 10B11; 6E9; APE1922; APE1923; APE1924; APE1950; APE1963; APE2058; GA1; GA2; GB1; GB6; GH1; A2; C7; H7; SH-A4; SH-A9; RG1H10; RG1H11; RG2H7; RG2H10; RG3E12; RG4A6; RG5D9; RG1H10-H2A-22-15; RG1H10-H2A-27-25; RG1H10-3C; RG1H10-16C; RG1H10-17C; RG1H10-19C; RG1H10-21C; RG1H10-23C2; H1M7789N; H1M7799N; H1M7800N; H2M7780N; H2M7788N; H2M7790N; H2M7791N; H2M7794N; H2M7795N; H2M7796N; H2M7798N; H4H9019P; H4xH9034P2; H4xH9035P2; H4xH9037P2; H4xH9045P2; H4xH9048P2; H4H9057P2; H4H9068P2; H4xH9119P2; H4xH9120P2; H4xH9128P2; H4xH9135P2; H4xH9145P2; H4xH8992P; H4xH8999P; and H4xH9008P; or

- (2) a heavy chain variable domain comprising the amino acid sequence of SEQ ID NO:46, and a light chain variable domain comprising the amino acid sequence of SEQ ID NO:47; or
- (3) a heavy chain variable domain comprising the amino acid sequence of SEQ ID NO:50, and a light chain variable domain comprising the amino acid sequence of SEQ ID NO:51; or
- (4) a heavy chain variable domain comprising the amino acid sequence of SEQ ID NO:52, and a light chain variable domain comprising the amino acid sequence of SEQ ID NO:53; or
- (5) a heavy chain variable domain comprising the amino acid sequence of SEQ ID NO:54, and a light chain variable domain comprising the amino acid sequence of SEQ ID NO:55; or
- (6) a heavy chain variable domain comprising the amino acid sequence of SEQ ID NO:56, and a light chain variable domain comprising the amino acid sequence of SEQ ID NO:57.

Claim 4. The use of any one of claims 1-3, wherein said anti-B7-H3 antibody or antigen-binding fragment thereof comprises an Fc Domain, and said anti-PD-1 antibody or antigen-binding fragment thereof comprises an Fc Domain.

Claim 5. The use of claim 4, wherein said anti-B7-H3 antibody or antigen-binding fragment thereof, comprises a variant Fc Domain having at least one modification in the Fc Domain that enhances ADCC.

Claim 6. The use of claim 5, wherein said variant Fc Domain of said anti-B7-H3 antibody or antigen-binding fragment thereof comprises any one, any two, any three, any four, or all five of the substitutions L235V, F243L, R292P, Y300L, and P396L, wherein the numbering is according to the Kabat numbering scheme.

Claim 7. The use of any one of claims 5-6, wherein said variant Fc Domain of said anti-B7-H3 antibody or antigen-binding fragment thereof comprises:

- (A) at least one substitution selected from the group consisting of F243L, R292P, Y300L, V305I, and P396L;
- (B) at least two substitutions selected from the group consisting of:

- (1) F243L and P396L;
 - (2) F243L and R292P; and
 - (3) R292P and V305I;
 - (C) at least three substitutions selected from the group consisting of:
 - (1) F243L, R292P and Y300L;
 - (2) F243L, R292P and V305I;
 - (3) F243L, R292P and P396L; and
 - (4) R292P, V305I and P396L;
 - (D) at least four substitutions selected from the group consisting of:
 - (1) F243L, R292P, Y300L and P396L; and
 - (2) F243L, R292P, V305I and P396L; or
 - (E) at least the five substitutions selected from the group consisting of:
 - (1) F243L, R292P, Y300L, V305I and P396L; and
 - (2) L235V, F243L, R292P, Y300L and P396L;
- wherein the numbering is according to the Kabat numbering scheme.

Claim 8. The use of any one of claims 4-7, wherein said anti-PD-1 antibody or antigen-binding fragment thereof, comprises:

- (a) a variant Fc Domain having at least one modification in the Fc Domain that reduces or abolishes ADCC activity; or
- (b) an IgG4 Fc Domain.

Claim 9. The use of claim 8, wherein said variant Fc Domain of said anti-PD-1 antibody or antigen-binding fragment thereof comprises any one, any two, any three, any four, or all five of the substitutions L234A, L235A, D265A, N297A, N297Q; wherein the numbering is according to the Kabat numbering scheme.

Claim 10. The use of any one of claims 8-9, wherein said variant Fc Domain of said anti-PD-1 antibody or antigen-binding fragment thereof comprises the substitution:

- (A) L234A, L235A;
- (B) D265A;
- (C) N297A; or
- (D) N297Q;

wherein the numbering is according to the Kabat numbering scheme.

- Claim 11. The use of any one of claims 1-10, wherein said anti-PD-1 antibody or antigen-binding fragment thereof is to be administered at a fixed dosage of between 50 mg and 500 mg.
- Claim 12. The use of claim 11, wherein said anti-PD-1 antibody or antigen-binding fragment thereof is to be administered at a fixed dosage of 300 mg.
- Claim 13. The use of claim 11, wherein said anti-PD-1 antibody or antigen-binding fragment thereof is to be administered at a fixed dosage of 200 mg.
- Claim 14. The use of any one of claims 1-10, wherein said anti-PD-1 antibody or antigen-binding fragment thereof is to be administered at a dosage of 1-10 mg/kg body weight.
- Claim 15. The use of any one of claims 1-14, wherein said anti-B7-H3 antibody or antigen-binding fragment thereof is to be administered at a dosage of 1 mg/kg body weight, 3 mg/kg body weight, 10 mg/kg body weight or 15 mg/kg body weight.
- Claim 16. The use of claim 15, wherein said anti-B7-H3 antibody or antigen-binding fragment thereof is to be administered at a dosage of 15 mg/kg body weight.
- Claim 17. The use of claim 14, wherein said anti-B7-H3 antibody or antigen-binding fragment thereof is to be administered at a dosage of 1 mg/kg body weight, 3 mg/kg body weight, 10 mg/kg body weight or 15 mg/kg body weight, and said anti-PD-1 antibody or antigen-binding fragment thereof is to be administered at a dosage of 1 mg/kg body weight, 2 mg/kg body weight, 3 mg/kg body weight, 5 mg/kg body weight, 6 mg/kg body weight, or 10 mg/kg body weight.
- Claim 18. The use of claim 17, wherein said anti-B7-H3 antibody or antigen-binding fragment thereof is to be administered at a dosage of 3 mg/kg body weight, 10 mg/kg body weight, or 15 mg/kg body weight, and said anti-PD-1 antibody or antigen-binding fragment thereof is to be administered at a dosage of 5 mg/kg body weight.

- Claim 19. The use of claim 17, wherein said anti-B7-H3 antibody or antigen-binding fragment thereof is to be administered at a dosage of 3 mg/kg body weight, 10 mg/kg body weight, or 15 mg/kg body weight, and said anti-PD-1 antibody or antigen-binding fragment thereof is to be administered at a dosage of 6 mg/kg body weight.
- Claim 20. The use of claim 17, wherein said anti-B7-H3 antibody or antigen-binding fragment thereof is to be administered at a dosage of 3 mg/kg body weight, 10 mg/kg body weight, or 15 mg/kg body weight, and said anti-PD-1 antibody or antigen-binding fragment thereof is to be administered at a dosage of 10 mg/kg body weight.
- Claim 21. The use of any one of claims 1-20, wherein said anti-B7-H3 antibody or antigen-binding fragment thereof is to be administered every week.
- Claim 22. The use of any one of claims 1-20, wherein said anti-B7-H3 antibody or antigen-binding fragment thereof is to be administered every three weeks.
- Claim 23. The use of any one of claims 1-22, wherein the anti-PD-1 antibody or antigen-binding fragment thereof is to be administered every two weeks.
- Claim 24. The use of any one of claims 1-22, wherein the anti-PD-1 antibody or antigen-binding fragment thereof is to be administered every three weeks.
- Claim 25. The use of any one of claims 1-10, wherein said anti-B7-H3 antibody or antigen-binding fragment thereof is to be administered at a dosage of 15 mg/kg body weight every three weeks, and said anti-PD-1 antibody or antigen-binding fragment thereof is to be administered at a fixed dosage of between 50 mg and 500 mg every three weeks.
- Claim 26. The use of claim 25, wherein said anti-PD-1 antibody or antigen-binding fragment thereof is to be administered at a fixed dosage of 300 mg every three weeks.
- Claim 27. The use of claim 25, wherein said anti-PD-1 antibody or antigen-binding fragment thereof is to be administered at a fixed dosage of 200 mg every three weeks.

- Claim 28. The use of any one of claims 1-10, wherein said anti-B7-H3 antibody or antigen-binding fragment thereof is to be administered at a dosage of 15 mg/kg body weight every three weeks and said anti-PD-1 antibody or antigen-binding fragment thereof is to be administered at a dosage of 5 mg/kg body weight every three weeks.
- Claim 29. The use of any one of claims 1-28, wherein the anti-B7-H3 antibody or antigen-binding fragment thereof and the anti-PD-1 antibody or antigen-binding fragment thereof are to be administered by IV infusion.
- Claim 30. The use of any one of claims 1-20, wherein said anti-B7-H3 antibody or antigen-binding fragment thereof and said anti-PD-1 antibody or antigen-binding fragment thereof are to be administered every three weeks and within a 48-hour period of each other.
- Claim 31. The use of any one of claims 1-20, wherein said anti-B7-H3 antibody or antigen-binding fragment thereof and said anti-PD-1 antibody or antigen-binding fragment thereof are to be administered every two weeks and within a 48-hour period of each other.
- Claim 32. The use of any one of claims 1-31, wherein said B7-H3-expressing cancer is selected from the group consisting of: a squamous cell cancer of the head and neck (SCCHN), a bladder cancer, a breast cancer, a colorectal cancer, a gastric cancer, a glioblastoma, a kidney cancer, a lung cancer, a melanoma, an ovarian cancer, a pancreatic cancer, a pharyngeal cancer, a prostate cancer, a renal cell carcinoma, a small round blue cell tumor, a neuroblastoma, and a rhabdomyosarcoma.
- Claim 33. The use of claim 32, wherein said B7-H3-expressing cancer is a squamous cell cancer of the head and neck (SCCHN).
- Claim 34. The use of any one of claims 1-33, wherein said anti-B7-H3 antibody or antigen-binding fragment thereof and said anti-PD-1 antibody or antigen-binding fragment thereof are to be administered in further combination with a third therapeutic agent selected from the group consisting of an anti-

angiogenic agent, an anti-neoplastic agent, a chemotherapeutic agent, and a cytotoxic agent.

- Claim 35. The use of any one of claims 1-34, wherein said anti-B7-H3 antibody comprises a light chain comprising the amino acid sequence of SEQ ID NO:39, and a heavy chain comprising the amino acid sequence of SEQ ID NO:40.
- Claim 36. The use of any one of claims 1-35, wherein said anti-PD-1 antibody is pembrolizumab.
- Claim 37. The use of any one of claims 1-35, wherein said anti-PD-1 antibody is nivolumab.
- Claim 38. The use of any one of claims 1-35, wherein said anti-PD-1 antibody is pidilizumab.
- Claim 39. The use of any one of claims 1-35, wherein said anti-PD-1 antibody or antigen-binding fragment thereof comprises a heavy chain variable domain comprising the amino acid sequence of SEQ ID NO:46 and a light chain variable domain comprising the amino acid sequence of SEQ ID NO:47.
- Claim 40. The use of any one of claims 1-35, wherein said anti-PD-1 antibody or antigen-binding fragment thereof comprises a heavy chain variable domain comprising the amino acid sequence of SEQ ID NO:50 and a light chain variable domain comprising the amino acid sequence of SEQ ID NO:51.
- Claim 41. The use of any one of claims 1-35, wherein said anti-PD-1 antibody or antigen-binding fragment thereof comprises a heavy chain variable domain comprising the amino acid sequence of SEQ ID NO:52 and a light chain variable domain comprising the amino acid sequence of SEQ ID NO:53.
- Claim 42. The use of claim 41, wherein said anti-PD-1 antibody comprises a light chain comprising the amino acid sequence of SEQ ID NO:58 and a heavy chain comprising the amino acid sequence of SEQ ID NO:59.

- Claim 43. The use of any one of claims 1-35, wherein said anti-PD-1 antibody or antigen-binding fragment thereof comprises a heavy chain variable domain comprising the amino acid sequence of SEQ ID NO:54 and a light chain variable domain comprising the amino acid sequence of SEQ ID NO:55.
- Claim 44. The use of any one of claims 1-35, wherein said anti-PD-1 antibody or antigen-binding fragment thereof comprises a heavy chain variable domain comprising the amino acid sequence of SEQ ID NO:56 and a light chain variable domain comprising the amino acid sequence of SEQ ID NO:57.
- Claim 45. The use of any one of claims 1-35, wherein said anti-PD-1 antibody is selected from the group consisting of: PD1-17; PD1-28; PD1-33; PD1-35; PD1-F2; 17D8; 2D3; 4H1; 5C4; 4A11; 7D3; 5F4; hPD-1.08A; hPD-1.09A; h409A11; h409A16; h409A17; 1E3; 1E8; 1H3; 9A2; 10B11; 6E9; APE1922; APE1923; APE1924; APE1950; APE1963; APE2058; GA1; GA2; GB1; GB6; GH1; A2; C7; H7; SH-A4; SH-A9; RG1H10; RG1H11; RG2H7; RG2H10; RG3E12; RG4A6; RG5D9; RG1H10-H2A-22-15; RG1H10-H2A-27-25; RG1H10-3C; RG1H10-16C; RG1H10-17C; RG1H10-19C; RG1H10-21C; RG1H10-23C2; H1M7789N; H1M7799N; H1M7800N; H2M7780N; H2M7788N; H2M7790N; H2M7791N; H2M7794N; H2M7795N; H2M7796N; H2M7798N; H4H9019P; H4xH9034P2; H4xH9035P2; H4xH9037P2; H4xH9045P2; H4xH9048P2; H4H9057P2; H4H9068P2; H4xH9119P2; H4xH9120P2; H4xH9128P2; H4xH9135P2; H4xH9145P2; H4xH8992P; H4xH8999P; and H4xH9008P.