CLAIMS

What is claimed is:

1. An anti-CD3 antibody or antigen binding fragment thereof, comprising:

a heavy chain variable region CDR1 having an amino acid sequence as set forth in SEQ ID NO: 1,

a heavy chain variable region CDR2 having an amino acid sequence as set forth in SEQ ID NO: 2,

a heavy chain variable region CDR3 having an amino acid sequence as set forth in one of SEQ ID NO: 3, SEQ ID NOs: 7 to 8, and SEQ ID NOs: 74 to 86;

a light chain variable region CDR1 having an amino acid sequence as set forth in SEQ ID NO: 4,

a light chain variable region CDR2 having an amino acid sequence as set forth in SEQ ID NO: 5,

a light chain variable region CDR3 having an amino acid sequence as set forth in one of SEQ ID NOs: 6, 9, and 87 to 92.

2. The antibody or antigen binding fragment thereof according to claim 1, comprising any one of the following groups:

1) the heavy chain variable region CDR1, the heavy chain variable region CDR2, and the heavy chain variable region CDR3 as set forth in SEQ ID NOs: 1, 2, and 74, respectively, and the light chain variable region CDR1, the light chain variable region CDR2, and the light chain variable region CDR3 as set forth in SEQ ID NOs: 4, 5, and 6, respectively;

2) the heavy chain variable region CDR1, the heavy chain variable region CDR2, and the heavy chain variable region CDR3 as set forth in SEQ ID NOs: 1, 2, and 75, respectively; and the light chain variable region CDR1, the light chain variable region CDR2, and the light chain variable region CDR3 as set forth in SEQ ID NOs: 4, 5, and 6, respectively;

3) the heavy chain variable region CDR1, the heavy chain variable region CDR2,

and the heavy chain variable region CDR3 as set forth in SEQ ID NOs: 1, 2, and 76, respectively; and the light chain variable region CDR1, the light chain variable region CDR2, and the light chain variable region CDR3 as set forth in SEQ ID NOs: 4, 5, and 6, respectively;

4) the heavy chain variable region CDR1, the heavy chain variable region CDR2, and the heavy chain variable region CDR3 as set forth in SEQ ID NOs: 1, 2, and 77, respectively; and the light chain variable region CDR1, the light chain variable region CDR2, and the light chain variable region CDR3 as set forth in SEQ ID NOs: 4, 5, and 6, respectively;

5) the heavy chain variable region CDR1, the heavy chain variable region CDR2, and the heavy chain variable region CDR3 as set forth in SEQ ID NOs: 1, 2, and 78, respectively; and the light chain variable region CDR1, the light chain variable region CDR2, and the light chain variable region CDR3 as set forth in SEQ ID NOs: 4, 5, and 6, respectively;

6) the heavy chain variable region CDR1, the heavy chain variable region CDR2, and the heavy chain variable region CDR3 as set forth in SEQ ID NOs: 1, 2, and 79, respectively; and the light chain variable region CDR1, the light chain variable region CDR2, and the light chain variable region CDR3 as set forth in SEQ ID NOs: 4, 5, and 6, respectively;

7) the heavy chain variable region CDR1, the heavy chain variable region CDR2, and the heavy chain variable region CDR3 as set forth in SEQ ID NOs: 1, 2, and 80, respectively; and the light chain variable region CDR1, the light chain variable region CDR2, and the light chain variable region CDR3 as set forth in SEQ ID NOs: 4, 5, and 6, respectively;

8) the heavy chain variable region CDR1, the heavy chain variable region CDR2, and the heavy chain variable region CDR3 as set forth in SEQ ID NOs: 1, 2, and 81, respectively; and the light chain variable region CDR1, the light chain variable region CDR2, and the light chain variable region CDR3 as set forth in SEQ ID NOs: 4, 5, and 6, respectively;

9) the heavy chain variable region CDR1, the heavy chain variable region CDR2, and the heavy chain variable region CDR3 as set forth in SEQ ID NOs: 1, 2, and 82, respectively; and the light chain variable region CDR1, the light chain variable region CDR2, and the light chain variable region CDR3 as set forth in SEQ ID NOs: 4, 5, and 6, respectively;

10) the heavy chain variable region CDR1, the heavy chain variable region CDR2, and the heavy chain variable region CDR3 as set forth in SEQ ID NOs: 1, 2, and 83, respectively; and the light chain variable region CDR1, the light chain variable region CDR2, and the light chain variable region CDR3 as set forth in SEQ ID NOs: 4, 5, and 6, respectively;

11) the heavy chain variable region CDR1, the heavy chain variable region CDR2, and the heavy chain variable region CDR3 as set forth in SEQ ID NOs: 1, 2, and 3, respectively; and the light chain variable region CDR1, the light chain variable region CDR2, and the light chain variable region CDR3 as set forth in SEQ ID NOs: 4, 5, and 6, respectively;

12) the heavy chain variable region CDR1, the heavy chain variable region CDR2, and the heavy chain variable region CDR3 as set forth in SEQ ID NOs: 1, 2, and 7, respectively; and the light chain variable region CDR1, the light chain variable region CDR2, and the light chain variable region CDR3 as set forth in SEQ ID NOs: 4, 5, and 6, respectively;

13) the heavy chain variable region CDR1, the heavy chain variable region CDR2, and the heavy chain variable region CDR3 as set forth in SEQ ID NOs: 1, 2, and 8, respectively; and the light chain variable region CDR1, the light chain variable region CDR2, and the light chain variable region CDR3 as set forth in SEQ ID NOs: 4, 5, and 87, respectively;

14) the heavy chain variable region CDR1, the heavy chain variable region CDR2, and the heavy chain variable region CDR3 as set forth in SEQ ID NOs: 1, 2, and 8, respectively; and the light chain variable region CDR1, the light chain variable region CDR2, and the light chain variable region CDR3 as set forth in SEQ ID NOs: 4, 5, and

88, respectively;

15) the heavy chain variable region CDR1, the heavy chain variable region CDR2, and the heavy chain variable region CDR3 as set forth in SEQ ID NOs: 1, 2, and 8, respectively; and the light chain variable region CDR1, the light chain variable region CDR2, and the light chain variable region CDR3 as set forth in SEQ ID NOs: 4, 5, and 9, respectively;

16) the heavy chain variable region CDR1, the heavy chain variable region CDR2, and the heavy chain variable region CDR3 as set forth in SEQ ID NOs: 1, 2, and 84, respectively; and the light chain variable region CDR1, the light chain variable region CDR2, and the light chain variable region CDR3 as set forth in SEQ ID NOs: 4, 5, and 89, respectively;

17) the heavy chain variable region CDR1, the heavy chain variable region CDR2, and the heavy chain variable region CDR3 as set forth in SEQ ID NOs: 1, 2, and 85, respectively; and the light chain variable region CDR1, the light chain variable region CDR2, and the light chain variable region CDR3 as set forth in SEQ ID NOs: 4, 5, and 90, respectively;

18) the heavy chain variable region CDR1, the heavy chain variable region CDR2, and the heavy chain variable region CDR3 as set forth in SEQ ID NOs: 1, 2, and 86, respectively; and the light chain variable region CDR1, the light chain variable region CDR2, and the light chain variable region CDR3 as set forth in SEQ ID NOs: 4, 5, and 92, respectively; or

19) the heavy chain variable region CDR1, the heavy chain variable region CDR2, and the heavy chain variable region CDR3 as set forth in SEQ ID NOs: 1, 2 and 8, respectively; and the light chain variable region CDR1, the light chain variable region CDR2, and the light chain variable region CDR3 as set forth in SEQ ID NOs: 4, 5 and 91, respectively.

3. The antibody or antigen binding fragment thereof according to claim 1, satisfying one of the following conditions:

the antibody or antigen binding fragment thereof comprises a heavy chain variable

region having an amino acid sequence as set forth in one of SEQ ID NOs: 10, 12 to 13, 15 to 24, 27, and 31, or a conservative modification form thereof; and/or a light chain variable region having an amino acid sequence as set forth in one of SEQ ID NOs: 11, 14, 25 to 26, 28, and 30, or a conservative modification form thereof; or

the antibody or antigen binding fragment thereof comprises amino acid sequences as set forth in a combination of the heavy chain variable region and the light chain variable region in any one of the following groups, or amino acid sequences having at least 90% sequence identity thereto:

Group number of the antibody or antigen binding fragment	Heavy chain variable region	Light chain variable region
1	SEQ ID NO: 15	SEQ ID NO: 11
2	SEQ ID NO: 16	SEQ ID NO: 11
3	SEQ ID NO: 17	SEQ ID NO: 11
4	SEQ ID NO: 17	SEQ ID NO: 11
5	SEQ ID NO: 19	SEQ ID NO: 11
6	SEQ ID NO: 20	SEQ ID NO: 11
7	SEQ ID NO: 21	SEQ ID NO: 11
8	SEQ ID NO: 22	SEQ ID NO: 11
9	SEQ ID NO: 23	SEQ ID NO: 11
10	SEQ ID NO: 24	SEQ ID NO: 11
11	SEQ ID NO: 10	SEQ ID NO: 11
12	SEQ ID NO: 12	SEQ ID NO: 11
13	SEQ ID NO: 13	SEQ ID NO: 25
14	SEQ ID NO: 13	SEQ ID NO: 26
15	SEQ ID NO: 13	SEQ ID NO: 14
16	SEQ ID NO: 27	SEQ ID NO: 28
17	SEQ ID NO: 29	SEQ ID NO: 28
18	SEQ ID NO: 13	SEQ ID NO: 30
19	SEQ ID NO: 31	SEQ ID NO: 26

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4. The antibody or antigen binding fragment thereof according to any one of claims 1 to 3, further comprising a constant region, wherein:

the constant region comprises at least one of a heavy chain constant region or a light chain constant region.

5. The antibody or antigen binding fragment thereof according to claim 4, wherein the heavy chain constant region and light chain constant region satisfy one of the following conditions:

at least a portion of at least one of the heavy chain constant region or the light chain constant region is derived from at least one of a murine antibody, a human antibody, a primate antibody, a bovine antibody, an equine antibody, a dairy bovine antibody, a porcine antibody, an ovine antibody, a caprine antibody, a canine antibody, a feline antibody, a rabbit-derived antibody, a camelid antibody, a donkey-derived antibody, a deer-derived antibody, a mink-derived antibody, a chicken-derived antibody, a duck-derived antibody, a goose-derived antibody, a turkey-derived antibody, a gamecock-derived antibody, or a mutant thereof;

the heavy chain constant region comprises a heavy chain constant region selected from IgG1, IgG2, IgG3, IgG4, IgA, IgM, IgE, or IgD; and/or the light chain constant region comprises a light chain constant region selected from a κ-type light chain constant region or a λ-type light chain constant region;

the N-terminus of the heavy chain constant region is linked to the C-terminus of the heavy chain variable region; and/or the N-terminus of the light chain constant region is linked to the C-terminus of the light chain variable region; or

the heavy chain constant region has an amino acid sequence as set forth in SEQ ID NO: 93 or an amino acid sequence having at least 80% identity thereto; and/or the light chain constant region has an amino acid sequence as set forth in SEQ ID NO: 94 or an amino acid sequence having at least 80% identity thereto.

6. The antibody or antigen binding fragment thereof according to claim 4, wherein:

the C-terminus of the heavy chain variable region is linked to the N-terminus of the light chain variable region, or

the N-terminus of the heavy chain variable region is linked to the C-terminus of the light chain variable region.

7. The antibody or antigen binding fragment thereof according to claim 6, further comprising a first linking peptide, wherein:

the C-terminus of the heavy chain variable region is linked to the N-terminus of the first linking peptide, and the C-terminus of the first linking peptide is linked to the N-terminus of the light chain variable region, or

the C-terminus of the light chain variable region is linked to the N-terminus of the first linking peptide, and the C-terminus of the first linking peptide is linked to the N-terminus of the heavy chain variable region.

8. The antibody or antigen binding fragment thereof according to any one of claims 1 to 3, wherein:

the antibody comprises at least one of a full-length monoclonal antibody, chimeric antibody, humanized antibody, Fv, scFv, Fab, Fab', Fab'-SH, or $F(ab')_2$; and

the antigen binding fragment of the antibody comprises at least one of a $F(ab')_2$ fragment, Fab' fragment, Fab fragment, $F(ab)_2$ fragment, Fv fragment, scFv fragment, scFv-Fc fusion protein, scFv-Fv fusion protein, or a minimum recognition unit.

9. The antibody or antigen binding fragment thereof according to claim 8, satisfying one of the following conditions:

the antibody or antigen binding fragment thereof comprises a heavy chain having an amino acid sequence as set forth in one of SEQ ID NOs: 32, 34, 35, and 37 to 46, or an amino acid sequence having at least 80% identity thereto; and/or a light chain having an amino acid sequence as set forth in one of SEQ ID NOs: 33, 36, and 47 to 48, or an amino acid sequence having at least 80% identity thereto;

the antibody or antigen binding fragment thereof has amino acid sequences as set forth in a combination of a heavy chain and a light chain in any one of the following groups, or amino acid sequences having at least 80% sequence identity thereto:

Group number of the antibody or antigen binding fragment thereof	Heavy chain	Light chain
1	SEQ ID NO: 37	SEQ ID NO: 33
2	SEQ ID NO: 38	SEQ ID NO: 33
3	SEQ ID NO: 39	SEQ ID NO: 33

4	SEQ ID NO: 40	SEQ ID NO: 33
5	SEQ ID NO: 41	SEQ ID NO: 33
6	SEQ ID NO: 42	SEQ ID NO: 33
7	SEQ ID NO: 43	SEQ ID NO: 33
8	SEQ ID NO: 44	SEQ ID NO: 33
9	SEQ ID NO: 45	SEQ ID NO: 33
10	SEQ ID NO: 46	SEQ ID NO: 33
11	SEQ ID NO: 32	SEQ ID NO: 33
12	SEQ ID NO: 34	SEQ ID NO: 33
13	SEQ ID NO: 35	SEQ ID NO: 47
14	SEQ ID NO: 35	SEQ ID NO: 48
15	SEQ ID NO: 35	SEQ ID NO: 36
16	SEQ ID NO: 95	SEQ ID NO: 119
17	SEQ ID NO: 96	SEQ ID NO: 120
18	SEQ ID NO: 97	SEQ ID NO: 121
19	SEQ ID NO: 98	SEQ ID NO: 122

;

the antibody or antigen binding fragment thereof has an amino acid sequence as set forth in any one of SEQ ID NOs: 99 to 117, or an amino acid sequence having at least 80% sequence identity thereto;

the antibody or antigen binding fragment thereof has amino acid sequences as set forth in a combination of Fab VL-CL and Fab VH-CH1 in any one of the following groups, or amino acid sequences having at least 80% sequence identity thereto:

Group number of the antibody or antigen binding fragment	Fab VH-CH1	Fab VL-CL
1	SEQ ID NO: 123	SEQ ID NO: 33
2	SEQ ID NO: 124	SEQ ID NO: 33
3	SEQ ID NO: 125	SEQ ID NO: 33

4	SEQ ID NO: 126	SEQ ID NO: 33
5	SEQ ID NO: 127	SEQ ID NO: 33
6	SEQ ID NO: 128	SEQ ID NO: 33
7	SEQ ID NO: 129	SEQ ID NO: 33
8	SEQ ID NO: 130	SEQ ID NO: 33
9	SEQ ID NO: 131	SEQ ID NO: 33
10	SEQ ID NO: 132	SEQ ID NO: 33
11	SEQ ID NO: 133	SEQ ID NO: 33
12	SEQ ID NO: 134	SEQ ID NO: 33
13	SEQ ID NO: 135	SEQ ID NO: 47
14	SEQ ID NO: 136	SEQ ID NO: 36
15	SEQ ID NO: 137	SEQ ID NO: 48
16	SEQ ID NO: 138	SEQ ID NO: 119
17	SEQ ID NO: 139	SEQ ID NO: 120
18	SEQ ID NO: 140	SEQ ID NO: 121
19	SEQ ID NO: 141	SEQ ID NO: 122

; or

the antibody or antigen binding fragment thereof has an amino acid sequence as set forth in any one of SEQ ID NOs: 142 to 160, or an amino acid sequence having at least 80% sequence identity thereto.

10. A multi-specific antibody, comprising:

a first antigen binding region, wherein the first antigen binding region comprises the anti-CD3 antibody or antigen binding fragment thereof according to any one of claims 1 to 9; and

a second antigen binding region, wherein the second antigen binding region has biomolecule binding activity, the biomolecule not being CD3.

11. The multi-specific antibody according to claim 10, wherein the second antigen binding region is a binding protein of the biomolecule or a fragment thereof;

wherein the biomolecule is selected from at least one of PDL1, CD47, TIGIT, CD73, CD33, CEACAM1, CEACAM5, CEACAM6, STING, WNT, Beta catenin, B7H3, VISITA, CD19, BCMA, CD22, CD20, CD123, CD38, CEA, CD25, CD46, CD138, PSCA, PSMA, PSA, MUC1, MUC16, NY-ESO-1, GD2, WT1, Mesothelin, MAGE-A3, GPC3, PRAME, Globo H, AFP, Trop2, FOLR1, SP, Sca-1, CD133, or EPCAM.

12. The multi-specific antibody according to claim 10, wherein the first antigen binding region comprises a first scFv fragment, a first Fv fragment, a first Fab fragment, or a first Fab-Linker fragment.

13. The multi-specific antibody according to claim 12, wherein the first antigen binding region further comprises a first Fc peptide segment, the first Fc peptide segment satisfying one of the following conditions:

the N-terminus of the first Fc peptide segment is linked to the C-terminus of the scFv fragment or the C-terminus of the Fv fragment; or the N-terminus of the first Fc peptide segment is linked to the C-terminus of CH1 of the Fab fragment or the C-terminus of the Fab-Linker fragment;

the first antigen binding region further comprises a second linking peptide, wherein the N-terminus of the first Fc peptide segment is linked to the C-terminus of the second linking peptide, and the N-terminus of the second linking peptide is linked to the C-terminus of the scFv fragment or the C-terminus of the Fv fragment; or the N-terminus of the first Fc peptide segment is linked to the C-terminus of the second linking peptide, and the N-terminus of the second linking peptide is linked to the C-terminus of CH1 of the Fab fragment or the C-terminus of the Fab-Linker fragment;

the first Fc peptide segment is selected from a human Fc peptide segment;

the first Fc peptide segment is a human IgG1 Fc peptide segment; or

the first Fc peptide segment has an amino acid sequence as set forth in SEQ ID NO: 118; or the first Fc peptide segment has an amino acid sequence as set forth in SEQ ID NO: 166.

14. The multi-specific antibody according to claim 12, satisfying one of the

following conditions:

the first scFv fragment has an amino acid sequence as set forth in any one of SEQ ID NOs: 95 to 117;

the first Fab fragment has amino acid sequences as set forth in a combination of Fab VL-CL and Fab VH-CH1 in any one of the following groups:

Group number of the first Fab fragment	Fab VH-CH1	Fab VL-CL
1	SEQ ID NO: 123	SEQ ID NO: 33
2	SEQ ID NO: 124	SEQ ID NO: 33
3	SEQ ID NO: 125	SEQ ID NO: 33
4	SEQ ID NO: 126	SEQ ID NO: 33
5	SEQ ID NO: 127	SEQ ID NO: 33
6	SEQ ID NO: 128	SEQ ID NO: 33
7	SEQ ID NO: 129	SEQ ID NO: 33
8	SEQ ID NO: 130	SEQ ID NO: 33
9	SEQ ID NO: 131	SEQ ID NO: 33
10	SEQ ID NO: 132	SEQ ID NO: 33
11	SEQ ID NO: 133	SEQ ID NO: 33
12	SEQ ID NO: 134	SEQ ID NO: 33
13	SEQ ID NO: 135	SEQ ID NO: 47
14	SEQ ID NO: 136	SEQ ID NO: 36
15	SEQ ID NO: 137	SEQ ID NO: 48
16	SEQ ID NO: 138	SEQ ID NO: 119
17	SEQ ID NO: 139	SEQ ID NO: 120
18	SEQ ID NO: 140	SEQ ID NO: 121
19	SEQ ID NO: 141	SEQ ID NO: 122

; or

the first Fab-Linker has an amino acid sequence as set forth in any one of SEQ ID NOs: 142 to 160.

15. The multi-specific antibody according to claim 10, wherein the first antigen binding region has an amino acid sequence as set forth in any one of SEQ ID NOs: 49 to 52 and 54 to 68.

16. The multi-specific antibody according to claim 11, wherein the biomolecule is

Trop2 or PDL1.

17. The multi-specific antibody according to claim 16, wherein the second antigen binding region comprises a first anti-Trop2 antibody or antigen binding fragment thereof; or a first anti-PDL1 antibody or an antigen binding fragment thereof;

the first anti-Trop2 antibody or antigen binding fragment thereof is a second scFab fragment or a second Fab fragment of anti-Trop2; or the first anti-PDL1 antibody or antigen binding fragment thereof is a third scFab fragment or a third Fab fragment of anti-PDL1; wherein:

the second scFab fragment has an amino acid sequence as set forth in SEQ ID NO: 161;

the second Fab fragment has an amino acid sequence as set forth in SEQ ID NO: 162 and 70;

the third scFab fragment has an amino acid sequence as set forth in SEQ ID NO: 163; or

the third Fab fragment has an amino acid sequence as set forth in SEQ ID NO: 164 and 72.

18. The multi-specific antibody according to claim 17, wherein the second antigen binding region further comprises a second Fc fragment, the second Fc peptide segment satisfying one of the following conditions:

the N-terminus of the second Fc fragment is linked to the C-terminus of CH1 of the second scFab fragment, the C-terminus of CH1 of the second Fab fragment, the C-terminus of CH1 of the third scFab fragment, or the C-terminus of CH1 of the third Fab fragment;

the second Fc peptide segment is selected from a human Fc peptide segment;

the second Fc peptide segment is a human IgG1 Fc peptide segment;

the second Fc peptide segment has an amino acid sequence as set forth in SEQ ID NO: 165; or

the first Fc peptide segment and the second Fc peptide segment are linked via a knob-into-hole structure.

19. The multi-specific antibody according to claim 18, wherein:

the second antigen binding region has an amino acid sequence as set forth in SEQ ID NO: 161 or 163;

the second antigen binding region has an amino acid sequence as set forth in SEQ ID NO: 162 and 70; or

the second antigen binding region has an amino acid sequence as set forth in SEQ ID NO: 164 and 72.

20. Use of the antibody or antigen binding fragment thereof according to any one of claims 1 to 9, or the multi-specific antibody according to any one of claims 10 to 19 in the manufacture of a medicament for regulating an immune response and/or inhibiting tumor growth, or for the prevention and/or treatment of a CD3-related disease and/or cancer or tumor or infection or autoimmune disease, wherein the cancer or tumor or infection or autoimmune disease is a Trop2- or PDL1-related disease.