CLAIMS

1. A CLDN18.2-targeting antibody comprising a heavy chain variable region comprising HCDR1, HCDR2 and HCDR3, wherein the HCDR1 comprises an amino acid sequence as set forth in any one of SEQ ID NOs: 16–18, the HCDR2 comprises an amino acid sequence as set forth in any one of SEQ ID NOs: 42–46 and SEQ ID NOs: 48–54, and the HCDR3 comprises an amino acid sequence as set forth in any one of SEQ ID NOs: 77–82.

2. The antibody according to claim 1, wherein the HCDR1, the HCDR2 and the HCDR3 comprise amino acid sequences as set forth in SEQ ID NO: 16, SEQ ID NO: 42 and SEQ ID NO: 77, respectively; or

the HCDR1, the HCDR2 and the HCDR3 comprise amino acid sequences as set forth in SEQ ID NO: 16, SEQ ID NO: 43 and SEQ ID NO: 78, respectively; or

the HCDR1, the HCDR2 and the HCDR3 comprise amino acid sequences as set forth in SEQ ID NO: 16, SEQ ID NO: 44 and SEQ ID NO: 79, respectively; or

the HCDR1, the HCDR2 and the HCDR3 comprise amino acid sequences as set forth in SEQ ID NO: 17, SEQ ID NO: 45 and SEQ ID NO: 80, respectively; or

the HCDR1, the HCDR2 and the HCDR3 comprise amino acid sequences as set forth in SEQ ID NO: 18, SEQ ID NO: 43 and SEQ ID NO: 80, respectively; or

the HCDR1, the HCDR2 and the HCDR3 comprise amino acid sequences as set forth in SEQ ID NO: 18, SEQ ID NO: 43 and SEQ ID NO: 78, respectively; or

the HCDR1, the HCDR2 and the HCDR3 comprise amino acid sequences as set forth in SEQ ID NO: 16, SEQ ID NO: 43 and SEQ ID NO: 81, respectively; or

the HCDR1, the HCDR2 and the HCDR3 comprise amino acid sequences as set forth in SEQ ID NO: 16, SEQ ID NO: 46 and SEQ ID NO: 82, respectively; or

the HCDR1, the HCDR2 and the HCDR3 comprise amino acid sequences as set forth in SEQ ID NO: 16, SEQ ID NO: 48 and SEQ ID NO: 78, respectively; or

the HCDR1, the HCDR2 and the HCDR3 comprise amino acid sequences as set forth in SEQ ID NO: 16, SEQ ID NO: 49 and SEQ ID NO: 78, respectively; or

the HCDR1, the HCDR2 and the HCDR3 comprise amino acid sequences as set forth in SEQ ID NO: 16, SEQ ID NO: 50 and SEQ ID NO: 78, respectively; or

the HCDR1, the HCDR2 and the HCDR3 comprise amino acid sequences as set forth in SEQ ID NO: 16, SEQ ID NO: 51 and SEQ ID NO: 78, respectively; or

the HCDR1, the HCDR2 and the HCDR3 comprise amino acid sequences as set forth in SEQ ID NO: 16, SEQ ID NO: 52 and SEQ ID NO: 78, respectively; or

the HCDR1, the HCDR2 and the HCDR3 comprise amino acid sequences as set forth in SEQ ID NO: 16, SEQ ID NO: 53 and SEQ ID NO: 79, respectively; or

the HCDR1, the HCDR2 and the HCDR3 comprise amino acid sequences as set forth in SEQ ID NO: 16, SEQ ID NO: 54 and SEQ ID NO: 78, respectively.

3. The antibody according to claim 1, wherein the heavy chain variable region further comprises framework regions, among which the HFR1 comprises an amino acid sequence as set forth in SEQ ID NO: 6 or 7, the HFR2 comprises an amino acid sequence as set forth in any one of SEQ ID NOs: 28–34, the HFR3 comprises an amino acid sequence as set forth in any one of SEQ ID NOs: 63–68, and the HFR4 comprises an amino acid sequence as set forth in any one of SEQ ID NOs: 84 and 86–89.

4. The antibody according to claim 3, wherein the heavy chain variable region comprises an amino acid sequence as set forth in any one of SEQ ID NOs: 150–157 and SEQ ID NOs: 159–165.

5. The antibody according to claim 1, wherein the antibody further comprises a heavy chain constant region; preferably, the heavy chain constant region is selected from hIgG1, hIgG2, hIgG3 and hIgG4 and a variant thereof; more preferably, the heavy chain constant region is hIgG1.

6. The antibody according to any one of claims 1–5, wherein the antibody is a full-length antibody, an Fab, an Fab', an $F(ab')_2$, an Fv, an scFv, a bispecific antibody, a multispecific antibody, a heavy-chain antibody or a single-domain antibody, or a monoclonal or polyclonal antibody prepared from the antibodies above.

7. The antibody according to claim 6, wherein the antibody is a single-domain antibody comprising an amino acid sequence as set forth in any one of SEQ ID NOs: 182–189 and SEQ ID NOs: 191–197.

8. A bispecific antibody comprising a first protein functional region targeting CD3 and a second protein functional region targeting CLDN18.2; wherein

the first protein functional region is in the form of an Fab, and the second protein functional region is in the form of VHs and preferably comprises 2 or 3 VHs; when the second protein functional region comprises 3 VHs linked in series, the first protein functional region and the second protein functional region are each linked to an Fc's double strand; when the

second protein functional region comprises 2 VHs linked in series, the first protein functional region and the second protein functional region are each linked to an Fc's double strand; when the second protein functional region comprises 3 VHs and one of the 3 VHs is linked to the first protein functional region, the remaining two VHs are linked in series, and the first protein functional region and the two VHs linked in series of the second protein functional region are each linked to an Fc's double strand;

alternatively, the first protein functional region is in the form of Fab and the second protein functional region is in the form of HCAb;

alternatively, the first protein functional region is in the form of Fab and the second protein functional region is in the form of VH-HCAb, the second protein functional region preferably comprising a total of 4 VHs.

9. The bispecific antibody according to claim 8, wherein the second protein functional region comprises a heavy chain variable region comprising HCDR1, HCDR2 and HCDR3, wherein the HCDR1 comprises an amino acid sequence as set forth in any one of SEQ ID NOs: 16–18, the HCDR2 comprises an amino acid sequence as set forth in any one of SEQ ID NOs: 42–46 and SEQ ID NOs: 48–54, and the HCDR3 comprises an amino acid sequence as set forth in any one of SEQ ID NOs: 77–82;

preferably, the HCDR1, the HCDR2 and the HCDR3 comprise amino acid sequences as set forth in SEQ ID NO: 16, SEQ ID NO: 42 and SEQ ID NO: 77, respectively; or the HCDR1, the HCDR2 and the HCDR3 comprise amino acid sequences as set forth in SEQ ID NO: 16, SEQ ID NO: 43 and SEQ ID NO: 78, respectively; or the HCDR1, the HCDR2 and the HCDR3 comprise amino acid sequences as set forth in SEQ ID NO: 16, SEQ ID NO: 44 and SEQ ID NO: 79, respectively; or the HCDR1, the HCDR2 and the HCDR3 comprise amino acid sequences as set forth in SEQ ID NO: 16, SEQ ID NO: 48 and SEQ ID NO: 78, respectively; or the HCDR1, the HCDR2 and the HCDR3 comprise amino acid sequences as set forth in SEQ ID NO: 16, SEQ ID NO: 49 and SEQ ID NO: 78, respectively; or the HCDR1, the HCDR2 and the HCDR3 comprise amino acid sequences as set forth in SEQ ID NO: 16, SEQ ID NO: 50 and SEQ ID NO: 78, respectively; or the HCDR1, the HCDR2 and the HCDR3 comprise amino acid sequences as set forth in SEQ ID NO: 16, SEQ ID NO: 51 and SEQ ID NO: 78, respectively; or the HCDR1, the HCDR2 and the HCDR3 comprise amino acid sequences as set forth in SEQ ID NO: 16, SEQ ID NO: 52 and SEQ ID NO: 78, respectively; or the HCDR1, the HCDR2 and the HCDR3 comprise amino acid sequences as

set forth in SEQ ID NO: 16, SEQ ID NO: 53 and SEQ ID NO: 79, respectively; or the HCDR1, the HCDR2 and the HCDR3 comprise amino acid sequences as set forth in SEQ ID NO: 16, SEQ ID NO: 54 and SEQ ID NO: 78, respectively;

more preferably, the heavy chain variable region comprises an amino acid sequence as set forth in any one of SEQ ID NOs: 150–152 and SEQ ID NOs: 159–165.

10. The bispecific antibody according to claim 8 or 9, wherein the first protein functional region comprises a light chain variable region comprising LCDR1, LCDR2 and LCDR3 as set forth in SEQ ID NO: 101, SEQ ID NO: 116 and SEQ ID NO: 131, respectively, and a heavy chain variable region comprising HCDR1, HCDR2 and HCDR3 as set forth in SEQ ID NO: 11, SEQ ID NO: 38 and SEQ ID NO: 72, respectively;

preferably, the heavy chain variable region comprises an amino acid sequence as set forth in SEQ ID NO: 149 or SEQ ID NO: 144 and the light chain variable region comprises an amino acid sequence as set forth in SEQ ID NO: 168.

11. The bispecific antibody according to claim 8 or 9, wherein

the bispecific antibody comprises three polypeptide chains in the following forms:

two N-termini of the Fc are linked to the Fab and the VH, respectively; preferably, the bispecific antibody has a first polypeptide chain as shown in formula: $VH_{CLDN18.2}$-$VH_{CLDN18.2}$-hinge-CH2-CH3 or $VH_{CLDN18.2}$-$VH_{CLDN18.2}$-$VH_{CLDN18.2}$-hinge-CH2-CH3, a second polypeptide chain as shown in formula: VH_{CD3}-CH1-hinge-CH2-CH3 and a third polypeptide chain as shown in formula: VL_{CD3}-CL;

alternatively, one C-terminus of the HCAb is linked to a VH or VL of the Fab; preferably, the bispecific antibody has a first polypeptide chain as shown in formula: $VH_{CLDN18.2}$-hinge-CH2-CH3, a second polypeptide chain as shown in formula: $VH_{CLDN18.2}$-hinge-CH2-CH3-VH_{CD3}-CH1 and a third polypeptide chain as shown in formula: VL_{CD3}-CL; alternatively, the bispecific antibody has a first polypeptide chain as shown in formula: $VH_{CLDN18.2}$-hinge-CH2-CH3, a second polypeptide chain as shown in formula: $VH_{CLDN18.2}$-hinge-CH2-CH3-VL_{CD3}-CL and a third polypeptide chain as shown in formula: VH_{CD3}-CH1; alternatively, the bispecific antibody has a first polypeptide chain as shown in formula: $VH_{CLDN18.2}$-$VH_{CLDN18.2}$-hinge-CH2-CH3, a second polypeptide chain as shown in formula: $VH_{CLDN18.2}$-$VH_{CLDN18.2}$-hinge-CH2-CH3-VH_{CD3}-CH1 and a third polypeptide chain as shown in formula: VL_{CD3}-CL; alternatively, the bispecific antibody has a first polypeptide

chain as shown in formula: $VH_{CLDN18.2}$-$VH_{CLDN18.2}$-hinge-CH2-CH3, a second polypeptide chain as shown in formula: $VH_{CLDN18.2}$-$VH_{CLDN18.2}$-hinge-CH2-CH3-VL_{CD3}-CL and a third polypeptide chain as shown in formula: VH_{CD3}-CH1;

alternatively, the N-terminus of the heavy chain of the Fab is linked to one $VH_{CLDN18.2}$, the C-terminus of the heavy chain is linked to one N-terminus of the Fc, and the C-terminus of the VHs linked in series is linked to the other N-terminus of the Fc; preferably, the bispecific antibody has a first polypeptide chain as shown in formula: $VH_{CLDN18.2}$-$VH_{CLDN18.2}$-hinge-CH2-CH3, a second polypeptide chain as shown in formula: $VH_{CLDN18.2}$-VH_{CD3}-CH1-hinge-CH2-CH3 and a third polypeptide chain as shown in formula: VL_{CD3}-CL;

more preferably, different functional units such as VH, CH2-CH3 and VL are operably linked by linker peptides preferably comprising an amino acid sequence as set forth in any one of SEQ ID NOs: 244–248, preferably the sequence set forth in SEQ ID NO: 246;

more preferably, two N-termini of the Fc are linked to the Fab and the VH, respectively; preferably, the bispecific antibody has a first polypeptide chain as shown in formula: $VH_{CLDN18.2}$-linker peptide-$VH_{CLDN18.2}$-hinge-CH2-CH3 or $VH_{CLDN18.2}$-linker peptide-$VH_{CLDN18.2}$-linker peptide-$VH_{CLDN18.2}$-hinge-CH2-CH3, a second polypeptide chain as shown in formula: VH_{CD3}-CH1-hinge-CH2-CH3 and a third polypeptide chain as shown in formula: VL_{CD3}-CL;

alternatively, one C-terminus of the HCAb is linked to a VH or VL of the Fab; preferably, the bispecific antibody has a first polypeptide chain as shown in formula: $VH_{CLDN18.2}$-hinge-CH2-CH3, a second polypeptide chain as shown in formula: $VH_{CLDN18.2}$-hinge-CH2-CH3-linker peptide-VH_{CD3}-CH1 and a third polypeptide chain as shown in formula: VL_{CD3}-CL; alternatively, the bispecific antibody has a first polypeptide chain as shown in formula: $VH_{CLDN18.2}$-hinge-CH2-CH3, a second polypeptide chain as shown in formula: $VH_{CLDN18.2}$-hinge-CH2-CH3-linker peptide-VL_{CD3}-CL and a third polypeptide chain as shown in formula: VH_{CD3}-CH1;

alternatively, one C-terminus of the VH-HCAb is linked to a VH or VL of the Fab; preferably, the bispecific antibody has a first polypeptide chain as shown in formula: $VH_{CLDN18.2}$-linker peptide-$VH_{CLDN18.2}$-hinge-CH2-CH3, a second polypeptide chain as shown in formula: $VH_{CLDN18.2}$-linker peptide-$VH_{CLDN18.2}$-hinge-CH2-CH3-linker peptide-VH_{CD3}-CH1 and a third polypeptide chain as shown in formula: VL_{CD3}-CL; alternatively, the bispecific

antibody has a first polypeptide chain as shown in formula: $VH_{CLDN18.2}$-linker peptide-$VH_{CLDN18.2}$-hinge-CH2-CH3, a second polypeptide chain as shown in formula: $VH_{CLDN18.2}$-linker peptide-$VH_{CLDN18.2}$-hinge-CH2-CH3-linker peptide-VL_{CD3}-CL and a third polypeptide chain as shown in formula: VH_{CD3}-CH1;

alternatively, the N-terminus of the heavy chain of the Fab is linked to one $VH_{CLDN18.2}$, the C-terminus of the heavy chain is linked to one N-terminus of the Fc, and the C-terminus of the VHs linked in series is linked to the other N-terminus of the Fc; preferably, the bispecific antibody has a first polypeptide chain as shown in formula: $VH_{CLDN18.2}$-linker peptide-$VH_{CLDN18.2}$-hinge-CH2-CH3, a second polypeptide chain as shown in formula: $VH_{CLDN18.2}$-linker peptide-VH_{CD3}-CH1-hinge-CH2-CH3 and a third polypeptide chain as shown in formula: VL_{CD3}-CL.

12. The bispecific antibody according to claim 11, wherein the first polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 214, the second polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 213, and the third polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 200;

alternatively, the first polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 219, the second polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 213, and the third polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 200;

alternatively, the first polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 220, the second polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 213, and the third polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 200;

alternatively, the first polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 221, the second polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 213, and the third polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 200;

alternatively, the first polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 222, the second polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 213, and the third polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 200;

alternatively, the first polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 223, the second polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 213, and the third polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 200;

alternatively, the first polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 224, the second polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 213, and the third polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 200;

alternatively, the first polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 225, the second polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 213, and the third polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 200;

alternatively, the first polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 226, the second polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 213, and the third polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 200;

alternatively, the first polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 227, the second polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 228, and the third polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 200;

alternatively, the first polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 227, the second polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 230, and the third polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 229;

alternatively, the first polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 219, the second polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 231, and the third polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 200;

alternatively, the first polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 219, the second polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 232, and the third polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 229;

alternatively, the first polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 219, the second polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 233, and the third polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 200;

alternatively, the first polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 234, the second polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 213, and the third polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 200;

alternatively, the first polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 219, the second polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 209, and the third polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 200;

alternatively, the first polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 221, the second polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 209, and the third polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 200;

alternatively, the first polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 236, the second polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 235, and the third polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 200;

alternatively, the first polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 236, the second polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 237, and the third polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 200;

alternatively, the first polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 238, the second polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 235, and the third polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 200;

alternatively, the first polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 239, the second polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 235, and the third polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 200;

alternatively, the first polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 240, the second polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 235, and the third polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 200;

alternatively, the first polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 241, the second polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 235, and the third polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 200;

alternatively, the first polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 242, the second polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 235, and the third polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 200;

alternatively, the first polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 243, the second polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 235, and the third polypeptide chain comprises an amino acid sequence as set forth in SEQ ID NO: 200.

13. An isolated nucleic acid encoding the antibody according to any one of claims 1–7 or the bispecific antibody according to any one of claims 8–12.

14. A recombinant expression vector comprising the isolated nucleic acid according to claim 13, wherein preferably, the recombinant expression vector is a plasmid, a cosmid, a phage or a viral vector, wherein the viral vector is preferably a retroviral vector, a lentiviral vector, an adenoviral vector or an adeno-associated viral vector.

15. A transformant comprising the recombinant expression vector according to claim 14 in a host cell, wherein preferably, the host cell is an *E. coli* TG1, BL21 cell, or CHO-K1 cell.

16. A chimeric antigen receptor comprising the antibody according to any one of claims 1–7 or the bispecific antibody according to any one of claims 8–12.

17. A genetically modified cell comprising the antibody according to any one of claims 1–7 or the bispecific antibody according to any one of claims 8–12, wherein preferably, the genetically modified cell is a eukaryotic cell, preferably an isolated human cell, and more preferably an immune cell such as a T cell or an NK cell.

18. A method for preparing a bispecific antibody comprising culturing the transformant according to claim 15, and obtaining the antibody or the bispecific antibody from the culture.

19. An antibody-drug conjugate comprising a cytotoxic agent and the antibody according to any one of claims 1–7 or the bispecific antibody according to any one of claims 8–12, wherein preferably, the cytotoxic agent is MMAF or MMAE.

20. A pharmaceutical composition comprising the antibody according to any one of claims 1–7 or the bispecific antibody according to any one of claims 8–12, and a pharmaceutically acceptable carrier; wherein

preferably, the pharmaceutical composition further comprises one or more of the group consisting of a hormonal agent, a small molecule-targeted agent, a proteasome inhibitor, an imaging agent, a diagnostic agent, a chemotherapeutic agent, an oncolytic drug, a cytotoxic agent, a cytokine, an activator of a costimulatory molecule, an inhibitor of an inhibitory molecule, and a vaccine.

21. Use of the antibody according to any one of claims 1–7 or the bispecific antibody according to any one of claims 8–12 or the pharmaceutical composition according to claim 20 in the manufacture of a medicament for the prevention or treatment of a CD3 and/or CLDN18.2-associated disease, wherein

the disease is preferably cancer, wherein the cancer is preferably breast cancer, ovarian cancer, endometrial cancer, renal cancer, melanoma, lung cancer, gastric cancer, liver cancer, esophageal cancer, cervical cancer, head and neck tumor, cholangiocarcinoma, gallbladder cancer, bladder cancer, sarcoma or colorectal cancer; preferably, the cancer is breast cancer, ovarian cancer, endometrial cancer, renal cancer or cholangiocarcinoma; more preferably, the cancer is breast cancer.

22. A kit comprising the antibody according to any one of claims 1–7 or the bispecific antibody according to any one of claims 8–12, the chimeric antigen receptor according to claim 16, the genetically modified cell according to claim 17, or the antibody-drug conjugate according to claim 19 or the pharmaceutical composition according to claim 20;

preferably, the kit further comprises (i) a device for administering the antibody or an antigen-binding fragment thereof or the antibody-drug conjugate or the pharmaceutical composition; and/or (ii) instructions.

23. A kit of parts comprising a kit A and a kit B, wherein:

the kit A comprises the antibody according to any one of claims 1–7 or the bispecific antibody according to any one of claims 8–12, the chimeric antigen receptor according to claim

16, the genetically modified cell according to claim 17, the antibody-drug conjugate according to claim 19 and/or the pharmaceutical composition according to claim 20;

the kit B comprises other anti-tumor antibodies or a pharmaceutical composition comprising the other anti-tumor antibodies, and/or one or more of the group consisting of a hormonal agent, a small molecule-targeted agent, a proteasome inhibitor, an imaging agent, a diagnostic agent, a chemotherapeutic agent, an oncolytic drug, a cytotoxic agent, a cytokine, an activator of a co-stimulatory molecule, an inhibitor of an inhibitory molecule, and a vaccine.

24. Use of the antibody according to any one of claims 1–7 or the bispecific antibody according to any one of claims 8–12, the chimeric antigen receptor according to claim 16, the antibody-drug conjugate according to claim 19 or the pharmaceutical composition according to claim 20 in the manufacture of a medicament for diagnosing, treating and/or preventing a CLDN18.2-mediated disease or disorder, wherein a therapeutically effective amount of the antibody, bispecific antibody, chimeric antigen receptor, antibody-drug conjugate or the pharmaceutical composition is to be administered to a patient in need thereof.

25. The use according to claim 24, wherein the disease or disorder is a tumor, preferably a CLDN18.2 positive tumor, and more preferably gastric cancer, esophageal cancer, lung cancer, ovarian cancer, melanoma, renal cancer, breast cancer, colorectal cancer, liver cancer, pancreatic cancer, bladder cancer, head and neck cancer, bronchial carcinoma, glioma and/or leukemia.

26. A method for immunodetection or determination of CLDN18.2 comprising using the antibody according to any one of claims 1–7 or the bispecific antibody according to any one of claims 8–12, the chimeric antigen receptor according to claim 16, the antibody-drug conjugate according to claim 19 or the pharmaceutical composition according to claim 20, wherein preferably, the detection is for non-diagnostic and/or therapeutic purposes.

27. Use of the antibody according to any one of claims 1–7 or the bispecific antibody according to any one of claims 8–12, the chimeric antigen receptor according to claim 16, the antibody-drug conjugate according to claim 19 or the pharmaceutical composition according to claim 20, and a second therapeutic agent in the manufacture of a medicament for prevention or treatment of a CD3 and/or CLDN18.2-associated disease, wherein the second therapeutic agent preferably comprises other anti-tumor antibodies or a pharmaceutical composition comprising the other anti-tumor antibodies, and/or one or more of the group consisting of a hormonal agent, a small molecule-targeted agent, a proteasome inhibitor, an imaging agent, a diagnostic

agent, a chemotherapeutic agent, an oncolytic drug, a cytotoxic agent, a cytokine, an activator of a co-stimulatory molecule, an inhibitor of an inhibitory molecule, and a vaccine.

28. The antibody according to any one of claims 1–7 or the bispecific antibody according to any one of claims 8–12, the chimeric antigen receptor according to claim 16, the antibody-drug conjugate according to claim 19 or the pharmaceutical composition according to claim 20 for use in therapy.