

CLAIMS

1. An anti-TIGIT antibody or an antigen-binding fragment thereof, wherein

a heavy chain variable region of the antibody comprises HCDR1-HCDR3 with amino acid sequences set forth in SEQ ID NOs: 3-5, respectively, and a light chain variable region of the antibody comprises LCDR1-LCDR3 with amino acid sequences set forth in SEQ ID NOs: 8-10, respectively.

2. The anti-TIGIT antibody or the antigen-binding fragment thereof according to claim 1, wherein the heavy chain variable region of the antibody comprises an amino acid sequence selected from SEQ ID NO: 1, SEQ ID NO: 11, SEQ ID NO: 13, SEQ ID NO: 15, and SEQ ID NO: 17; and

the light chain variable region of the antibody comprises an amino acid sequence selected from SEQ ID NO: 6, SEQ ID NO: 19, SEQ ID NO: 21, SEQ ID NO: 23, and SEQ ID NO: 25.

3. The anti-TIGIT antibody or the antigen-binding fragment thereof according to any one of claims 1 to 2, wherein

the heavy chain variable region of the antibody comprises an amino acid sequence set forth in SEQ ID NO: 1, and the light chain variable region of the antibody comprises an amino acid sequence set forth in SEQ ID NO: 6;

the heavy chain variable region of the antibody comprises an amino acid sequence set forth in SEQ ID NO: 11, and the light chain variable region of the antibody comprises an amino acid sequence set forth in

SEQ ID NO: 19;

the heavy chain variable region of the antibody comprises an amino acid sequence set forth in SEQ ID NO: 17, and the light chain variable region of the antibody comprises an amino acid sequence set forth in SEQ ID NO: 19;

the heavy chain variable region of the antibody comprises an amino acid sequence set forth in SEQ ID NO: 13, and the light chain variable region of the antibody comprises an amino acid sequence set forth in SEQ ID NO: 21;

the heavy chain variable region of the antibody comprises an amino acid sequence set forth in SEQ ID NO: 13, and the light chain variable region of the antibody comprises an amino acid sequence set forth in SEQ ID NO: 23;

the heavy chain variable region of the antibody comprises an amino acid sequence set forth in SEQ ID NO: 15, and the light chain variable region of the antibody comprises an amino acid sequence set forth in SEQ ID NO: 21;

the heavy chain variable region of the antibody comprises an amino acid sequence set forth in SEQ ID NO: 15, and the light chain variable region of the antibody comprises an amino acid sequence set forth in SEQ ID NO: 23;

the heavy chain variable region of the antibody comprises an amino acid sequence set forth in SEQ ID NO: 11, and the light chain variable region of the antibody comprises an amino acid sequence set forth in SEQ ID NO: 25; or

the heavy chain variable region of the antibody comprises an amino acid sequence set forth in SEQ ID NO: 17, and the light chain variable region of the antibody comprises an amino acid sequence set forth in SEQ ID NO: 25.

4. The anti-TIGIT antibody or the antigen-binding fragment thereof according to any one of claims 1 to 3, wherein the anti-TIGIT antibody or the antigen-binding fragment thereof is selected from Fab, Fab', F(ab')₂, Fd, Fv, dAb, a complementarity determining region fragment, a single chain antibody, a humanized antibody, a chimeric antibody, and a diabody.

5. The anti-TIGIT antibody or the antigen-binding fragment thereof according to any one of claims 1 to 4, wherein the antibody comprises a non-CDR region derived from a species other than murine, such as from a human antibody.

6. The anti-TIGIT antibody or the antigen-binding fragment thereof according to any one of claims 1 to 5, wherein a heavy chain constant region of the antibody is Ig gamma-1 chain C region (e.g., NCBI ACCESSION: P01857) or Ig gamma-4 chain C region (e.g., NCBI ACCESSION: P01861.1); a light chain constant region of the antibody is Ig kappa chain C region (e.g., NCBI ACCESSION: P01834).

7. The anti-TIGIT antibody or the antigen-binding fragment thereof according to any one of claims 1 to 6, wherein the antibody binds to TIGIT-mFc with a K_D of less than 4E-10 or less than 4E-11; preferably, the K_D is measured by a Fortebio molecular interaction instrument.

8. The anti-TIGIT antibody or the antigen-binding fragment thereof according to any one of claims 1 to 7, wherein the antibody binds to TIGIT-mFc with an EC₅₀ of less than 1.5 nM, less than 1.2 nM, or less than 1 nM; preferably, the EC₅₀ is measured by a flow cytometer.

9. The anti-TIGIT antibody or the antigen-binding fragment thereof according to any one of claims 1 to 8, wherein the anti-TIGIT antibody is an antibody produced by a hybridoma cell line LT019 deposited at China Center for Type Culture Collection (CCTCC) under CCTCC NO. C2020208.

10. An isolated nucleic acid molecule, encoding the anti-TIGIT antibody or the antigen-binding fragment according to any one of claims 1 to 9.

11. A vector, comprising the isolated nucleic acid molecule according to claim 10.

12. A host cell, comprising the isolated nucleic acid molecule according to claim 10 or the vector according to claim 11.

13. A hybridoma cell line LT019 deposited at China Center for Type Culture Collection (CCTCC) under CCTCC NO. C2020208.

14. A conjugate, comprising an antibody and a conjugated moiety, wherein the antibody is the anti-TIGIT antibody or the antigen-binding fragment thereof according to any one of claims 1 to 9, and the conjugated moiety is a detectable label; preferably, the conjugated moiety is a radioisotope, a fluorescent substance, a luminescent substance, a colored substance, or an enzyme.

15. A kit, comprising the anti-TIGIT antibody or the antigen-binding fragment thereof according to any one of claims 1 to 9, or the conjugate

according to claim 14;

wherein preferably, the kit further comprises a secondary antibody specifically recognizing the antibody; optionally, the secondary antibody further comprises a detectable label, for example, a radioisotope, a fluorescent substance, a luminescent substance, a colored substance, or an enzyme.

16. Use of the antibody according to any one of claims 1 to 9 or the conjugate according to claim 14 in preparing a kit for detecting the presence or level of TIGIT in a sample.

17. A bispecific antibody, comprising a first protein functional region and a second protein functional region, wherein the first protein functional region targets TIGIT; the second protein functional region targets a target other than TIGIT (e.g., PD-1);

wherein the first protein functional region is the antibody or the antigen-binding fragment according to any one of claims 1 to 9; preferably, the bispecific antibody is in IgG-scFv format; preferably, the first protein functional region is the antibody according to any one of claims 1 to 9 and is in immunoglobulin form, and the second protein functional region is a single chain antibody; or preferably, the first protein functional region is a single chain antibody, and the second protein functional region is an antibody in immunoglobulin form targeting a target other than TIGIT (e.g., PD-1).

18. The bispecific antibody according to claim 17, wherein the first protein functional region and the second protein functional region are linked directly or via a linker fragment.

19. The bispecific antibody according to any one of claims 17 to 18, wherein the numbers of the first protein functional region and the second protein functional region are each independently 1, 2 or more.

20. The bispecific antibody according to any one of claims 17 to 19, wherein the single chain antibody is linked to the C-termini of two heavy chains of the antibody in immunoglobulin form.

21. A pharmaceutical composition, comprising the anti-TIGIT antibody or the antigen-binding fragment thereof according to any one of claims 1 to 9 or the conjugate according to claim 14, wherein, optionally, the pharmaceutical composition further comprises a pharmaceutically acceptable carrier and/or excipient.

22. The pharmaceutical composition according to claim 21, further comprising one or more anti-PD-1 antibodies, or one or more anti-PD-L1 antibodies.

23. The pharmaceutical composition according to claim 21 or 22, wherein a mass ratio of the anti-TIGIT antibody or the antigen-binding fragment thereof to the anti-PD-1 antibody or the anti-PD-L1 antibody is (1:5)-(5:1), based on the mass of the antibodies.

24. A combination product, comprising a first product and a second product in separate packages, wherein the first product comprises the anti-TIGIT antibody or the antigen-binding fragment thereof according to any one of claims 1 to 9, the conjugate according to claim 14, or the pharmaceutical composition

according to any one of claims 21 to 23;
the second product comprises at least one anti-PD-1 antibody or at least one anti-PD-L1 antibody;
preferably, the first product and the second product further independently comprise one or more pharmaceutically acceptable adjuvants;
preferably, the combination product further comprises a package insert.

25. The combination product according to claim 24, wherein a mass ratio of the anti-TIGIT antibody or the antigen-binding fragment thereof to the anti-PD-1 antibody or the anti-PD-L1 antibody is (1:5)-(5:1), based on the mass of the antibodies.

26. Use of the antibody or the antigen-binding fragment thereof according to any one of claims 1 to 9, the conjugate according to claim 14, the bispecific antibody according to any one of claims 17 to 20, or the pharmaceutical composition according to any one of claims 21 to 23 in preparing a medicament for treating and/or preventing a tumor, wherein

preferably, the tumor is selected from one or more of liver cancer, kidney cancer, brain tumor, urothelial carcinoma, bone tumor, cholangiocarcinoma, non-small cell lung cancer, small cell lung cancer, breast cancer, ovarian cancer, colorectal cancer, melanoma, pancreatic cancer, cervical tumor, multiple myeloma, Hodgkin's lymphoma, non-Hodgkin's lymphoma, B-lymphoma, plasma cell cancer, endometrial cancer, prostate cancer, and testicular cancer.

27. The antibody or the antigen-binding fragment thereof according to

any one of claims 1 to 9 or the bispecific antibody according to any one of claims 17 to 20 for use in treating and/or preventing a tumor, wherein preferably, the tumor is selected from one or more of liver cancer, kidney cancer, brain tumor, urothelial carcinoma, bone tumor, cholangiocarcinoma, non-small cell lung cancer, small cell lung cancer, breast cancer, ovarian cancer, colorectal cancer, melanoma, pancreatic cancer, cervical tumor, multiple myeloma, Hodgkin's lymphoma, non-Hodgkin's lymphoma, B-lymphoma, ovarian cancer, plasma cell cancer, endometrial cancer, prostate cancer, and testicular cancer.

~~28. A method for treating and/or preventing a tumor, comprising a step of administering to a subject in need an effective amount of the antibody or the antigen-binding fragment thereof according to any one of claims 1 to 9 or the bispecific antibody according to any one of claims 17 to 20, wherein preferably, the tumor is selected from one or more of liver cancer, kidney cancer, brain tumor, urothelial carcinoma, bone tumor, cholangiocarcinoma, non-small cell lung cancer, small cell lung cancer, breast cancer, ovarian cancer, colorectal cancer, melanoma, pancreatic cancer, cervical tumor, multiple myeloma, Hodgkin's lymphoma, non-Hodgkin's lymphoma, B-lymphoma, ovarian cancer, plasma cell cancer, endometrial cancer, prostate cancer, and testicular cancer.~~