

What is claimed is:

1. An anti-HER3 antibody or an antigen-binding fragment thereof, comprising a heavy chain variable region (VH), wherein the VH comprise: CDR-H1 comprising the amino acid sequence of SEQ ID NO: 15, CDR-H2 comprising the amino acid sequence of SEQ ID NO: 17 and CDR-H3 comprising the amino acid sequence of SEQ ID NO: 19;

preferably, the anti-HER3 antibody or an antigen-binding fragment thereof further comprises a light chain variable region (VL), wherein the VL comprises CDR-L1 comprising the amino acid sequence of SEQ ID NO: 5, CDR-L2 comprising the amino acid sequence of SEQ ID NO: 7 and CDR-L3 comprising the amino acid sequence of SEQ ID NO: 9;

more preferably, the VH comprise CDR-H1 of SEQ ID NO: 15, CDR-H2 of SEQ ID NO: 17 and CDR-H3 of SEQ ID NO: 19 and/or the VL comprises CDR-L1 of SEQ ID NO: 5, CDR-L2 of SEQ ID NO: 7 and CDR-L3 of SEQ ID NO: 9.

2. The anti-HER3 antibody or an antigen-binding fragment of claim 1, wherein the VH comprises the amino acid sequence of SEQ ID NO: 12 with or without a leader sequence of SEQ ID NO: 13, or an amino acid sequence at least 85%, 86%, 87%, 88%, 89%, 90%, 91%, 92%, 93%, 94%, 95%, 96%, 97%, 98%, or 99% identical thereto; and/or wherein the VL comprises the amino acid sequence of SEQ ID NO: 2 with or without a leader sequence of SEQ ID NO: 3, or an amino acid sequence at least 85%, 86%, 87%, 88%, 89%, 90%, 91%, 92%, 93%, 94%, 95%, 96%, 97%, 98%, or 99% identical thereto.

3. The anti-HER3 antibody or an antigen-binding fragment of claim 1 or 2, wherein the antibody is a mouse, chimeric, humanized or human antibody;

preferably, the heavy chain of the antibody is of the type of IgG1.

4. The anti-HER3 antibody or an antigen-binding fragment of any one of claims 1-3, wherein the antibody is a humanized antibody, and the heavy chain comprises the amino acid sequence of SEQ ID NO: 21, 25 or 27 with or without the leader sequence in it, or an amino acid sequence at least 85%, 86%, 87%, 88%, 89%, 90%, 91%, 92%, 93%, 94%, 95%, 96%, 97%, 98%, or 99% identical thereto;

preferably, the leader sequence comprises an amino acid sequence of amino acid positions 1 to 19 of SEQ ID NO: 21, 25 or 27;

more preferably, the heavy chain comprises an amino acid sequence of positions 20 to 467 of SEQ ID NO: 21, 25 or 27.

5. The anti-HER3 antibody or an antigen-binding fragment of any one of claims 1-4, wherein the antibody is a humanized antibody, and the light chain comprises the amino acid sequence of SEQ ID NO: 23 with or without the leader sequence in it, or an amino acid sequence at least 85%, 86%, 87%, 88%, 89%, 90%, 91%, 92%, 93%, 94%, 95%, 96%, 97%,

98%, or 99% identical thereto;

preferably, the leader sequence comprises an amino acid sequence of amino acid positions 1 to 19 of SEQ ID NO: 23;

more preferably, the light chain comprises an amino acid sequence of amino acid positions 20 to 233 of SEQ ID NO: 23.

6. The anti-HER3 antibody or an antigen-binding fragment of any one of claims 1-3, wherein the VH comprises the VH sequence comprised in SEQ ID NO: 21, 25 or 27;

preferably, the VH comprises an amino acid sequence of amino acid positions 20-137 of SEQ ID NO: 21, 25 or 27.

7. The anti-HER3 antibody or an antigen-binding fragment of any one of claims 1-3, wherein the VL comprises the VL sequence comprised in SEQ ID NO: 23;

preferably, the VL comprises an amino acid sequence of amino acid positions 20-126 of SEQ ID NO: 23.

8. The anti-HER3 antibody or an antigen-binding fragment of any one of claims 1-7, wherein the HER3 is human or monkey HER3;

preferably, the anti-HER3 antibody blocks NRG1 induced phosphorylation of the HER3, the anti-HER3 antibody binds to human or monkey HER3 with an EC₅₀ lower than 1 nM and/or the anti-HER3 antibody has an internalization activity upon binding to the HER3.

9. An isolated nucleic acid, wherein the isolated nucleic acid comprises a polynucleotide acid sequence encoding the anti-HER3 antibody or antigen-binding fragment of any one of the claims 1-8;

preferably, the isolated nucleic acid is selected from SEQ ID NOs: 1, 11, 22, 24, 26 and 28.

10. A vector, wherein the vector comprises the isolated nucleic acid of claim 9.

11. A host cell, wherein the host cell comprises the isolated nucleic acid of claim 9 or the vector of claim 10;

preferably, the host cell expresses the anti-HER3 antibody or antigen-binding fragment of any one of the claims 1-8.

12. An antibody conjugate, wherein the antibody conjugate comprises the anti-HER3 antibody or antigen-binding fragment of any one of claims 1-8 conjugated to a chemical moiety;

preferably, the antibody conjugate is an antibody drug conjugate (ADC);

more preferably, the chemical moiety is a radioactive isotope, a chemotherapeutic agent, or a cytotoxic agent;

more preferably, the cytotoxic agent is a toxin; and more preferably, the toxin is selected

from auristatin E, auristatin F, MMAE and MMAF.

13. The antibody conjugate of claim 12, wherein the anti-HER3 antibody or antigen-binding fragment is conjugated to the chemical moiety via a linker;

preferably, the linker is enzyme-cleavable;

more preferably, the linker comprises a Val-Cit moiety.

14. A pharmaceutical composition, wherein the pharmaceutical composition comprises the anti- HER3 antibody or antigen-binding fragment of any one of the claims 1-8 or the antibody conjugate of claim 12 or 13 and a pharmaceutically acceptable carrier;

preferably, the pharmaceutical composition further comprises one or more other anti-cancer agents.

15. Use of the anti- HER3 antibody or antigen-binding fragment of any one of the claims 1-8 or the antibody conjugate of claim 12 or 13 in the manufacture of a medicament for the treatment of a cancer.

16. The use of claim 15, wherein the cancer expresses the HER3.

17. The use of claim 15 or 16, wherein the cancer is a gastric or colorectal cancer.