# CLAIMS

What is claimed is:

1. Use of an antibody-drug conjugate (ADC) in the preparation of a medicine for treating of a patient with Human Epidermal Growth Factor Receptor 2 (HER2)-low expressing breast cancer, wherein the ADC has the structure of the general formula Ab-$(L\text{-}U)_n$, wherein:

Ab represents an anti-HER2 antibody,

L represents a linker,

U represents a conjugated cytotoxic molecule, and

n is an integer from 1 to 8 and represents the number of cytotoxic molecules bound to each antibody;

wherein the antibody comprises a heavy chain variable region and a light chain variable region, wherein the CDR sequences of the heavy chain variable region and/or the CDR sequences of the light chain variable region have the same CDR sequences as Disitamab vedotin;

wherein the linker L comprises Maleimido-Caproyl-Valine-Citrulline-p-Aminobenzyloxy (mc-vc-pAB), wherein the linker is covalently linked to the anti-HER2 antibody by means of sulfhydryl conjugation, and the linking site is the interchain disulfide bond site of the anti-HER2 antibody; and

wherein the cytotoxic molecule U comprises MMAE (monomethyl auristatin E).

2. The use according to claim 1, wherein the HER2-low expressing breast cancer patient is a patient whose HER2 is detected as immunohistochemistry (IHC) 2+/fluorescence in situ hybridization (FISH) negative or IHC1+.

3. The use according to claim 2, wherein HER2 is detected as IHC 2+/FISH negative or IHC1+ in a sample from the breast cancer.

4. The use according to claim 2 or claim 3, wherein HER2 is detected using an immunohistochemistry (IHC) assay and/or a fluorescence in situ hybridization (FISH) assay.

5. The use according to any one of claims 1-4, wherein the anti-HER2 antibody is a murine, chimeric, humanized or fully human antibody.

6. The use according to claim 5, wherein the anti-HER2 antibody is of the IgG class.

7. The use according to claim 6, wherein the anti-HER2 antibody has an IgG1, IgG2, or IgG4 isotype.

8. The use according to any one of claims 1-7, wherein the anti-HER2 antibody comprises a heavy chain variable region (VH) and a light chain variable region (VL), wherein:
(a) the VH comprises a CDR-H1 comprising the amino acid sequence GYTFTDYY (SEQ ID NO:3), a CDR-H2 comprising the amino acid sequence VNPDHGDS (SEQ ID NO:4), and a CDR-H3 comprising the amino acid sequence ARNYLFDH (SEQ ID NO:5), and
(b) the VL comprises a CDR-L1 comprising the amino acid sequence QDVGTA (SEQ ID NO:6), a CDR-L2 comprising the amino acid sequence WAS (SEQ ID NO:7 ), and a CDR-L3 comprising the amino acid sequence HQFATYT (SEQ ID NO:8).

9. The use according to any one of claims 1-7, wherein the anti-HER2 antibody comprises a heavy chain variable region (VH) and a light chain variable region (VL), wherein:
(a) the VH comprises a CDR-H1 comprising the amino acid sequence DYYIH (SEQ ID NO: 11), a CDR-H2 comprising the amino acid sequence RVNPDHGDSYYNQKFKD (SEQ ID NO: 12), and a CDR-H3 comprising the amino acid sequence ARNYLFDHW (SEQ ID NO: 13), and
(b) the VL comprises a CDR-L1 comprising the amino acid sequence KASQDVGTAVA (SEQ ID NO: 14), a CDR-L2 comprising the amino acid sequence WASIRHT (SEQ ID NO: 15), and a CDR-L3 comprising the amino acid sequence HQFATYT (SEQ ID NO: 16).

10. The use according to any one of claims 1-9, wherein the anti-HER2 antibody comprises a heavy chain variable region (VH) comprising the amino acid sequence of SEQ ID NO: 9, and a light chain variable region (VL) comprising the amino acid sequence of SEQ ID NO: 10.

11. The use according to any one of claims 1-10, wherein the anti-HER2 antibody is a human IgG antibody.

12. The use according to claim 11, wherein the anti-HER2 antibody is a human IgG1, IgG2, IgG3, or IgG4 antibody.

13. The use according to any one of claims 1-12, wherein the amino acid sequence of the heavy chain of the antibody is shown in SEQ ID NO:1, and the amino acid sequence of the light chain of the antibody is shown in SEQ ID NO:2.

14. The use according to any one of claims 1-12, wherein the ADC is Disitamab vedotin or a biosimilar thereof.

15. The use according to any one of claims 1-14, wherein the average Drug-to-Antibody Ratio (DAR) value of the ADC is any number from 2 to 7.

16. The use according to claim 15, wherein the average DAR value is $4 \pm 0.5$.

17. The use according to any one of claims 1-16, wherein the breast cancer is infiltrating locally advanced or metastatic breast cancer as established by histology and/or cytology, and is unresectable.

18. The use according to any one of claims 1-17, wherein the patient has previously received one or more prior treatments.

19. The use according to claim 18, wherein the one or more prior treatments are selected from the group consisting of a chemotherapy drug, a targeted therapy, an immunotherapy and an endocrine therapy.

20. The use according to claim 18 or claim 19, wherein the patient has previously received taxane systemic therapy.

21. The use according to any one of claims 18-20, wherein the patient has previously received systemic therapy with trastuzumab or a biosimilar thereof at least once.

22. The use according to any one of claims 1-21, wherein the medicine is to be administered intranasally, subcutaneously, intradermally, intramuscularly or intravenously.

23. The use according to any one of claims 1-22, wherein the ADC is to be administered at a dose of 2.0 mg/kg every 2 weeks.