CLAIMS

1. An anti-HER2 antibody-drug conjugate (ADC) for use in the treatment of cancer in a patient, wherein the ADC comprises an anti-HER2 antibody conjugated to an anti-cancer drug, and wherein the anti-HER2 ADC is administered at least twice every week, at least weekly (QW), at least every 2 weeks (Q2W), at least every 3 weeks (Q3W) or at least every 4 weeks (Q4W).

2. The anti-HER2 ADC for use of claim 1, wherein the anti-HER2 ADC is administered every 3 weeks (Q3W).

3. The anti-HER2 ADC for use of claim 1 or 2, wherein the anti-HER2 ADC is administered at a dose of about 0.010 mg/kg to about 10 mg/kg, about 0.010 mg/kg to about 5 mg/kg, about 0.10 mg/kg to about 1 mg/kg or about 0.10 mg/kg to about 0.50 mg/kg.

4. The anti-HER2 ADC for use of any one of claims 1 to 3, wherein the anti-HER2 ADC is administered at a dose of at least 0.10, 0.15, 0.20, 0.25, 0.30, 0.35, 0.40, 0.45, 0.50, 0.55, 0.60, 0.65, 0.70, 0.75, 0.80, 0.95, 1.00, 1.10, 1.20, 1.30, 1.40, 1.50, 2.00, 2.50, 2.70, 3.00, 3.50, 4.00, 4.50, 5.00, 5.50, 6.00 mg/kg.

5. The anti-HER2 ADC for use of any one of claims 1 to 4, wherein the anti-HER2 ADC is administered at a dose of about 0.15 mg/kg, 0.50 mg/kg, 1.20 mg/kg, 2.00 mg/kg, 2.70 mg/kg, 3.00 mg/kg, 4.00 mg/kg, 5.00 mg/kg, or 6.00 mg/kg.

6. The anti-HER2 ADC for use of any one of claims 1 to 5, wherein the anti-HER2 ADC is administered every 3 weeks (Q3W) at a dose of about 0.15 mg/kg, 0.50 mg/kg, 1.20 mg/kg, 2.00 mg/kg, 2.70 mg/kg, 3.00 mg/kg, 4.00 mg/kg, 5.00 mg/kg, or 6.00 mg/kg.

7. The anti-HER2 ADC for use of claim 6, wherein the anti-HER2 ADC is administered every 3 weeks (Q3W) at a dose of about 3.00 mg/kg, 4.00 mg/kg, 5.00 mg/kg, or 6.00 mg/kg.

8. The anti-HER2 ADC for use of claim 7, wherein the anti-HER2 ADC is administered every 3 weeks (Q3W) at a dose of about 4.00 mg/kg mg/kg.

9. The anti-HER2 ADC for use of any one of claims 1 to 8, wherein the anti-HER2 ADC is administered intravenously, subcutaneously, intramuscularly, by bolus injection, intracerebrally or by sustained release.

10. The anti-HER2 ADC for use of any one of claims 1 to 9, wherein the anti-HER2 ADC is formulated in a pharmaceutical composition.

11. The anti-HER2 ADC for use of any one of claims 1 to 10, wherein the antibody comprises a VH CDR1 comprising the amino acid sequence of SEQ ID NO: 2, VH CDR2 comprising the amino acid sequence of SEQ ID NO: 3, and VH CDR3 comprising the amino acid sequence of SEQ ID NO: 4, and VL CDR1 comprising the amino acid sequence of SEQ ID NO: 8, VL CDR2 comprising the amino acid sequence of SEQ ID NO: 9, and VL CDR3 comprising the amino acid sequence of SEQ ID NO: 10.

12. The anti-HER2 ADC for use of any one of claims 1 to 11, wherein the anti-HER2 ADC comprises an antibody having three CDRS from a heavy chain protein comprising the amino acid sequence of SEQ ID NO: 14 and three CDRS from a light chain protein comprising the amino acid sequence of SEQ ID NO: 16.

13. The anti-HER2 ADC for use of any one of claims 1 to 12, wherein the antibody is T(kK183C+K290C).

14. The anti-HER2 ADC for use of any one of claims 1 to 13, wherein the anti-HER2 ADC further comprises a linker moiety that joins the antibody to the anti-cancer drug.

15. The anti-HER2 ADC for use of any one of claims 1 to 14, wherein the anti-cancer drug is 2-methylalanyl-N-[(3R,4S,5S)-3-methoxy-1-{(2S)-2-[(1R,2R)-1-methoxy-2-methyl-3-oxo-3-{[(1S)-2-phenyl-1-(1,3-thiazol-2-yl)ethyl]amino}propyl]pyrrolidin-1-yl}-5-methyl-1-oxoheptan-4-yl]-N-methyl-L-valinamide (0101).

16. The anti-HER2 ADC for use of any one of claims 1 to 15, wherein the linker is maleimidocaproyl–valine-citrulline-p-aminobenzyloxycarbonyl (vc).

17. The anti-HER2 ADC for use of any one of claims 1 to 16, wherein the anti-HER2 ADC is T(kK183C+K290C)-vc0101.

18. The anti-HER2 ADC for use of any one of claims 1 to 17, wherein the cancer is characterized by overexpression of HER2.

19. The anti-HER2 ADC for use of any one of claims 1-17, wherein the cancer is hormone receptor positive.

20. The anti-HER2 ADC for use of any one of claims 1 to 19, wherein the cancer is breast cancer, hormone receptor positive breast cancer, estrogen receptor and progesterone receptor negative breast cancer, triple negative breast cancer (TNBC), ovarian cancer, lung cancer, non-small cell lung cancer (NSCLC), gastric cancer, esophageal cancer, colorectal cancer, urothelial cancer, pancreatic cancer, salivary gland cancer and brain cancer or metastases thereof.

21. The anti-HER2 ADC for use of claim 19, wherein the cancer is breast cancer, gastric cancer, or NSCLC.

22. The anti-HER2 ADC for use of any one of claims 1 to 21, wherein the treatment results in a decrease in tumor size of at least 1%, at least 5%, at least 10%, at least 15%, at least 20%, at least 25%, at least 30%, at least 35%, at least 40%, at least 45%, at least 50%, at least 55%, at least 60%, at least 65%, at least 70%, at least 75%, at least 80%, at least 85%, at least 90%, at least 95% or 100% as compared to the tumor size in the patient prior to first administration of the anti-HER2 ADC.

23. The anti-HER2 ADC for use of any one of claims 1 to 22, wherein the treatment is an initial treatment.

24. The anti-HER2 ADC for use of any one of claims 1 to 22, wherein the cancer is unresponsive to conventional therapies.

25. The anti-HER2 ADC for use of any one of claims 1 to 24, wherein the patient is a human.

26. A method for the treatment of a patient having cancer, comprising administering to the patient an effective amount of an anti-HER2 ADC at least twice every week, at least weekly (QW), at least every 2 weeks (Q2W), at least every 3 weeks (Q3W) or at least every 4 weeks (Q4W), wherein the anti-HER2 ADC comprises an anti-HER2 antibody conjugated to an anti-cancer drug.

27. The method of claim 26, wherein the anti-HER2 ADC is administered every 3 weeks (Q3W).

28. The method of claim 26 or 27, wherein the anti-HER2 ADC is administered at a dose of about 0.010 mg/kg to about 10 mg/kg, about 0.010 mg/kg to about 5 mg/kg, about 0.10 mg/kg to about 1 mg/kg or about 0.10 mg/kg to about 0.50 mg/kg.

29. The method of any one of claims 26 to 28, wherein the anti-HER2 ADC is administered at a dose of at least 0.10, 0.15, 0.20, 0.25, 0.30, 0.35, 0.40, 0.45, 0.50, 0.55, 0.60, 0.65, 0.70, 0.75, 0.80, 0.95, 1.00, 1.10, 1.20, 1.30, 1.40, 1.50, 2.00, 2.50, 2.70, 3.00, 3.50, 4.00, 4.50, 5.00, 5.50, 6.00 mg/kg.

30. The method of any one of claims 26 to 29, wherein the anti-HER2 ADC is administered at a dose of about 0.15 mg/kg, 0.50 mg/kg, 1.20 mg/kg, 2.00 mg/kg, 2.70 mg/kg, 3.00 mg/kg, 4.00 mg/kg, 5.00 mg/kg, or 6.00 mg/kg.

31. The method of any one of claims 26 to 30, wherein the anti-HER2 ADC is administered every 3 weeks (Q3W) at a dose of about 0.15 mg/kg, 0.50 mg/kg, 1.20 mg/kg, 2.00 mg/kg, 2.70 mg/kg, 3.00 mg/kg, 4.00 mg/kg, 5.00 mg/kg, or 6.00 mg/kg.

32. The method of claim 31, wherein the anti-HER2 ADC is administered every 3 weeks (Q3W) at a dose of about 3.00 mg/kg, 4.00 mg/kg, 5.00 mg/kg, or 6.00 mg/kg.

33. The method of claim 32, wherein the anti-HER2 ADC is administered every 3 weeks (Q3W) at a dose of about 4.00 mg/kg mg/kg.

34. The method of any one of claims 26-33, wherein the anti-HER2 ADC is administered intravenously, subcutaneously, intramuscularly, by bolus injection, intracerebrally or by sustained release.

35. The method of any one of claims 26 to 34, wherein the anti-HER2 ADC is formulated in a pharmaceutical composition.

36. The method of any one of claims 26 to 35, wherein the antibody comprises a VH CDR1 having the amino acid sequence shown in SEQ ID NO: 2, VH CDR2 having the amino acid sequence shown in SEQ ID NO: 3, and VH CDR3 having the amino acid sequence shown in SEQ ID NO: 4, and/or VL CDR1 having the amino acid sequence shown in SEQ ID NO: 8, VL CDR2 having the amino acid sequence shown in SEQ ID NO: 9, and VL CDR3 having the amino acid sequence shown in SEQ ID NO: 10.

37. The method of any one of claims 26 to 36, wherein the antibody comprises a heavy chain protein having the amino acid sequence shown in SEQ ID NO: 14 and a light chain protein having the amino acid sequence shown in SEQ ID NO: 16.

38. The method any one of claims 26 to 37, wherein the antibody is T(kK183C+K290C).

39. The method of any one of claims 26 to 39, wherein the anti-cancer drug is 2-methylalanyl-N-[(3R,4S,5S)-3-methoxy-1-{(2S)-2-[(1R,2R)-1-methoxy-2-methyl-3-oxo-3-{[(1S)-2-phenyl-1-(1,3-thiazol-2-yl)ethyl]amino}propyl]pyrrolidin-1-yl}-5-methyl-1-oxoheptan-4-yl]-N-methyl-L-valinamide (0101).

40. The method of any one of claims 26 to 39, wherein the anti-HER2 ADC further comprises a linker.

41. The method of claim 40, wherein the linker is maleimidocaproyl–valine-citrulline-p-aminobenzyloxycarbonyl (vc).

42. The method any one of claims 26 to 41, wherein the anti-HER2 ADC is T(kK183C+K290C)-vc0101.

43. The method of any one of claims 26 to 42, wherein the cancer is characterized by overexpression of HER2.

44. The method of any one of claims 26 to 42, wherein the cancer is hormone receptor positive.

45. The method of any one of claims 26 to 44, wherein the cancer is breast cancer, hormone receptor positive breast cancer, estrogen receptor and progesterone receptor negative breast cancer, triple negative breast cancer (TNBC), ovarian cancer, lung cancer, non-small cell lung cancer (NSCLC), gastric cancer, esophageal cancer, colorectal cancer, urothelial cancer, pancreatic cancer, salivary gland cancer and brain cancer or metastases thereof.

46. The method of claim 44, wherein the cancer is breast cancer, gastric cancer, or NSCLC.

47. The method of any one of claims 26 to 46, wherein the treatment results in a decrease in tumor size of at least 1%, at least 5%, at least 10%, at least 15%, at least 20%, at least 25%, at least 30%, at least 35%, at least 40%, at least 45%, at least 50%, at least 55%, at least 60%, at least 65%, at least 70%, at least 75%, at least 80%, at least 85%, at least 90%, at least 95% or 100% as compared to the tumor size in the patient prior to first administration of the anti-HER2 ADC.

48. The method of any one of claims 26 to 47, wherein the treatment is an initial treatment.

49. The method of any one of claims 26 to 48, wherein the cancer is unresponsive to conventional therapies.

50. The method of any one of claims 26 to 49, wherein the patient is a human.