WE CLAIM:

1. Use of an anti-HER2 biparatopic antibody in the manufacture of a medicament for treating a subject having a HER2-expressing cancer, wherein an effective amount of the medicament is to be administered to the subject, wherein the effective amount is to be administered according to a 2-tiered fixed dosing regimen comprising a low fixed dose to be administered at a fixed time interval to a subject whose weight is less than a dose cut-off weight, and a high fixed dose to be administered at a fixed time interval to a subject whose weight is equal to or greater than the dose cut-off weight.

2. The use according to Claim 1, wherein the low fixed dose is about 600 mg and the high fixed dose is about 800 mg, the dose cut-off weight is 70 kg and the fixed time interval is weekly (QW).

3. The use according to Claim 1, wherein the low fixed dose is about 800 mg and the high fixed dose is about 1200 mg, the dose cut-off weight is 70 kg and the fixed time interval is weekly (QW).

4. The use according to Claim 1, wherein the low fixed dose is about 800 mg and the high fixed dose is about 1000 mg, the dose cut-off weight is 70 kg and the fixed time interval is weekly (QW).

5. The use according to Claim 1, wherein the low fixed dose is about 1800 mg and the high fixed dose is about 2200 mg, the dose cut-off weight is 70 kg and the fixed time interval is every 2 weeks (Q2W).

6. The use according to Claim 1, wherein the low fixed dose is about 1200 mg and the high fixed dose is about 1600 mg, the dose cut-off weight is 70 kg and the fixed time interval is every 2 weeks (Q2W).

7. The use according to Claim 1, wherein the low fixed dose is about 1200 mg and the high fixed dose is about 1800 mg, the dose cut-off weight is 70 kg and the fixed time interval is every 3 weeks (Q3W).

8. The use according to Claim 1, wherein the low fixed dose is about 1800 mg and the high fixed dose is about 2400 mg, the dose cut-off weight is 70 kg and the fixed time interval is every 3 weeks (Q3W).

9. The use according to any one of Claims 1 to 8, wherein the anti-HER2 biparatopic antibody comprises (a) a first antigen-binding domain comprising CDR sequences CDRH1, CDRH2 and CDRH3 as set forth in SEQ ID NOs: 32, 34 and 33 respectively, and CDR sequences CDRL1, CDRL2 and CDRL3 as set forth in SEQ ID NOs: 22, 24 and 23 respectively, and (b) a second antigen-binding domain comprising CDR sequences CDRH1, CDRH2 and CDRH3 as set forth in SEQ ID NOs: 56, 57 and 58 respectively, and CDR sequences CDRL1, CDRL2 and CDRL3 as set forth in SEQ ID NOs: 53, 54 and 55 respectively.

10. The use according to Claim 9, wherein the first antigen-binding domain is a Fab and the second antigen-binding domain is an scFv.

11. The use according to Claim 9 or 10, wherein the anti-HER2 biparatopic antibody comprises (a) a first antigen-binding domain comprising a variable heavy chain region (VH) comprising the sequence as set forth in SEQ ID NO: 31, and a variable light chain region (VL) comprising the sequence as set forth in SEQ ID NO: 21, and (b) a second antigen-binding domain comprising a VH comprising the sequence as set forth in SEQ ID NO: 52, and a VL comprising the sequence as set forth in SEQ ID NO: 51.

12. The use according to any one of Claims 1 to 10, wherein the anti-HER2 biparatopic antibody comprises a heavy chain H1 comprising the sequence set forth in SEQ ID NO: 30, a heavy chain H2 comprising the sequence set forth in SEQ ID NO: 50, and a light chain L1 comprising the sequence set forth in SEQ ID NO: 20.

13. The use according to any one of Claims 1 to 12, wherein the HER2-expressing cancer is a solid tumor.

14. The use according to any one of Claims 1 to 13, wherein the HER2-expressing cancer is breast cancer, biliary tract cancer, gastroesophageal adenocarcinoma (GEA), gastroesophageal esophageal junction cancer (GEJ), gastric cancer, endometrial cancer, ovarian cancer, cervical cancer, non-small cell lung cancer (NSCLC), anal cancer or colorectal cancer (CRC).

15. The use according to any one of Claims 1 to 14, wherein the HER2-expressing cancer is gastroesophageal adenocarcinoma (GEA).

16. The use according to any one of Claims 1 to 15, wherein the subject has received prior treatment with one or more of the anti-HER2-targeted therapies trastuzumab, pertuzumab, T-DM1 or Enhertu™ (fam-trastuzumab deruxtecan-nxki).

17. The use according to any one of Claims 1 to 15, wherein the subject has not received prior treatment with an anti-HER2 targeted therapy.

18. The use according to any one of Claims 1 to 17, wherein the subject has not received prior systemic treatment with a chemotherapeutic agent.

19. The use according to any one of Claims 1 to 18, wherein the cancer is metastatic.

20. The use according to any one of Claims 1 to 18, wherein the cancer is locally advanced.

21. The use according to any one of Claims 1 to 20, wherein the cancer is HER2 3+, HER2 2+/3+, HER2 2+ or HER2 1+ as measured by immunohistochemistry (IHC) and is gene amplified as measured by fluorescence in situ hybridization (FISH) or in situ hybridization (ISH).

22. The use according to any one of Claims 1 to 20, wherein the cancer is HER2 3+, HER2 2+/3+ or HER2 2+ or HER2 1+ as measured by immunohistochemistry (IHC) with or without HER2 gene amplification as measured by fluorescence in situ hybridization (FISH) or in situ hybridization (ISH).

23. The use according to any one of Claims 1 to 20, wherein the cancer is HER2 3+ as measured by IHC with or without HER2 gene amplification.

24. The use according to any one of Claims 1 to 20, wherein the cancer is HER2 2+ as measured by IHC with HER2 gene amplification, as measured by FISH or ISH.

25. The use according to any one of Claims 1 to 24, wherein the anti-HER2 biparatopic antibody is to be administered in combination with one or more chemotherapy regimens.

26. The use according to Claim 25, wherein the chemotherapy regimen comprises mFOLFOX6 (5-FU and leucovorin plus oxaliplatin), CAPOX (capecitabine plus oxaliplatin) or FP (fluorouracil [5-FU] plus cisplatin).

27. The use according to Claim 25, wherein the chemotherapy regimen comprises a taxane.

28. The use according to any one of Claims 1 to 27, wherein the anti-HER2 biparatopic antibody is to be administered in combination with a PD-1 inhibitor.

29. The use according to any one of Claims 1 to 28, wherein the anti-HER2 biparatopic antibody is to be administered in combination with another anti-HER2 agent.

30. The use according to Claim 28, wherein the PD-1 inhibitor is an anti-PD-1 antibody.

31. The use according to Claim 30, wherein the anti-PD-1 antibody is selected from tislelizumab, pembrolizumab, nivolumab or cemiplimab.

32. The use according to Claim 30, wherein the anti-PD-1 antibody is tislelizumab.

33. A pharmaceutical kit comprising: (i) one or more containers comprising an anti-HER2 biparatopic antibody and (ii) a label or package insert in or associated with the one or more containers indicating that the anti-HER2 biparatopic antibody is for administration to a subject having a HER2-expressing cancer (a) at a dose of 1800 mg for a subject weighing less than 70 kg or (b) at a dose of 2400 mg for a subject weighing 70 kg or more, administered every 3 weeks (Q3W).

34. A pharmaceutical kit comprising: (i) one or more containers comprising an anti-HER2 biparatopic antibody and (ii) a label or package insert in or associated with the one or more containers indicating that the anti-HER2 biparatopic antibody is for administration to a subject having a HER2-expressing cancer (a) at a dose of 1200 mg for a subject weighing less than 70 kg or (b) at a dose of 1600 mg for a subject weighing 70 kg or more, administered every 2 weeks (Q2W).

35. The pharmaceutical kit according to Claim 33 or 34, wherein the label or package insert further indicates that the HER2-expressing cancer is breast cancer, biliary tract cancer, gastroesophageal adenocarcinoma (GEA), gastroesophageal esophageal junction cancer (GEJ), gastric cancer, endometrial cancer, ovarian cancer, cervical cancer, non-small cell lung cancer (NSCLC), anal cancer or colorectal cancer (CRC).

36. The pharmaceutical kit according to any one of Claims 33 to 35, wherein the label or package insert further indicates that the HER2-expressing cancer is metastatic or locally advanced.

37. The pharmaceutical kit according to any one of Claims 33 to 36, wherein the label or package insert further indicates that the anti-HER2 biparatopic antibody is suitable for administration in combination with an anti-PD-1 antibody.

38. The pharmaceutical kit according to any one of Claims 33 to 37, wherein the label or package insert further indicates that the anti-HER2 biparatopic antibody is suitable for administration in combination with mFOLFOX6 (5-FU and leucovorin plus oxaliplatin), CAPOX (capecitabine plus oxaliplatin) or FP (fluorouracil [5-FU] plus cisplatin).

39. The pharmaceutical kit according to any one of Claims 33 to 36, wherein the label or package insert further indicates that the anti-HER2 biparatopic antibody is suitable for administration in combination with another anti-HER2 agent, optionally Tucatinib.

40. The pharmaceutical kit according to any one of Claims 33 to 39, wherein each of the containers comprises 300 mg of the anti-HER2 biparatopic antibody.

41. The pharmaceutical kit according to any one of Claims 33 to 39, wherein each of the containers comprises 600 mg of the anti-HER2 biparatopic antibody.

42. The pharmaceutical kit according to any one of Claims 33 to 36, wherein the label or package insert further indicates that the anti-HER2 biparatopic antibody is v10000.