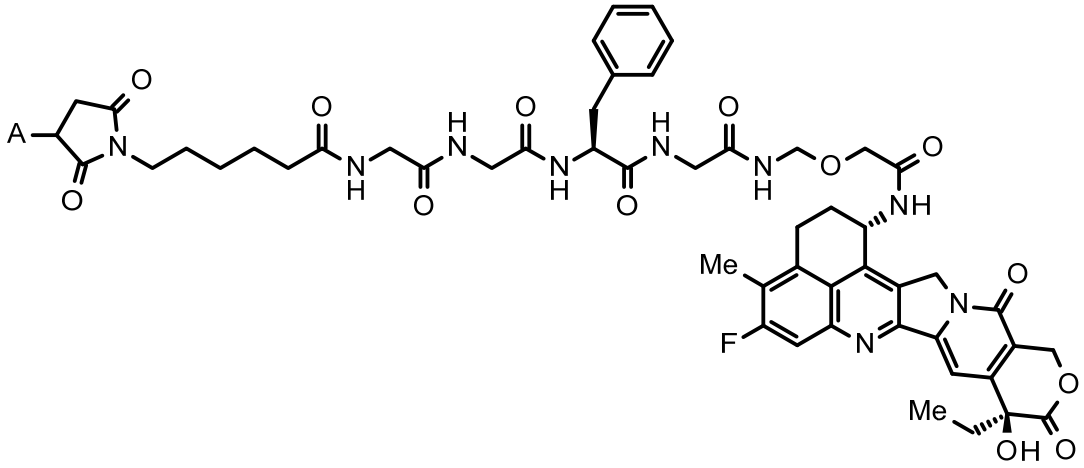
Claims

1. Use of an anti-HER2 antibody-drug conjugate for the manufacture of a medicament for treating HER2-mutated cancer, in which a drug-linker represented by the following formula:



wherein A represents a connecting position to an anti-HER2 antibody;
is conjugated to the anti-HER2 antibody via a thioether bond.

2. Use according to claim 1, wherein the HER2 mutation in the HER2-mutated cancer is at least one selected from the group consisting of Y772_A775dup, G778_P780dup, G776delinsVC, L755S, V777L, V659E, G660D, S310F, A20T, A21S, R143Q, K200N, A242V, D277Y, A293P, N302K, V308M, S310Y, N319Y, S335C, R340P, S418T, W452C, V541M, I613V, P627H, A644V, R647G, I654V, I655V, I661V, R678Q, Q680H, V697L, G704R, Q709L, Q711H, G727A, T733I, E744G, N745D,

L755P, L755A, L755F, S760F, D769H, D769N, D769Y, E770_A771insAYVM, A771_Y772insYVMA, M774_A775insAYVM, A775_G776insYVMA, A775G, G776delinsLC, G776C, G776delinsAVGC, G776delinsVV, G776_V777insL, G776L, G776_V777insVC, G776_V777insVGC, V777_G778insCG, V777_G778insG, G778_S779insG, S779P, S779_P780insVGS, P780_Y781insGSP, R784C, R784H, L785R, L786V, T791I, G804S, L807F, S819F, I829T, V842I, L846F, T862I, R868W, L869R, T875I, W906*, T917S, Q943*, S1007*, and S1151L.

3. Use according to claim 2, wherein the HER2 mutation in the HER2-mutated cancer is at least one selected from the group consisting of Y772_A775dup, G778_P780dup, G776delinsVC, L755S, V777L, and S310F.

4. Use according to claim 1, wherein the HER2 mutation in the HER2-mutated cancer is an exon 20 insertion mutation.

5. Use according to claim 4, wherein the exon 20 insertion mutation is at least one selected from the group consisting of Y772_A775dup, G778_P780dup, G776delinsVC, E770_A771insAYVM, A771_Y772insYVMA, M774_A775insAYVM, A775_G776insYVMA, G776delinsLC, G776delinsAVGC, G776delinsVV, G776_V777insL, G776_V777insVC, G776_V777insVGC, V777_G778insCG,

V777_G778insG, G778_S779insG, S779_P780insVGS, and P780_Y781insGSP.

6. Use according to claim 5, wherein the exon 20 insertion mutation is at least one selected from the group consisting of Y772_A775dup, G778_P780dup, and G776delinsVC.

7. Use according to claim 1, wherein the HER2 mutation in the HER2-mutated cancer is a single base pair substitution mutation at a transmembrane domain of a HER2 protein.

8. Use according to claim 7, wherein the single base pair substitution mutation at the transmembrane domain of the HER2 protein is at least one selected from the group consisting of V659E, G660D, I654V, I655V, and I661V.

9. Use according to claim 8, wherein the single base pair substitution mutation at the transmembrane domain of the HER2 protein is G660D.

10. Use according to claim 1, wherein the HER2 mutation in the HER2-mutated cancer is a single base pair substitution mutation at an extracellular domain of a HER2 protein.

11. Use according to claim 10, wherein the single base pair substitution mutation at the extracellular domain of the HER2 protein is at least one selected from the group consisting of S310F, A20T, A21S, R143Q, K200N, A242V, D277Y, A293P, N302K, V308M, S310Y, N319Y, S335C, R340P, S418T, W452C, V541M, I613V, P627H, A644V, and R647G.

12. Use according to claim 11, wherein the single base pair substitution mutation at the extracellular domain of the HER2 protein is S310F.

13. Use according to any one of claims 1 to 12, wherein the cancer in the HER2-mutated cancer is at least one selected from the group consisting of non-small cell lung cancer, breast cancer, gastric cancer, colorectal cancer, esophageal cancer, salivary gland cancer, gastroesophageal junction adenocarcinoma, biliary tract cancer, Paget's disease, pancreatic cancer, ovarian cancer and uterine carcinosarcoma.

14. Use according to any one of claims 1 to 12, wherein the cancer is non-small cell lung cancer.

15. Use according to claim 14, wherein the non-small cell lung cancer is unresectable and/or metastatic non-small cell lung cancer.

16. Use according to any one of claims 1 to 15, wherein the anti-HER2 antibody is an antibody comprising a heavy chain consisting of an amino acid sequence consisting of amino acid residues 1 to 449 of SEQ ID NO: 1 and a light chain consisting of an amino acid sequence consisting of amino acid residues 1 to 214 of SEQ ID NO: 2.

17. Use according to any one of claims 1 to 15, wherein the anti-HER2 antibody is an antibody comprising a heavy chain consisting of an amino acid sequence represented by SEQ ID NO: 1 and a light chain consisting of an amino acid sequence represented by SEQ ID NO: 2.

18. Use according to any one of claims 1 to 17, wherein the average number of units of the drug-linker conjugated per antibody in the anti-HER2 antibody-drug conjugate is in the range of from 7 to 8.

19. Use according to any one of claims 1 to 17, wherein the average number of units of the drug-linker conjugated per antibody in the anti-HER2 antibody-drug conjugate is in the range of from 7.5 to 8.

20. Use according to any one of claims 1 to 19, wherein a dose per administration of the anti-HER2 antibody-drug conjugate is in a range of 5.4 mg/kg to 8 mg/kg.

21. Use according to any one of claims 1 to 19, wherein a dose per administration of the anti-HER2 antibody-drug conjugate is 5.4 mg/kg or 6.4 mg/kg.

~~21~~22. Use according to any one of claims 1 to 19, wherein a dose per administration of the anti-HER2 antibody-drug conjugate is 6.4 mg/kg.

23. Use according to any one of claims 1 to 19, wherein a dose per administration of the anti-HER2 antibody-drug conjugate is 5.4 mg/kg.

~~22~~24. Use according to any one of claims 1 to 21, wherein the anti-HER2 antibody-drug conjugate is to be administered once every 3 weeks.