CLAIMS

1. Use of an antibody-drug conjugate (ADC) in combination with an immune checkpoint inhibitor in the preparation of a medicament for treating a urothelial cancer patient, wherein the antibody-drug conjugate has the structure of the general formula Ab-(L-U)$_n$, wherein Ab represents anti-Her2 (Human epidermal growth factor receptor 2) 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, and wherein:

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

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

the cytotoxic molecule U comprises MMAE (monomethyl auristatin E); and

the immune checkpoint inhibitor is a PD-1 antibody or a PD-L1 antibody.

2. Use of an antibody-drug conjugate (ADC) and an immune checkpoint inhibitor in the manufacture of a medicament for combination therapy for treating a urothelial cancer patient,

wherein the antibody-drug conjugate has the structure of the general formula Ab-(L-U)$_n$, wherein Ab represents anti-Her2 (Human epidermal growth factor receptor 2) 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, and wherein:

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

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

the cytotoxic molecule U comprises MMAE (monomethyl auristatin E); and

the immune checkpoint inhibitor is a PD-1 antibody or a PD-L1 antibody.

3. The use according to any one of the above claims, wherein the patient is positive for HER2 expression.

4. The use according to any one of the above claims, wherein a sample obtained from urothelial cancer of the patient is HER2 positive.

5. The use according to any one of the above claims, wherein the sample obtained from urothelial cancer of the patient is HER2 positive based on a immunohistochemistry (IHC) assay.

6. The use according to any one of the above claims, wherein HER2 expression in the sample obtained from urothelial cancer of the patient is IHC 3+ or IHC 2+.

7. The use according to any one of the above claims, wherein the patient is positive for PD-L1 or PD-1 expression.

8. The use according to any one of the above claims, wherein the antibody comprises a heavy chain variable (VH) region and a light chain variable (VL) region;

wherein the VH region comprises an HCDR1 comprising the amino acid sequence of GYTFTDYY (**SEQ ID NO:3**), an HCDR2 comprising the amino acid sequence of VNPDHGDS (**SEQ ID NO:4**), and an HCDR3 comprising the amino acid sequence of ARNYLFDH (**SEQ ID NO:5**); and

wherein the VL region comprises a LCDR1 comprising the amino acid sequence of QDVGTA (**SEQ ID NO:6**), a LCDR2 comprising the amino acid sequence of WAS (**SEQ ID NO:7**), and a LCDR3 comprising the amino acid sequence of HQFATYT (**SEQ ID NO:8**).

9. The use according to any one of the above claims, wherein the antibody comprises a heavy chain variable (VH) region and a light chain variable (VL) region;

wherein the VH region comprises an HCDR1 comprising the amino acid sequence of DYYIH (**SEQ ID NO:31**), an HCDR2 comprising the amino acid sequence of RVNPDHGDSYYNQKFKD (**SEQ ID NO:32**), and an HCDR3 comprising the amino acid sequence of ARNYLFDHW (**SEQ ID NO:33**); and

wherein the VL region comprises a LCDR1 comprising the amino acid sequence of KASQDVGTAVA (**SEQ ID NO:34**), a LCDR2 comprising the amino acid sequence of WASIRHT (**SEQ ID NO:35**), and a LCDR3 comprising the amino acid sequence of HQFATYT (**SEQ ID NO:8**).

10. The use according to any one of the above claims, wherein the antibody is a murine, chimeric, or humanized antibody.

11. The use according to any one of the above claims, wherein the antibody comprises a heavy chain variable (VH) region and a light chain variable (VL) region; wherein the VH region comprises the amino acid sequence of EVQLVQSGAEVKKPGATVKISCKVSGYTFTDYYIHWVQQAPGKGLEWMGRVNPDHGDS YYNQKFKDKATITADKSTDTAYMELSSLRSEDTAVYFCARNYLFDHWGQGTLVTVSS (**SEQ ID NO:9**); and wherein the VL region comprises the amino acid sequence of DIQMTQSPSSVSASVGDRVTITCKASQDVGTAVAWYQQKPGKAPKLLIYWASIRHTGVPS RFSGSGSGTDFTLTISSLQPEDFATYYCHQFATYTFGGGTKVEIK (**SEQ ID NO:10**).

12. The use according to any one of the above claims, wherein the antibody is a human IgG antibody.

13. The use according to any one of the above claims, wherein the antibody is a human IgG1, IgG2, and IgG4 antibody.

14. The use according to any one of the above claims, wherein the amino acid sequence of the heavy chain of the antibody is SEQ ID NO:1, and the amino acid sequence of the light chain of the antibody is SEQ ID NO:2.

15. The use according to any one of the above claims, wherein the antibody-drug conjugate is Disitamab vedotin or a biosimilar thereof.

16. The use according to any one of the above claims, wherein the average DAR (i.e., Drug-to-Antibody Ratio) value of the antibody-drug conjugate is any number from 2 to 7.

17. The use according to claim 16, wherein the average DAR value is 4 ± 0.5.

18. The use according to any one of the above claims, wherein the immune checkpoint inhibitor is a PD-1 antibody.

19. The use according to claim 18, wherein the PD-1 antibody is selected from the group consisting of Toripalimab, Dostarlimab, Prolgolimab, Tislelizumab, Camrelizumab, Sintilimab, Cemiplimab, Pembrolizumab, Nivolumab, Penpulimab, Genolimzumab, Zimberelimab, and Balstilimab.

20. The use according to any of the above claims, wherein the immune checkpoint inhibitor is a PD-L1 antibody.

21. The use according to claim 20, wherein the immune checkpoint inhibitor is a PD-L1 antibody is selected from the group consisting of Durvalumab, Avelumab, Atezolizumab, Envafolimab, and RC98.

22. The use according to any one of the above claims, wherein the patient has previously received one or more prior treatments selected from the group consisting of chemotherapy drugs, targeted therapy, immunotherapy and endocrine therapy.

23. The use according to any one of the above claims, wherein the urothelial cancer patient is selected from the group consisting of a patient with locally advanced urothelial cancer that cannot be surgically resected, a patient with locally advanced or metastatic urothelial cancer, a patient with HER2-positive urothelial cancer, a patient with HER2 positive locally advanced or metastatic urothelial cancer, and a urothelial cancer patient who cannot tolerate platinum-based chemotherapy.

24. The use according to any one of the above claims, wherein the urothelial cancer patient is a patient with unresectable locally advanced or metastatic urothelial carcinoma

25. The use according to any one of the above claims, wherein the urothelial cancer patient is a patient who is ineligible for or has refused cisplatin based chemotherapy;

26. The use according to any one of the above claims, wherein the urothelial cancer patient is a patient who has progressed after chemotherapy.

27. The use according to any one of the above claims, wherein the urothelial cancer patient is a patient who has experienced disease progression within 12 months of completion of neoadjuvant or adjuvant cisplatin-based chemotherapy.

28. The use according to any one of the above claims, wherein the medicament is to be administered intranasally, subcutaneously, intradermally, intramuscularly or intravenously.

29. The use according to any one of the above claims, wherein the ADC is to be administered at a dosage of 1.5 mg/kg or 2.0 mg/kg.

30. The use according to any one of the above claims, wherein the ADC is to be administered every 2 weeks or 14 days.

31. The use according to any one of the above claims, wherein administration of the antibody-drug conjugate and immune checkpoint inhibitor to the urothelial cancer patient results in progression-free survival (PFS) of greater than 7.5 months.

32. Use of an effective amount of antibody-drug conjugate (ADC) and an immune checkpoint inhibitor for the manufacture of a first medicament comprising the ADC and a second medicament comprising the immune checkpoint inhibitor for treating urothelial cancer in a patient,

wherein the antibody-drug conjugate has the structure of the general formula Ab-(L-U)n, wherein Ab represents anti-Her2 (Human epidermal growth factor receptor 2) 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, and wherein:

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

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

the cytotoxic molecule U comprises MMAE (monomethyl auristatin E); and

the immune checkpoint inhibitor is a PD-1 antibody or a PD-L1 antibody.

33. Use of an effective amount of an antibody-drug conjugate (ADC) in the manufacture of a medicament for treating urothelial cancer in a patient, wherein the ADC is to be used in combination with an immune checkpoint inhibitor,

wherein the antibody-drug conjugate has the structure of the general formula Ab-(L-U)n, wherein Ab represents anti-Her2 (Human epidermal growth factor receptor 2) 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, and wherein:

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

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

the cytotoxic molecule U comprises MMAE (monomethyl auristatin E); and

the immune checkpoint inhibitor is a PD-1 antibody or a PD-L1 antibody.

34. Use of an effective amount of an immune checkpoint inhibitor in the manufacture of a medicament for treating urothelial cancer in a patient, wherein the immune checkpoint inhibitor is to be used in combination with an antibody-drug conjugate,

wherein the antibody-drug conjugate has the structure of the general formula Ab-(L-U)n, wherein Ab represents anti-Her2 (Human epidermal growth factor receptor 2) 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, and wherein:

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

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

the cytotoxic molecule U comprises MMAE (monomethyl auristatin E); and

the immune checkpoint inhibitor is a PD-1 antibody or a PD-L1 antibody.

35. A pharmaceutical composition comprising an antibody-drug conjugate (ADC) for use in treating urothelial cancer in combination with an immune checkpoint inhibitor,

wherein the antibody-drug conjugate has the structure of the general formula Ab-(L-U)n, wherein

Ab represents anti-Her2 (Human epidermal growth factor receptor 2) 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, and wherein:

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

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

the cytotoxic molecule U comprises MMAE (monomethyl auristatin E); and

the immune checkpoint inhibitor is a PD-1 antibody or a PD-L1 antibody.

36. A pharmaceutical composition comprising an immune checkpoint inhibitor for use in treating urothelial cancer in combination with an antibody-drug conjugate (ADC),

wherein the antibody-drug conjugate has the structure of the general formula Ab-(L-U)n, wherein Ab represents anti-Her2 (Human epidermal growth factor receptor 2) 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, and wherein:

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

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

the cytotoxic molecule U comprises MMAE (monomethyl auristatin E); and

the immune checkpoint inhibitor is a PD-1 antibody or a PD-L1 antibody.

37. Use of a pharmaceutical composition comprising an antibody-drug conjugate (ADC) in the manufacture of a medicament for use in combinatorial therapy for treating urothelial cancer,

wherein said medicament is to be administered in combination with an immune checkpoint inhibitor,

wherein the antibody-drug conjugate has the structure of the general formula Ab-(L-U)n, wherein Ab represents anti-Her2 (Human epidermal growth factor receptor 2) 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, and wherein:

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

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

the cytotoxic molecule U comprises MMAE (monomethyl auristatin E); and

the immune checkpoint inhibitor is a PD-1 antibody or a PD-L1 antibody.

38. Use of a pharmaceutical composition comprising an immune checkpoint inhibitor in the manufacture of a medicament for use in combinatorial therapy for treating urothelial cancer, wherein said medicament is to be administered in combination with an antibody-drug conjugate (ADC),

wherein the antibody-drug conjugate has the structure of the general formula Ab-(L-U)n, wherein Ab represents anti-Her2 (Human epidermal growth factor receptor 2) 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, and wherein:

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

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

the cytotoxic molecule U comprises MMAE (monomethyl auristatin E); and

the immune checkpoint inhibitor is a PD-1 antibody or a PD-L1 antibody.