

What is claimed is:

1. A conjugate, comprising an antibody or an antigen-binding fragment thereof conjugated with one or more drug molecules, wherein the antibody comprises a heavy chain and a light chain, and the heavy chain comprises three CDR regions having the amino acid sequences as set forth in SEQ ID NOs: 1, 2 and 3 respectively and/or the light chain comprises three CDR regions having the amino acid sequences as set forth in SEQ ID NOs: 4, 5 and 6 respectively.

2. The conjugate of claim 1, wherein the antibody is a monoclonal antibody or a bispecific antibody, preferably a monoclonal antibody, more preferably a humanized antibody, and most preferably a fully human antibody.

~~3. The conjugate according to any one of claims 1-2, wherein the antibody is an IgG-type antibody, preferably an IgG1-type antibody.~~

~~4. The conjugate of any one of claims 1-3, wherein the antigen-binding fragment is a Fab fragment, an F(ab')₂ fragment, or a single-chain Fv fragment (scFv).~~

~~53. The conjugate of any one of claims 1-42, wherein the heavy chain comprises a heavy chain variable region having the amino acid sequence as set forth in SEQ ID NO:7, and/or the light chain comprises a light chain variable region having the amino acid sequence as set forth in SEQ ID NO:8; preferably,~~

~~6. The conjugate of any one of claims 1-5, wherein the heavy chain comprises the amino acid sequence as set forth in SEQ ID NO:9, and/or the light chain comprises the amino acid sequence as set forth in SEQ ID NO: 10.~~

~~74. The conjugate of any one of claims 1-63, wherein the drug molecule is an anticancer drug; preferably, such as a cytotoxic drug, an immunopotentiator, or a radioisotope; more preferably,~~

~~8. The conjugate of claim 7, wherein the cytotoxic drug is selected from the group consisting of a tubulin inhibitor, a DNA topoisomerase inhibitor, a DNA damaging agent, an antimetabolite and an antitumor antibiotic, or wherein the immunopotentiating agent is selected from the group consisting of levamisole, pidotimod, imiquimod, isoprinosine, polyinosinic:polycytidylic acid and polyinosinic:polyuridylic acid, or the radioisotope is selected from the group consisting of ²¹¹At, ¹³¹I, ¹²⁵I, ⁹⁰Y, ¹⁸⁶Re, ¹⁸⁸Re, ¹⁵³Sm, ²¹²Bi, ³²P, ⁶⁰Co and ¹⁷⁷Lu.~~

~~95. The conjugate of claim 84, wherein the tubulin inhibitor is an auristatin derivative (preferably, e.g. MMAE (Monomethyl auristatin E), MMAF (Monomethyl auristatin F)) or a maytansine alkaloid derivative (preferably, e.g. DM1, DM4, Ansamitocin, Mertansine, or dolastatin or a derivative thereof); or~~

~~10. The conjugate of claim 8, wherein the DNA topoisomerase inhibitor is a camptothecin analogue, a DNA topoisomerase I inhibitor or a derivative thereof, for example, DXD, SN38, irinotecan, irinotecan hydrochloride, camptothecin, 9-aminocamptothecin, 9-nitrocamptothecin, 10-hydroxycamptothecin, 9-chloro-10-hydroxycamptothecin, 22-hydroxyacuminatine, topotecan, lertonotecan, belotecan, ixitecan, homosilatecan, 6,8-dibromo-2-methyl-3-[2-(D-xylopyranosylamino)phenyl]-4(3H)-quinazolinone, 2-cyano-3-(3,4-dihydroxyphenyl)-N-(phenylmethyl)-(2E)-2-acrylamide, 2-cyano-3-(3,4-dihydroxyphenyl)-N-(3-hydroxyphenylpropyl)-(E)-2-acrylamide,~~

12-β-D-glucopyranosyl-12,13-dihydro-2,10-dihydroxy-6-[[2-hydroxy-1-(hydroxymethyl)ethyl] amino]-5H-indoleindolo[2,3-a]pyrrolo[3,4-c]carbazole-5,7(6H)-dione, N-[2-(dimethylamino)ethyl]-4-acridine formamide dihydrochloride, N-[2-(dimethylamino)ethyl]-4-acridinecarboxamide; or:-

~~11. The conjugate of claim 8, wherein the DNA damaging agent is selected from the group consisting of calicheamicin, duocarmycin, and pyrrolobenzodiazepine or:-~~

~~12. The conjugate of claim 7, wherein the immunopotentiating agent is selected from the group consisting of levamisole, pidotimod, imiquimod, isoprinosine, polyinosinic:polycytidylic acid and polyinosinic:polyuridylic acid; and/or the antimetabolite is selected from the group consisting of methotrexate, 6-mercaptopurine and 5-fluorouracil; and/or the antitumor antibiotic is selected from the group consisting of a polypeptide antibiotic (preferably, such as actinomycetes D or bleomycin) and an anthraquinone (preferably, such as doxorubicin or mitoxantrone hydrochloride).~~

~~13. The conjugate of claim 7, wherein the radioisotope is selected from the group consisting of ²¹¹At, ¹³¹I, ¹²⁵I, ⁹⁰Y, ¹⁸⁶Re, ¹⁸⁸Re, ¹⁵³Sm, ²¹²Bi, ³²P, ⁶⁰Co and ¹⁷⁷Lu.~~

146. The conjugate of any one of claims 1-135, wherein the drug molecule is conjugated with the antibody or antigen-binding fragment thereof via a linker, which is linked to the antibody or antigen-binding fragment via a sulfhydryl or an amino group.

~~15. The conjugate of claim 14, wherein, preferably, the linker is selected from the group consisting of mc-Val-Cit-pAB, mc-Val-Cit-pABC, mc-Val-Cit, NH₂-(PEG)_m-Val-Cit, NH₂-(PEG)_m-Val-Cit-pAB, where m is an integer from 1 to 8.~~

1467. The conjugate of claim 146, wherein the conjugate has a structure represented by Ab-(L-U)_n, wherein Ab represents the antibody or an antigen-binding fragment thereof, L represents the linker, U represents the drug molecule, and n is an integer or decimal from 1 to 8.

178. A pharmaceutical composition comprising the conjugate of any one of claims 1 to 1467, and a pharmaceutically acceptable carrier.

189. The pharmaceutical composition of claim 178, wherein the pharmaceutical composition is for use in the treatment or prevention of cancer.

~~19. The pharmaceutical composition of claim 18, wherein the cancer is, preferably CLDN18.2 positive cancer.~~

~~20~~10. The pharmaceutical composition ~~any one~~ of claim ~~18-199~~, wherein the cancer is gastric cancer, esophageal cancer, pancreatic cancer, lung cancer, ovarian cancer, colon cancer, liver cancer, head and neck cancer or gallbladder cancer.

~~21~~11. The pharmaceutical composition of claim 9~~any one of claims 18-20~~, wherein the cancer is an adenocarcinoma of stomach, esophagus, pancreatic duct, bile duct, lung, or ovary.

~~22~~12. The pharmaceutical composition of claim 9~~any one of claims 18-21~~, wherein the cancer is gastric cancer or pancreatic cancer.

~~23. Use of the conjugate of any one of claims 1 to 16 or the pharmaceutical composition of claim 17 in the manufacture of a medicament for the treatment or prevention of cancer.~~

~~24. The use of claim 23, wherein the cancer is CLDN18.2 positive cancer.~~

~~25. The use of claim 23 or 24, wherein the cancer is gastric cancer, esophageal cancer, pancreatic cancer, lung cancer, ovarian cancer, colon cancer, liver cancer, head and neck cancer or gallbladder cancer.~~

~~26. The use of any one of claims 23-25, wherein the cancer is an adenocarcinoma of stomach, esophagus, pancreatic duct, bile duct, lung or ovary.~~

~~27. The use of any one of claims 23-26, wherein the cancer is gastric cancer or pancreatic cancer.~~

~~28. A method of treating cancer in a subject, comprising administering to the subject a therapeutically effective amount of the conjugate of any one of claims 1 to 16 or the pharmaceutical composition of claim 17.~~

~~29. The method of claim 28, wherein the cancer is CLDN18.2 positive cancer.~~

~~30. The method of claim 28 or 29, wherein the cancer is gastric cancer, esophageal cancer, pancreatic cancer, lung cancer, ovarian cancer, colon cancer, liver cancer, head and neck cancer, or gallbladder cancer.~~

~~31. The method of any one of claims 28-30, wherein the cancer is an adenocarcinoma of stomach, esophagus, pancreatic duct, bile duct, lung, or ovary.~~

~~32. The method of any one of claims 28-31, wherein the cancer is gastric cancer or pancreatic cancer.~~

~~33. A medical preparation, comprising the conjugate of any one of claims 1 to 16 or the pharmaceutical composition of claim 17.~~

~~34. The medical preparation of claim 33, which is a kit comprising a container containing the conjugate of any one of claims 1 to 16 or the pharmaceutical composition of claim 17.~~

~~35. Use of the conjugate of any one of claims 1-16 and an antiproliferative agent in the manufacture of a medicament for treating a tumor.~~

~~36. A pharmaceutical composition comprising the conjugate of any one of claims 1-16 and an antiproliferative agent.~~

~~37. A method of treating a tumor in a subject, comprising administering to the subject a therapeutically effective amount of the conjugate of any one of claims 1 to 16 or the pharmaceutical composition of claim 17 and an antiproliferative agent.~~

~~38. The use of claim 35 or the pharmaceutical composition of claim 36 or the method of claim 37, wherein the antiproliferative agent is selected from the group consisting of paclitaxel, doxorubicin, docetaxel, cisplatin, carboplatin, and iproplatin.~~