

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 of any one of claims 1-2, 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, 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.

4. The conjugate of any one of claims 1-3, wherein the drug molecule is an anticancer drug; preferably, a cytotoxic drug, an immunopotentiator, or a radioisotope; more preferably, 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.

5. The conjugate of claim 4, wherein the tubulin inhibitor is an auristatin derivative (preferably, MMAE (Monomethyl auristatin E), MMAF (Monomethyl auristatin F)) or a maytansine alkaloid derivative (preferably, DM1, DM4, Ansamitocin, Mertansine, or dolastatin or a derivative thereof); or

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

the DNA damaging agent is selected from the group consisting of calicheamicin, duocarmycin, and pyrrolobenzodiazepine or

the antimetabolite is selected from the group consisting of methotrexate, 6-mercaptopurine and 5-fluorouracil; or

the antitumor antibiotic is selected from the group consisting of a polypeptide antibiotic (preferably, actinomycetes D or bleomycin) and an anthraquinone (preferably, doxorubicin or

mitoxantrone hydrochloride).

6. The conjugate of any one of claims 1-5, 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, 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.

7. The conjugate of claim 6, 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.

8. A pharmaceutical composition comprising the conjugate of any one of claims 1 to 7, and a pharmaceutically acceptable carrier.

9. The pharmaceutical composition of claim 8, wherein the pharmaceutical composition is for use in the treatment or prevention of cancer, preferably CLDN18.2 positive cancer.

10. The pharmaceutical composition of claim 9, 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.

11. The pharmaceutical composition of claim 9, wherein the cancer is an adenocarcinoma of stomach, esophagus, pancreatic duct, bile duct, lung, or ovary.

12. The pharmaceutical composition of claim 9, wherein the cancer is gastric cancer or pancreatic cancer.

13. A kit comprising a container containing the conjugate of any one of claims 1 to 7 or the pharmaceutical composition of claim 8.

14. A pharmaceutical composition comprising the conjugate of any one of claims 1-7 and an antiproliferative agent.

15. The pharmaceutical composition of claim 14, wherein the antiproliferative agent is selected from the group consisting of paclitaxel, doxorubicin, docetaxel, cisplatin, carboplatin, and iproplatin.