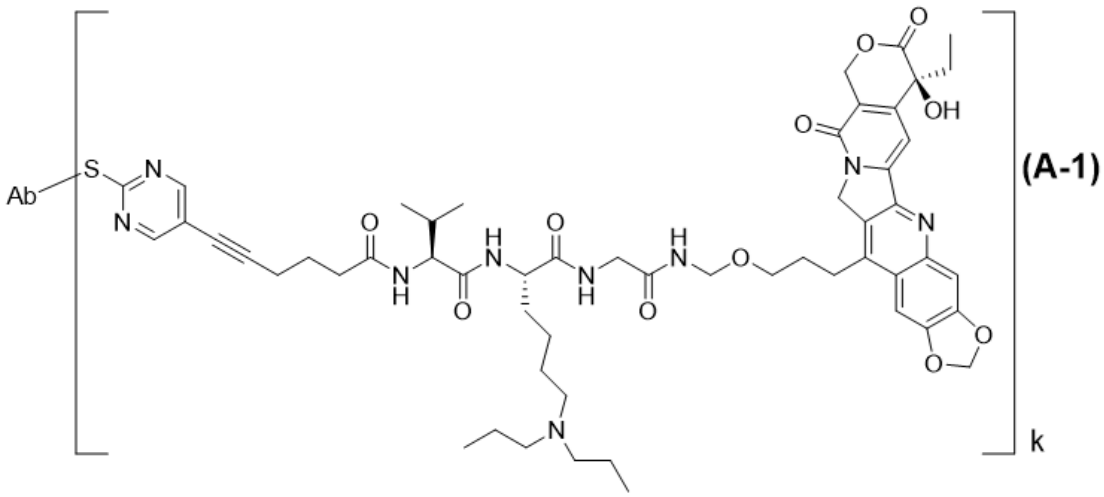
Claims

1. An antibody-drug conjugate, a prodrug, pharmaceutically acceptable salt, or solvate thereof, or a solvate of the pharmaceutically acceptable salt, characterized in that the antibody-drug conjugate has a structure represented by formula (A-1):



wherein:

Ab represents an antibody or an antigen-binding fragment selectively binding to or recognizing EGFR;

and

k represents any numerical value between 0.1 and 10.0.

2. The antibody-drug conjugate, the prodrug, pharmaceutically acceptable salt, or solvate thereof, or the solvate of the pharmaceutically acceptable salt according to claim 1, characterized in that the antigen-binding fragment is selected from a full-length immunoglobulin, a single-chain Fv (scFv) fragment, an Fab fragment, an Fab' fragment, $F(ab')_2$, an Fv fragment, a disulfide-stabilized Fv fragment (dsFv), $(dsFv)_2$, an Fv-Fc fusion, an scFv-Fc fusion, an scFv-Fv fusion, a diabody, a tribody, a tetrabody, or any combination thereof.

3. The antibody-drug conjugate, the prodrug, pharmaceutically acceptable salt, or solvate thereof, or the solvate of the pharmaceutically acceptable salt according to claim 1 or 2, characterized in that the Ab is a humanized antibody or an antigen-binding fragment thereof.

4. The antibody-drug conjugate, the prodrug, pharmaceutically acceptable salt, or solvate thereof, or the solvate of the pharmaceutically acceptable salt according to any one

of the preceding claims, characterized in that the Ab comprises a heavy chain variable region (VH) and a light chain variable region (VL), wherein the heavy chain variable region (VH) comprises heavy chain complementarity determining region 1 (HCDR1), heavy chain complementarity determining region 2 (HCDR2), and heavy chain complementarity determining region 3 (HCDR3) contained in SEQ ID NO: 7, and the light chain variable region (VL) comprises light chain complementarity determining region 1 (LCDR1), light chain complementarity determining region 2 (LCDR2), and light chain complementarity determining region 3 (LCDR3) contained in SEQ ID NO: 8.

5. The antibody-drug conjugate, the prodrug, pharmaceutically acceptable salt, or solvate thereof, or the solvate of the pharmaceutically acceptable salt according to claim 4, characterized in that the amino acid sequence of HCDR1 is SEQ ID NO: 1, the amino acid sequence of HCDR2 is SEQ ID NO: 2, and the amino acid sequence of HCDR3 is SEQ ID NO: 3; and the amino acid sequence of LCDR1 is SEQ ID NO: 4, the amino acid sequence of LCDR2 is SEQ ID NO: 5, and the amino acid sequence of LCDR3 is SEQ ID NO: 6.

6. The antibody-drug conjugate, the prodrug, pharmaceutically acceptable salt, or solvate thereof, or the solvate of the pharmaceutically acceptable salt according to any one of the preceding claims, characterized in that the Ab comprises an Fc sequence of human IgG selected from a group consisting of IgG1, IgG2, IgG3, and IgG4.

7. The antibody-drug conjugate, the prodrug, pharmaceutically acceptable salt, or solvate thereof, or the solvate of the pharmaceutically acceptable salt according to any one of the preceding claims, characterized in that the Ab comprises a heavy chain variable region (VH), and the amino acid sequence of the heavy chain variable region (VH) has at least 70%, at least 80%, at least 90%, at least 95%, at least 99%, or 100% identity to SEQ ID NO: 7, and/or the Ab comprises a light chain variable region (VL), and the amino acid sequence of the light chain variable region (VL) has at least 70%, at least 80%, at least 90%, at least 95%, at least 99%, or 100% identity to SEQ ID NO: 8.

8. The antibody-drug conjugate, the prodrug, pharmaceutically acceptable salt, or solvate thereof, or the solvate of the pharmaceutically acceptable salt according to any one of the preceding claims, characterized in that the Ab comprises a heavy chain (HC), and the amino acid sequence of the heavy chain (HC) has at least 70%, at least 80%, at least 90%, at

least 95%, at least 99%, or 100% identity to SEQ ID NO: 9, and/or the Ab comprises a light chain (LC), and the amino acid sequence of the light chain (LC) has at least 70%, at least 80%, at least 90%, at least 95%, at least 99%, or 100% identity to SEQ ID NO: 10.

9. The antibody-drug conjugate, the prodrug, pharmaceutically acceptable salt, or solvate thereof, or the solvate of the pharmaceutically acceptable salt according to any one of the preceding claims, characterized in that the Ab is a multispecific antibody.

10. The antibody-drug conjugate, the prodrug, pharmaceutically acceptable salt, or solvate thereof, or the solvate of the pharmaceutically acceptable salt according to any one of the preceding claims, characterized in that the Ab is an afucosylated antibody.

11. The antibody-drug conjugate, the prodrug, pharmaceutically acceptable salt, or solvate thereof, or the solvate of the pharmaceutically acceptable salt according to any one of claims 6-10, characterized in that the Fc region comprises a C-terminal lysine or a deletion of the C-terminal lysine.

12. The antibody-drug conjugate, the prodrug, pharmaceutically acceptable salt, or solvate thereof, or the solvate of the pharmaceutically acceptable salt according to any one of the preceding claims, characterized in that k is about 4.0 to about 8.0, preferably k is about 4.0, about 6.0, or about 8.0.

13. A pharmaceutical composition comprising the antibody-drug conjugate, the prodrug, pharmaceutically acceptable salt, or solvate thereof, or the solvate of the pharmaceutically acceptable salt according to any one of claims 1-12, and optionally, a pharmaceutically acceptable carrier, diluent, or excipient.

14. The antibody-drug conjugate, the prodrug, pharmaceutically acceptable salt, or solvate thereof, or the solvate of the pharmaceutically acceptable salt according to any one of claims 1-12 or the pharmaceutical composition according to claim 13, for use as a drug.

15. The antibody-drug conjugate, the prodrug, pharmaceutically acceptable salt, or solvate thereof, or the solvate of the pharmaceutically acceptable salt according to any one of claims 1-12 or the pharmaceutical composition according to claim 13, for use in the

treatment or prevention of a tumor or cancer, optionally the tumor or cancer is an EGFR-related tumor or cancer.

16. The antibody-drug conjugate, the prodrug, pharmaceutically acceptable salt, or solvate thereof, or the solvate of the pharmaceutically acceptable salt, or the pharmaceutical composition for use in the treatment or prevention of a tumor or cancer according to claim 15, characterized in that the tumor or cancer is selected from epidermal cancer, colon cancer, rectal cancer, head and neck cancer, lung cancer, ovarian cancer, cervical cancer, bladder cancer, esophageal cancer, breast cancer, kidney cancer, prostate cancer, gastric cancer, pancreatic cancer, and glioma.

17. The antibody-drug conjugate, the prodrug, pharmaceutically acceptable salt, or solvate thereof, or the solvate of the pharmaceutically acceptable salt, or the pharmaceutical composition for use in the treatment or prevention of a tumor or cancer according to claim 16, characterized in that the lung cancer is small cell lung cancer or non-small cell lung cancer.

18. The antibody-drug conjugate, the prodrug, pharmaceutically acceptable salt, or solvate thereof, or the solvate of the pharmaceutically acceptable salt, or the pharmaceutical composition for use in the treatment or prevention of a tumor or cancer according to claim 16, characterized in that the lung cancer is osimertinib-resistant lung cancer.

19. The antibody-drug conjugate, the prodrug, pharmaceutically acceptable salt, or solvate thereof, or the solvate of the pharmaceutically acceptable salt, or the pharmaceutical composition for use in the treatment or prevention of a tumor or cancer according to claim 16, characterized in that the gastric cancer is ENHERTU-resistant gastric cancer.

20. The antibody-drug conjugate, the prodrug, pharmaceutically acceptable salt, or solvate thereof, or the solvate of the pharmaceutically acceptable salt, or the pharmaceutical composition for use in the treatment or prevention of a tumor or cancer according to any one of claims 15-19, characterized in that the tumor or cancer is a tumor or cancer with a KRAS gene mutation and/or a BRAF gene mutation, optionally the tumor or cancer with the KRAS gene mutation and/or the BRAF gene mutation is colon cancer, rectal cancer, lung cancer, or pancreatic cancer with the KRAS gene mutation and/or the BRAF gene mutation.

21. An article of manufacture or kit comprising the antibody-drug conjugate, the prodrug, pharmaceutically acceptable salt, or solvate thereof, or the solvate of the pharmaceutically acceptable salt according to any one of claims 1-12 or the pharmaceutical composition according to claim 13, and instructions for use.

22. Use of the antibody-drug conjugate, the prodrug, pharmaceutically acceptable salt, or solvate thereof, or the solvate of the pharmaceutically acceptable salt according to any one of claims 1-12 or the pharmaceutical composition according to claim 13 in the preparation of a medicament for use in the treatment or prevention of a tumor or cancer.

23. Use of the antibody-drug conjugate, the prodrug, pharmaceutically acceptable salt, or solvate thereof, or the solvate of the pharmaceutically acceptable salt according to any one of claims 1-12 or the pharmaceutical composition according to claim 13 in combination with an additional therapeutic agent in the preparation of a medicament for treating or preventing an EGFR-related disease or disorder or an osimertinib-resistant tumor or cancer.

24. The use according to claim 22 or 23, characterized in that the additional therapeutic agent is osimertinib or an anti-PD1 antibody.

25. The use according to claim 24, characterized in that the anti-PD1 antibody is serplulimab.