CLAIMS

1. An antibody against human TROP-2, which has anti-tumor activity *in vivo*.

2. The antibody according to claim 1, which exhibits 50% or more of tumor growth inhibitory activity at a dosage of 5 to 20 mg/kg body weight.

3. The antibody according to claim 2, wherein the frequency of administration for exhibiting the tumor growth inhibitory activity is at most once a week.

4. The antibody according to claim 1, which exhibits 50% or more of the tumor growth inhibitory activity by a single administration of the antibody at a dosage of 10 mg/kg body weight.

5. The antibody according to any one of claims 1 to 4, which has anti-tumor activity on two or more types of human tumor cell lines.

6. The antibody according to any one of claims 1 to 5, wherein the dissociation constant (Kd value) is 1.0×10^{-10} M or less.

7. The antibody according to any one of claims 1 to 6, which is a monoclonal antibody.

8. The antibody according to any one of claims 1 to 7, wherein the tumor is at least one type selected from the group consisting of human pancreatic cancer, human prostate cancer, human colon cancer and human breast cancer.

9. The antibody according to any one of claims 1 to 7, wherein the tumor is human pancreatic cancer.

10. The antibody according to any one of claims 1 to 9, wherein the tumor is a recurrent cancer or a metastatic cancer.

11. The antibody according to any one of claims 5 to 10, wherein the tumor cell lines are at least two types selected from the group consisting of a human pancreatic cancer cell line PK-59, a human pancreatic cancer cell line BxPC-3, a human pancreatic cancer cell line KP-3L, a human pancreatic cancer cell line KP-2, a human pancreatic cancer cell line PK-1, a human pancreatic cancer cell line PK-45H, a human pancreatic cancer cell line PK-45P, a human pancreatic cancer cell line TCC-PAN2, a human pancreatic cancer cell line SUIT-2, a human colon cancer cell line CACO-2, a human colon cancer cell line SW480, a human colon cancer cell line DLD-1, a human colon cancer cell line HCT 116, a human breast cancer cell line JIMT-1, a human breast cancer

cell line HCC1143, a human breast cancer cell line MCF-7, a human prostate cancer cell line DU145 and a human prostate cancer cell line PC-3.

12. The antibody according to any one of claims 5 to 10, wherein the tumor cell lines are the human pancreatic cancer cell line PK-59 and the human pancreatic cancer cell line BxPC-3.

13. The antibody according to any one of claims 1 to 12, wherein the amino acid sequences of CDR 1 to 3 of the H chain V region of the antibody are shown in SEQ ID NOS: 36 to 38, respectively, and/or the amino acid sequences of CDR 1 to 3 of the L chain V region of the antibody are shown in SEQ ID NOS: 41 to 43, respectively.

14. The antibody according to any one of claims 1 to 12, wherein the amino acid sequences of CDR 1 to 3 of the H chain V region of the antibody are shown in SEQ ID NOS: 46 to 48, respectively, and/or the amino acid sequences of CDR 1 to 3 of the L chain V region of the antibody are shown in SEQ ID NOS: 51 to 53, respectively.

15. The antibody according to any one of claims 1 to 12, wherein the amino acid sequences of CDR 1 to 3 of the H chain V region of the antibody are shown in SEQ ID NOS: 56 to 58, respectively, and/or the amino acid sequences of CDR 1 to 3 of the L chain V region of the antibody are shown in SEQ ID NOS: 61 to 63, respectively.

16. The antibody according to any one of claims 1 to 12, wherein the amino acid sequences of CDR 1 to 3 of the H chain V region of the antibody are shown in SEQ ID NOS: 66 to 68, respectively, and/or the amino acid sequences of CDR 1 to 3 of the L chain V region of the antibody are shown in SEQ ID NOS: 71 to 73, respectively.

17. The antibody according to any one of claims 1 to 16, wherein the antibody is a genetically recombinant antibody.

18. The antibody according to claim 17, wherein the genetically recombinant antibody is a chimeric antibody, a humanized antibody, or a human antibody.

19. The antibody according to claim 18, wherein the H chain V region of the chimeric antibody consists of the amino acid sequence shown in SEQ ID NO: 35, and/or the L chain V region thereof consists of the amino acid sequence shown in SEQ ID NO: 40.

20. The antibody according to claim 18, wherein the H chain V region of the chimeric antibody consists of the amino acid sequence shown in SEQ ID NO: 45, and/or the L chain V region thereof consists of the amino acid sequence shown in SEQ ID NO:

50.

21. The antibody according to claim 18, wherein the H chain V region of the chimeric antibody consists of the amino acid sequence shown in SEQ ID NO: 55, and/or the L chain V region thereof consists of the amino acid sequence shown in SEQ ID NO: 60.

22. The antibody according to claim 18, wherein the H chain V region of the chimeric antibody consists of the amino acid sequence shown in SEQ ID NO: 65, and/or the L chain V region thereof consists of the amino acid sequence shown in SEQ ID NO: 70.

23. A monoclonal antibody against human TROP-2, which is produced by a hybridoma having accession No. FERM BP-11251.

24. A monoclonal antibody against human TROP-2, which is produced by a hybridoma having accession No. FERM BP-11252.

25. A monoclonal antibody against human TROP-2, which is produced by a hybridoma having accession No. FERM BP-11253.

26. A monoclonal antibody against human TROP-2, which is produced by a hybridoma having accession No. FERM BP-11346.

27. A monoclonal antibody against human TROP-2, which is produced by a hybridoma having accession No. FERM BP-11254.

28. The antibody according to any one of claims 1 to 22, which binds to a site, to which the monoclonal antibody produced by the hybridoma having accession No. FERM BP-11251, FERM BP-11252, FERM BP-11253, FERM BP-11346 or FERM BP-11254 binds.

29. The antibody according to any one of claims 1 to 22, which binds to a portion comprising at least one region selected from the group consisting of a region consisting of amino acids at positions 43 to 65, a region consisting of amino acids at positions 152 to 165, a region consisting of amino acids at positions 171 to 183, a region consisting of amino acids at positions 109 to 120, a region consisting of amino acids at positions 43 to 56, and a region consisting of amino acids at positions 193 to 206, in the amino acid sequence of human TROP-2 shown in SEQ ID NO: 2.

30. The antibody according to any one of claims 1 to 22, which binds to a portion comprising a region consisting of the amino acids at positions 43 to 65 in the amino acid

sequence of human TROP-2 shown in SEQ ID NO: 2.

31. The antibody according to any one of claims 1 to 22, which binds to a portion comprising a region consisting of the amino acids at positions 152 to 165 in the amino acid sequence of human TROP-2 shown in SEQ ID NO: 2.

32. The antibody according to any one of claims 1 to 22, which binds to a portion comprising a region consisting of the amino acids at positions 171 to 183 in the amino acid sequence of human TROP-2 shown in SEQ ID NO: 2.

33. The antibody according to any one of claims 1 to 22, which binds to a portion comprising a region consisting of the amino acids at positions 109 to 120 in the amino acid sequence of human TROP-2 shown in SEQ ID NO: 2.

34. An antibody fragment derived from the antibody according to any one of claims 1 to 33.

35. The antibody fragment according to claim 34, which comprises the amino acid sequences shown in SEQ ID NOS: 36 to 38 and/or the amino acid sequences shown in SEQ ID NOS: 41 to 43.

36. The antibody fragment according to claim 35, which comprises the amino acid sequence shown in SEQ ID NO: 35 and/or the amino acid sequence shown in SEQ ID NO: 40.

37. The antibody fragment according to claim 34, which comprises the amino acid sequences shown in SEQ ID NOS: 46 to 48 and/or the amino acid sequences shown in SEQ ID NOS: 51 to 53.

38. The antibody fragment according to claim 37, which comprises the amino acid sequence shown in SEQ ID NO: 45 and/or the amino acid sequence shown in SEQ ID NO: 50.

39. The antibody fragment according to claim 34, which comprises the amino acid sequences shown in SEQ ID NOS: 56 to 58 and/or the amino acid sequences shown in SEQ ID NOS: 61 to 63.

40. The antibody fragment according to claim 38, which comprises the amino acid sequence shown in SEQ ID NO: 55 and/or the amino acid sequence shown in SEQ ID NO: 60.

41. The antibody fragment according to claim 34, which comprises the amino acid sequences shown in SEQ ID NOS: 66 to 68 and/or the amino acid sequences shown in

SEQ ID NOS: 71 to 73.

42. The antibody fragment according to claim 41, which comprises the amino acid sequence shown in SEQ ID NO: 65 and/or the amino acid sequence shown in SEQ ID NO: 70.

43. A hybridoma, which produces the antibody according to any one of claims 1 to 22 and 28 to 33.

44. A hybridoma producing a monoclonal antibody against human TROP-2, which has accession No. FERM BP-11251.

45. A hybridoma producing a monoclonal antibody against human TROP-2, which has accession No. FERM BP-11252.

46. A hybridoma producing a monoclonal antibody against human TROP-2, which has accession No. FERM BP-11253.

47. A hybridoma producing a monoclonal antibody against human TROP-2, which has accession No. FERM BP-11346.

48. A hybridoma producing a monoclonal antibody against human TROP-2, which has accession No. FERM BP-11254.

49. An antibody-drug conjugate, which comprises the antibody according to any one of claims 1 to 33 and a substance having anti-tumor activity and/or cell-killing activity.

50. An antibody fragment-drug conjugate, which comprises the antibody fragment according to any one of claims 34 to 42 and a substance having anti-tumor activity and/or cell-killing activity.

51. The conjugate according to claim 49 or 50, wherein the tumor is at least one type selected from the group consisting of human pancreatic cancer, human prostate cancer, human colon cancer and human breast cancer.

52. The conjugate according to claim 49 or 50, wherein the tumor is human pancreatic cancer.

53. The conjugate according to any one of claims 49 to 52, wherein the tumor is a recurrent cancer of a metastatic cancer.

54. A pharmaceutical composition, which comprises at least one type selected from the group consisting of the antibody according to any one of claims 1 to 33, the antibody fragment according to any one of claims 34 to 42 and the conjugate according to any one of claims 49 to 53.

55. The composition according to claim 54, which is used in the treatment of tumor.

56. The composition according to claim 55, which does not cause weight reduction as a side effect.

57. The composition according to claim 54, which is used in the diagnosis of tumor.

58. The composition according to any one of claims 54 to 57, wherein the tumor is at least one type selected from the group consisting of human pancreatic cancer, human prostate cancer, human colon cancer and human breast cancer.

59. The composition according to any one of claims 55 to 58, wherein the tumor is a recurrent cancer or a metastatic cancer.

60. A tumor therapeutic agent, which comprises at least one type selected from the group consisting of the antibody according to any one of claims 1 to 33, the antibody fragment according to any one of claims 34 to 42 and the conjugate according to any one of claims 49 to 53.

61. The therapeutic agent according to claim 60, which does not cause weight reduction as a side effect.

62. The therapeutic agent according to claim 60 or 61, wherein the tumor is at least one type selected from the group consisting of human pancreatic cancer, human prostate cancer, human colon cancer and human breast cancer.

63. A tumor diagnostic agent, which comprises at least one type selected from the group consisting of the antibody according to any one of claims 1 to 33, the antibody fragment according to any one of claims 34 to 42 and the conjugate according to any one of claims 49 to 53.

64. The diagnostic agent according to claim 63, wherein the tumor is at least one type selected from the group consisting of human pancreatic cancer, human prostate cancer, human colon cancer and human breast cancer.

65. A method for detecting a tumor, which comprises: allowing at least one type selected from the group consisting of the antibody according to any one of claims 1 to 33, the antibody fragment according to any one of claims 34 to 42 and the conjugate according to any one of claims 49 to 53, to react with a sample collected from a living body; and then detecting a signal(s) of the reacted antibody and/or antibody fragment.

66. The method according to claim 65, wherein the tumor is at least one type selected from the group consisting of human pancreatic cancer, human prostate cancer,

human colon cancer and human breast cancer.

67. A kit for treating, diagnosing or detecting a tumor, which comprises at least one type selected from the group consisting of the antibody according to any one of claims 1 to 33, the antibody fragment according to any one of claims 34 to 42 and the conjugate according to any one of claims 49 to 53.

68. The kit according to claim 67, wherein the tumor is at least one type selected from the group consisting of human pancreatic cancer, human prostate cancer, human colon cancer and human breast cancer.

CLAIMS

1. A kit for diagnosing a tumor, which comprises an antibody against human TROP-2, which has anti-tumor activity in vivo.