CLAIMS

1. Use of an antibody-drug conjugate (ADC) comprising an anti-CEACAM5 antibody, in the manufacture of a medicament for treating a cancer in a subject in need thereof, wherein circulating carcinoembryonic antigen (CEA) in said subject is to be measured and an effective amount of said ADC is to be administered to said subject if the circulating CEA in said subject is ≥5 ng/mL, wherein the anti-CEACAM5 antibody comprises a HCDR1 having the amino acid sequence of SEQ ID NO: 1, a HCDR2 having the amino acid sequence of SEQ ID NO: 2, a HCDR3 having the amino acid sequence of SEQ ID NO: 3, a LCDR1 having the amino acid sequence of SEQ ID NO: 4, a LCDR2 having the amino acid sequence NTR, and a LCDR3 having the amino acid sequence of SEQ ID NO: 5.

2. The use according to claim 1, wherein the antibody is conjugated to an inhibitory growth agent, or wherein the antibody is conjugated to a cytotoxic agent.

3. The use according to claim 2, wherein the cytotoxic agent is selected in the group consisting of taxoid, vincas, maytansinoid or maytansinoid analog, tomaymycin or pyrrolobenzodiazepine derivative, cryptophycin derivative, leptomycin derivative, auristatin or dolastatin analog, topoisomerase II inhibitors, DNA alkylating agent, anti-tubulin agent, and CC-1065 or CC-1065 analog, and optionally wherein the cytotoxic agent maytansinoid analog is *N*2'-deacetyl-*N*2'-(3-mercapto-1-oxopropyl)-maytansine (DM1) or *N*2'-deacetyl-*N*-2'(4-methyl-4-mercapto-1-oxopentyl)-maytansine (DM4).

4. The use according to any one of claims 1 to 3, wherein the cancer is a solid tumor.

5. The use according to any one of claims 1 to 4, wherein the cancer is selected from the group consisting of colorectal cancer, gastric cancer, gastroesophageal junction cancer, esophageal cancer, lung cancer, uterine cervix cancer, pancreatic cancer, ovarian cancer, thyroid cancer, bladder cancer, endometrial cancer, breast cancer, liver cancer, biliary tract cancer (e.g., cholangiocarcinoma), prostate cancer, and skin cancer.

6. The use according to any one of claims 1 to 5, wherein the cancer is selected from the group consisting of gastric cancer, lung cancer, pancreatic cancer, prostate cancer, and colorectal cancer.

7. The use according to any one of claims 1-6, wherein the circulating CEA is measured after performing immunohistochemistry analysis of CEACAM5 expression on tumor cells of the subject.

8. The use according to any one of claims 1-7, wherein the subject has negative or low CEACAM5 expression on tumor cells (≥2+ intensity in <1% of cells) as measured by immunohistochemistry, or

the subject has moderate CEACAM5 expression on tumor cells (≥2+ intensity in ≥1% and <50% of cells) as measured by immunohistochemistry, or

the subject has high CEACAM5 expression on tumor cells (≥2+ intensity in ≥50% of cells) as measured by immunohistochemistry.

9. The use according to any one of claims 1-8, wherein prior to treatment the circulating CEA is ≥20 ng/mL, or

prior to treatment the circulating CEA is ≥50 ng/mL, or

prior to treatment the circulating CEA is ≥80 ng/mL, or

prior to treatment the circulating CEA is ≥100 ng/mL.

10. The use according to any one of claims 1-9, wherein the anti-CEACAM5 antibody is tusamitamab and/or wherein the ADC is tusamitamab ravtansine.

11. The use according to claim 10, wherein the tusamitamab ravtansine is to be administered in a dose of ≥100 mg/m^2 about once every two weeks, or the tusamitamab ravtansine is to be administered in a dose of ≥100 mg/m^2 about once every three weeks.

12. The use according to any one of claims 1-11, wherein an effective amount of at least one additional agent effective is to be administered to the subject to treat the cancer, and optionally, wherein the additional agent is selected from the group consisting of an immune checkpoint inhibitor (ICI), a platinum-based chemotherapy, pemetrexed, anti-VEGFR2, FOLFOX, FOLFIRI, TAS-102, anti-EGFR, and any combination thereof.

13. The use according to claim 12, wherein the ICI is an anti-PD-1 antibody or an anti-PD-L1 antibody, and wherein, optionally, the anti-PD-1 antibody is selected from the group consisting of pembrolizumab, nivolumab, cemiplimab, sintilimab, dostarlimab, and tislelizumab or, optionally, the anti-PD-L1 antibody is selected from the group consisting of atezolizumab, avelumab, and durvalumab.

14. The use according to any one of claims 1-13, wherein an effective amount of tusamitamab ravtansine and pembrolizumab is to be administered to the subject.

15. The use according to claim 14, wherein an effective amount of a platinum-based chemotherapy is to be administered to the subject, and, optionally, wherein the platinum-based chemotherapy is selected from cisplatin and carboplatin, and, further optionally, wherein an effective amount of pemetrexed is to be administered to the subject.

16. Use of an antibody-drug conjugate (ADC) comprising an anti-CEACAM5 antibody conjugated to a cytotoxic agent, in the manufacture of a medicament for treating a cancer in a subject in need thereof

the anti-CEACAM5 antibody comprising a HCDR1 having the amino acid sequence of SEQ ID NO: 1, a HCDR2 having the amino acid sequence of SEQ ID NO: 2, a HCDR3 having the amino acid sequence of SEQ ID NO: 3, a LCDR1 having the amino acid sequence of SEQ ID NO: 4, a LCDR2 having the amino acid sequence NTR, and a LCDR3 having the amino acid sequence of SEQ ID NO: 5, and

the cytotoxic agent being maytansinoid or maytansinoid analog, and

wherein circulating carcinoembryonic antigen (CEA) in said subject is to be measured and an effective amount of said ADC is to be administered to said subject if the circulating CEA in said subject is ≥5 ng/mL.

17. Use of an antibody-drug conjugate (ADC) comprising an anti-CEACAM5 antibody conjugated to a cytotoxic agent, in the manufacture of a medicament for treating a cancer in a subject in need thereof

the anti-CEACAM5 antibody comprising a HCDR1 having the amino acid sequence of SEQ ID NO: 1, a HCDR2 having the amino acid sequence of SEQ ID NO: 2, a HCDR3 having the amino acid sequence of SEQ ID NO: 3, a LCDR1 having the amino acid sequence of SEQ ID NO: 4, a LCDR2 having the amino acid sequence NTR, and a LCDR3 having the amino acid sequence of SEQ ID NO: 5,

wherein circulating carcinoembryonic antigen (CEA) in said subject is to be measured and an effective amount of said ADC is to be administered to said subject if the circulating CEA in said subject is ≥30 ng/mL.