

CLAIMS

1. An immunoconjugate comprising an anti-CEACAM5-antibody for use for treating cancer in combination with folinic acid, 5-fluoro-uracil and oxaliplatin (FOLFOX).
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2. The immunoconjugate for the use of claim 1, wherein the anti-CEACAM5-antibody comprises a CDR-H1 consisting of SEQ ID NO: 1, CDR-H2 consisting of SEQ ID NO: 2, CDR-H3 consisting of SEQ ID NO: 3, CDR-L1 consisting of SEQ ID NO: 4, CDR-L2 consisting of amino acid sequence NTR, and CDR-L3 consisting of SEQ ID
10 NO: 5.
3. The immunoconjugate for the use of claim 1 or 2, wherein the anti-CEACAM5-antibody comprises a variable domain of a heavy chain (VH) consisting of SEQ ID NO: 6 and a variable domain of a light chain (VL) consisting of SEQ ID NO: 7.
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4. The immunoconjugate for the use of any of claims 1 to 3, wherein the anti-CEACAM5-antibody comprises a heavy chain (VH) consisting of SEQ ID NO: 8 and a light chain (VL) consisting of SEQ ID NO: 9.
- 20 5. The immunoconjugate for the use of any of claims 1 to 4, wherein the immunoconjugate comprises at least one cytostatic agent.
6. The immunoconjugate for the use of claim 5, wherein the cytostatic agent is selected from the group consisting of radioisotopes, protein toxins, small molecule toxins, and combinations thereof.
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7. The immunoconjugate for the use of claim 6, wherein the small molecule toxins are selected from antimetabolites, DNA-alkylating agents, DNA-cross-linking agents, DNA-intercalating agents, anti-microtubule agents, topoisomerase inhibitors, and combinations thereof.
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8. The immunoconjugate for the use of claim 7, wherein the anti-microtubule agent is selected from the group consisting of taxanes, vinca alkaloids, maytansinoids, colchicine, podophyllotoxin, griseofulvin, and combinations thereof.
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9. The immunoconjugate for the use of claim 8, wherein the maytansinoids are selected from the group consisting of N2'-deacetyl-N2'-(3-mercapto-1-oxopropyl)-maytansine (DM1) or N2'-deacetyl-N-2'-(4-methyl-4-mercapto-1-oxopentyl)-maytansine (DM4), and combinations thereof.
- 5 10. The immunoconjugate for the use of any of claims 1 to 9, wherein the anti-CEACAM5-antibody is covalently attached via a cleavable or non-cleavable linker to the at least one cytotoxic agent.
- 10 11. The immunoconjugate for the use of claim 10, wherein said linker is selected from the group consisting of N-succinimidyl pyridyldithiobutyrate (SPDB), 4-(pyridin-2-yl)disulfanyl-2-sulfo-butyric acid (sulfo-SPDB), and succinimidyl(N-maleimidomethyl) cyclohexane-1-carboxylate (SMCC).
- 15 12. The immunoconjugate for the use of any of claims 1 to 11, comprising an CEACAM5-antibody, which comprises a heavy chain (VH) consisting of SEQ ID NO: 8 and a light chain (VL) consisting of SEQ ID NO: 9 (huMAb2-3), and which is covalently linked to N2'-deacetyl-N-2'-(4-methyl-4-mercapto-1-oxopentyl)-maytansine (DM4) via N-succinimidyl pyridyldithiobutyrate (SPDB).
- 20 13. The immunoconjugate for the use of any of claims 1 to 12, wherein the immunoconjugate is characterised by a drug-to-antibody ratio (DAR) ranging from 1 to 10.
- 25 14. The immunoconjugate for the use of any of claims 1 to 13, wherein the cancer is selected from the group consisting of colorectal, stomach, pancreas, and oesophagus cancer.
- 30 15. The immunoconjugate for the use of any of claims 1 to 14, wherein the immunoconjugate and FOLFOX are administered simultaneously to a subject in need thereof.
- 35 16. The immunoconjugate for the use of claim 15, wherein the immunoconjugate and FOLFOX are formulated (i) in a single pharmaceutical composition comprising the immunoconjugate and FOLFOX, or (ii) in the form of at least two separate pharmaceutical compositions, wherein at least one pharmaceutical composition

comprises the immunoconjugate, and one or more pharmaceutical compositions comprise folinic acid, 5-fluoro-uracil and oxaliplatin, in separate or combined formulations.

- 5 17. The immunoconjugate for the use of any of claims 1 to 14, wherein the immunoconjugate and FOLFOX are administered separately or sequentially to a subject in need thereof.
- 10 18. The immunoconjugate for the use of claim 17, wherein the immunoconjugate and FOLFOX are formulated in the form of at least two separate pharmaceutical compositions, wherein (i) at least one pharmaceutical composition comprises the immunoconjugate, and (ii) one or more pharmaceutical compositions comprise folinic acid, 5-fluoro-uracil and oxaliplatin, in separate or combined formulations.
- 15 19. The immunoconjugate for the use of any of claims 1 to 18, wherein the immunoconjugate comprising an anti-CEACAM5-antibody, and folinic acid, 5-fluoro-uracil and oxaliplatin (FOLFOX) are administered in 8 to 16 cycles, wherein one cycle comprises:
administering the immunoconjugate at a dose of from 60 to 210 mg/m², at least once
20 in the cycle;
administering folinic acid at a dose of from 100 to 300 mg/m² or L-folinic acid at a dose of 100 to 200 m/m², at least once in the cycle;
administering 5-fluoro-uracil at a dose of from 1000 to 2000 mg/m², at least once in the cycle, and
25 administering oxaliplatin at a dose of from 50 to 200 mg/m², at least once in the cycle.
20. A pharmaceutical composition comprising the immunoconjugate of any of claims 1 to 14, and folinic acid, 5-fluoro-uracil and oxaliplatin.
- 30 21. A kit comprising (i) a pharmaceutical composition of the immunoconjugate of any of claims 1 to 14 and (ii) one or more pharmaceutical compositions comprising folinic acid, 5-fluoro-uracil and oxaliplatin, in separate or combined formulations.
- 35 22. The pharmaceutical composition according to claim 20 or the kit according to claim 21 for the use for treating cancer.