

Claims:

1. A Fc fusion protein for use in the prevention and/or treatment of a cancer, wherein said Fc fusion protein is a homodimer of two polypeptides, each comprising (i) an immunoglobulin IgG Fc domain and (ii) a heterologous polypeptide comprising a sequence of a human IL-10 or a variant thereof, wherein the heterologous polypeptide is covalently linked to the N-terminus or the C-terminus of the Fc domain by a polypeptide linker (e.g. a flexible hinge) and the two heterologous polypeptides are non-covalently assembled in a homodimer.
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2. A fusion protein for use according to claim 1, wherein the sequence of said Fc fusion protein comprises the sequence of a human IL-10.
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3. A fusion protein for use according to claim 2, wherein the sequence of a human IL-10 is of **SEQ ID NO: 1** or a variant thereof.
4. A fusion protein for use according to any one of claims 1 to 3, wherein the sequence of said fusion protein comprises the sequence of an IgG1 Fc fragment or a variant thereof.
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5. A fusion protein for use according to any one of claims 1 to 4, wherein the immunoglobulin IgG Fc domain consists in or comprises a non-cytolytic IgG1 Fc.
6. A fusion protein for use according to claim 4 or 5, wherein the sequence of the said IgG1 Fc fragment or variant thereof comprises a sequence of **SEQ ID NO: 2** or a variant thereof.
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7. A fusion protein for use according to any one of claims 1 to 6, wherein the sequence of said fusion protein comprises the sequence of a flexible hinge selected from **SEQ ID NO: 3** and a sequence of a GS linker or a variant thereof.
8. A fusion protein for use according to any one of claims 1 to 7, wherein the sequence of said fusion protein comprises a sequence of **SEQ ID NO: 4** or a variant thereof.
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9. A fusion protein for use according to any one of claims 1 to 3, wherein the immunoglobulin IgG Fc domain consists in or comprises a non-cytolytic IgG2 Fc.

10. A fusion protein for use according to claim 9, wherein the sequence of the said IgG1 Fc fragment or variant thereof comprises a sequence of **SEQ ID NO: 5** or a variant thereof.
11. A fusion protein for use according to any one of claims 1 to 6 or 9 to 10, wherein
5 the sequence of said fusion protein comprises the sequence of a flexible hinge selected from **SEQ ID NO: 6** and a sequence of a GS linker or a variant thereof.
12. A fusion protein for use according to any one of claims 9 to 11, wherein the sequence of said fusion protein comprises a sequence of **SEQ ID NO: 7** or a variant thereof.
13. A fusion protein for use according to any one of claims 1 to 3, wherein the
10 immunoglobulin IgG Fc domain consists in or comprises IgG3 Fc.
14. A fusion protein for use according to claim 13, wherein the sequence of the said IgG3 Fc fragment or variant thereof comprises a sequence of **SEQ ID NO: 8** or a variant thereof.
15. A fusion protein for use according to any one of claims 13 to 14, wherein the sequence of said fusion protein comprises a sequence of **SEQ ID NO: 10** or a variant thereof.
16. A fusion protein for use according to any one of claims 1 to 3, wherein the immunoglobulin IgG Fc domain consists in or comprises a non-cytolytic IgG4 Fc.
17. A fusion protein for use according to claim 13, wherein the sequence of the said
20 IgG4 Fc fragment or variant thereof comprises a sequence of **SEQ ID NO: 11** or a variant thereof.
18. A fusion protein for use according to any one of claims 16 to 17, wherein the sequence of said fusion protein comprises a sequence of **SEQ ID NO: 13** or a variant
25 thereof.
19. A fusion protein for use in the prevention and/or treatment of a cancer according to any one of claims 1 to 18, wherein said use in the prevention and/or treatment of a cancer is anti-cancer immunotherapy.

20. A fusion protein for use according to claim 19, wherein said anticancer immunotherapy is selected from ACT therapy or immune checkpoint blockade therapy.
21. A fusion protein for use according to claim 18 or 19, wherein ACT therapy is selected from TCR-T, CAR-T or TILs therapies.
- 5 22. A fusion protein for use according to any one of claims 1 to 18, wherein said cancer is a solid tumor cancer, such as lung cancer, breast cancer, ovarian cancer, cervical cancer, uterus cancer, head and neck cancer, glioblastoma, hepatocellular carcinoma, colon cancer, rectal cancer, colorectal carcinoma, kidney cancer, prostate cancer, gastric cancer, bronchus cancer, pancreatic cancer, urinary bladder cancer, hepatic cancer and
10 brain cancer or skin cancer, in particular melanoma.
23. A pharmaceutical composition comprising at least one Fc fusion protein comprising an immunoglobulin IgG Fc domain and a heterologous polypeptide a comprising a sequence of a human IL-10 or a variant thereof, wherein the heterologous polypeptide is covalently linked to the N-terminus or the C-terminus of the Fc domain by a polypeptide
15 linker (e.g. a flexible hinge) and a pharmaceutically acceptable carrier, diluent or excipient thereof and at least one agent useful in anti-cancer immunotherapy.
24. A pharmaceutical composition according to claim 23, wherein the sequence of said Fc fusion protein comprises a sequence of **SEQ ID NO: 4** or a variant thereof.
25. A pharmaceutical composition according to claims 23 or 24 for use in the treatment
20 of cancer, in particular ACT therapy.
26. A pharmaceutical composition for use according to claim 25 wherein ACT therapy is selected from TCR-T, CAR-T or TILs therapies.
27. A method of preventing or treating a cancer, said method comprising administering in a subject in need thereof a therapeutically effective amount of at least one Fc fusion
25 protein, said at least one Fc fusion protein being a homodimer of two polypeptides, each comprising (i) an immunoglobulin IgG Fc domain and (ii) a heterologous polypeptide a comprising a sequence of a human IL-10 or a variant thereof, wherein the heterologous polypeptide is covalently linked to the N-terminus or the C-terminus of the Fc domain by a polypeptide linker (e.g. a flexible hinge) and the two heterologous polypeptides are
30 non-covalently assembled in a homodimer.

28. A method according to claim 27, wherein said method of preventing or treating a cancer is anti-cancer immunotherapy.

29. A method according to claim 27 or 28, wherein said fusion protein is to be administered in combination with an anticancer immunotherapy, in particular selected
5 from ACT therapy or immune checkpoint blockade therapy.

30. A method of inducing immunity or restoring of responsiveness to immunotherapy, in a subject, said method comprising administering at least one Fc fusion protein in a subject in need thereof, in combination with an immune check-point blockade therapy, said at least one Fc fusion protein being a homodimer of two polypeptides, each
10 comprising (i) an immunoglobulin IgG Fc domain and (ii) a heterologous polypeptide comprising a sequence of a human IL-10 or a variant thereof, wherein the heterologous polypeptide is covalently linked to the N-terminus or the C-terminus of the Fc domain by a polypeptide linker (e.g. a flexible hinge) and the two heterologous polypeptides are non-covalently assembled in a homodimer.

31. A method according to claim 27 to 30, wherein said at least one Fc fusion protein is
15 as described in any one of claims 1 to 18.