

Claims

[Claim 1]

A fusion protein comprising an IL-2 protein and a CD80 protein.

[Claim 2]

The fusion protein of claim 1, wherein the IL-2 protein and the CD80 protein are attached to each other via a linker.

[Claim 3]

The fusion protein of claim 1, wherein the IL-2 protein has the amino acid sequence of SEQ ID NO: 10.

[Claim 4]

The fusion protein of claim 1, wherein the IL-2 protein is an IL-2 variant.

[Claim 5]

The fusion protein of claim 4, wherein the IL-2 variant is obtained by substitution of at least one selected from the 38th, 42nd, 45th, 61st, and 72nd amino acids in the amino acid sequence of SEQ ID NO: 10.

[Claim 6]

The fusion protein of claim 4, wherein the IL-2 variant is obtained by at least one substitution selected from the group consisting of R38A, F42A, Y45A, E61R, and

L72G in the amino acid sequence of SEQ ID NO: 10.

[Claim 7]

The fusion protein of claim 4, wherein the IL-2 variant contains any one selected from the following substitution combinations (a) to (d) in the amino acid sequence of SEQ ID NO: 10:

(a) R38A/F42A

(b) R38A/F42A/Y45A

(c) R38A/F42A/E61R

(d) R38A/F42A/L72G.

[Claim 8]

The fusion protein of claim 4, wherein the IL-2 variant has the amino acid sequence of SEQ ID NO: 6, 22, 23, or 24.

[Claim 9]

The fusion protein of claim 1, wherein the CD80 protein has the amino acid sequence of SEQ ID NO: 11.

[Claim 10]

The fusion protein of claim 1, wherein the CD80 protein is a CD80 fragment.

[Claim 11]

The fusion protein of claim 10, wherein the CD80 fragment consists of the 35th

amino acid to 242nd amino acid in the amino acid sequence of SEQ ID NO: 11.

[Claim 12]

The fusion protein of claim 2, wherein the linker is an albumin or an Fc domain of an immunoglobulin.

[Claim 13]

The fusion protein of claim 12, wherein the Fc domain is a wild type or variant.

[Claim 14]

The fusion protein of claim 12, wherein the Fc domain has the amino acid sequence of SEQ ID NO: 4.

[Claim 15]

The fusion protein of claim 13, wherein the variant of the Fc domain has the amino acid sequence of SEQ ID NO: 12.

[Claim 16]

The fusion protein of claim 1, wherein the fusion protein consists of the following structural formula (I) or (II):

N'-X-[linker (1)]_n-Fc domain-[linker (2)]_m-Y-C' (I)

N'-Y-[linker (1)]_n-Fc domain-[linker (2)]_m-X-C' (II)

in the structural formulas (I) and (II),

N' is the N-terminus of the fusion protein,

C' is the C-terminus of the fusion protein,
X is the CD80 protein,
Y is the IL-2 protein,
the linkers (1) and (2) are peptide linkers, and
n and m are each independently 0 or 1.

[Claim 17]

The fusion protein of claim 16, wherein the linker (1) is a peptide linker consisting of the amino acid sequence of SEQ ID NO: 3.

[Claim 18]

The fusion protein of claim 16, wherein the linker (2) is a peptide linker consisting of the amino acid sequence of SEQ ID NO: 5.

[Claim 19]

The fusion protein of claim 16, wherein the fusion protein consists of the structural formula (I).

[Claim 20]

The fusion protein of claim 1, wherein the fusion protein has a sequence identity of 85% or higher to the amino acid sequence of SEQ ID NO: 9, 26, 28, or 30.

[Claim 21]

A fusion protein dimer wherein two fusion proteins of any one of claims 1 to

20 are attached to each other.

[Claim 22]

The fusion protein dimer of claim 21, wherein the fusion protein dimer is a homodimer.

[Claim 23]

A polynucleotide encoding the fusion protein of any one of claims 1 to 20.

[Claim 24]

The polynucleotide of claim 23, wherein the polynucleotide has a sequence identity of 85% or higher to the nucleotide sequence of SEQ ID NO: 8, 25, 27 or 29.

[Claim 25]

A vector comprising the polynucleotide of claim 23.

[Claim 26]

A transformed cell into which the vector of claim 25 has been introduced.

[Claim 27]

A pharmaceutical composition for preventing or treating cancer or an infectious disease, comprising as an active ingredient:

the fusion protein of any one of claims 1 to 20; or

the fusion protein dimer of claim 21 or 22.

[Claim 28]

The pharmaceutical composition of claim 27, further comprising a pharmaceutically acceptable carrier.

[Claim 29]

The pharmaceutical composition of claim 27, wherein the cancer is any one selected from the group consisting of gastric cancer, liver cancer, lung cancer, colorectal cancer, breast cancer, prostate cancer, ovarian cancer, pancreatic cancer, cervical cancer, thyroid cancer, laryngeal cancer, acute myeloid leukemia, brain tumor, neuroblastoma, retinoblastoma, head and neck cancer, salivary gland cancer, and lymphoma.

[Claim 30]

The pharmaceutical composition of claim 27, wherein the infectious disease is any one selected from the group consisting of hepatitis B, hepatitis C, human papilloma virus infection, cytomegalovirus infection, viral respiratory disease, and influenza.

[Claim 31]

A use of the fusion protein of claim 1 for treatment of cancer or an infectious disease.

[Claim 32]

A use of the fusion protein of claim 1 for manufacture of a medicament for treating cancer or an infectious disease.

[Claim 33]

A method for treating cancer or an infectious disease, comprising:

administering, to a subject, the fusion protein of any one of claims 1 to 20; or the fusion protein dimer of claim 21 or 22.

Claims

[Claim 1]

A fusion protein comprising an IL-2 protein and a CD80 protein,
wherein the fusion protein consists of the following structural formula (I) or (II):
N'-X-[linker (1)]n-Fc domain-[linker (2)]m,-Y-C' (I)
N'-Y-[linker (1)]n-Fc domain-[linker (2)]m,-X-C' (II)
in the structural formulas (I) and (II),
N' is the N-terminus of the fusion protein,
C' is the C-terminus of the fusion protein,
X is a CD80 protein,
Y is an IL-2 protein,
the linkers (1) and (2) are peptide linkers, and
n and m are each independently 0 or 1.

[Claim 2]

The fusion protein of claim 1, wherein the IL-2 protein has the amino acid sequence of SEQ ID NO: 10.

[Claim 3]

The fusion protein of claim 1, wherein the IL-2 protein is an IL-2 variant.

[Claim 4]

The fusion protein of claim 3, wherein the IL-2 variant is obtained by substitution of at least one selected from the 38th, 42nd, 45th, 61st, and 72nd amino acids in the amino acid sequence of SEQ ID NO: 10.

[Claim 5]

The fusion protein of claim 3, wherein the IL-2 variant is obtained by at least one substitution selected from the group consisting of R38A, F42A, Y45A, E61R, and L72G in the amino acid sequence of SEQ ID NO: 10.

[Claim 6]

The fusion protein of claim 3, wherein the IL-2 variant contains any one selected from the

following substitution combinations (a) to (d) in the amino acid sequence of SEQ ID NO: 10:

(a) R38A/F42A

(b) R38A/F42A/Y45A

(c) R38A/F42A/E61R

(d) R38A/F42A/L72G.

[Claim 7]

The fusion protein of claim 3, wherein the IL-2 variant has the amino acid sequence of SEQ ID NO: 6, 22, 23, or 24.

[Claim 8]

The fusion protein of claim 1, wherein the CD80 protein has the amino acid sequence of SEQ ID NO: 11.

[Claim 9]

The fusion protein of claim 1, wherein the CD80 protein is a CD80 fragment.

[Claim 10]

The fusion protein of claim 9, wherein the CD80 fragment consists of the 35th amino acid to 242nd amino acid in the amino acid sequence of SEQ ID NO: 11.

[Claim 11]

The fusion protein of claim 1, wherein the Fc domain is a wild type or variant.

[Claim 12]

The fusion protein of claim 1, wherein the Fc domain has the amino acid sequence of SEQ ID NO: 4.

[Claim 13]

The fusion protein of claim 11, wherein the variant of the Fc domain has the amino acid sequence of SEQ ID NO: 12.

[Claim 14]

The fusion protein of claim 1, wherein the linker (1) is a peptide linker consisting of the amino acid sequence of SEQ ID NO: 3.

[Claim 15]

The fusion protein of claim 1, wherein the linker (2) is a peptide linker consisting of the amino acid sequence of SEQ ID NO: 5.

[Claim 16]

The fusion protein of claim 1, wherein the fusion protein consists of the structural formula (I).

[Claim 17]

The fusion protein of claim 1, wherein the fusion protein has a sequence identity of 85% or higher to the amino acid sequence of SEQ ID NO: 9, 26, 28, or 30.

[Claim 18]

A fusion protein dimer wherein two fusion proteins of any one of claims 1 to 17 are attached to each other.

[Claim 19]

The fusion protein dimer of claim 18, wherein the fusion protein dimer is a homodimer.

[Claim 20]

A polynucleotide encoding the fusion protein of any one of claims 1 to 17.

[Claim 21]

The polynucleotide of claim 20, wherein the polynucleotide has a sequence identity of 85% or higher to the nucleotide sequence of SEQ ID NO: 8, 25, 27 or 29.

[Claim 22]

A vector comprising the polynucleotide of claim 20.

[Claim 23]

A transformed cell into which the vector of claim 22 has been introduced.

[Claim 24]

A pharmaceutical composition for preventing or treating cancer or an infectious disease, comprising as an active ingredient:

the fusion protein of any one of claims 1 to 17; or

the fusion protein dimer of claim 18 or 19.

[Claim 25]

The pharmaceutical composition of claim 24, further comprising a pharmaceutically acceptable carrier.

[Claim 26]

The pharmaceutical composition of claim 24, wherein the cancer is any one selected from the group consisting of gastric cancer, liver cancer, lung cancer, colorectal cancer, breast cancer, prostate cancer, ovarian cancer, pancreatic cancer, cervical cancer, thyroid cancer, laryngeal cancer, acute myeloid leukemia, brain tumor, neuroblastoma, retinoblastoma, head and neck cancer, salivary gland cancer, and lymphoma.

[Claim 27]

The pharmaceutical composition of claim 24, wherein the infectious disease is any one selected from the group consisting of hepatitis B, hepatitis C, human papilloma virus infection, cytomegalovirus infection, viral respiratory disease, and influenza.