The CDCA1 expression significantly up-regulates in cancer cells compared with normal tissues. Thus, a peptide of the present invention or a polynucleotide encoding the peptide can be used to treat and/or prevent cancer, and/or prevent postoperative recurrence thereof. Therefore, the present invention provides pharmaceutical compositions for treating and/or preventing cancer, and/or preventing postoperative recurrence thereof, comprising one or more types of peptides or polynucleotides of the present invention as an active ingredient. Alternatively, the peptides of the present invention can be made to be presented on the surface of exosomes or APCs for use as pharmaceutical compositions. In addition, CTLs of the present invention targeting any one of the peptides of the present invention can also be used as an active ingredient of the pharmaceutical compositions of the present invention. The pharmaceutical compositions of the present invention may comprise a therapeutically effective amount or a pharmaceutically effective amount of the above-described active ingredient.

The pharmaceutical compositions of the present invention may also be used as a vaccine. In the context of the present invention, the term "vaccine" (also called "immunogenic composition") refers to a composition that has a function of inducing an immune response that leads to antitumor action when inoculated into an animal. Thus, a pharmaceutical composition of the present invention can be used to induce an immune response that leads to antitumor action. The immune response induced by a peptide, a polynucleotide, an APC, a CTL and a pharmaceutical composition of the present invention is not particularly limited as long as it is an immune response that leads to antitumor action, and examples include induction of cancer cell-specific CTLs and induction of cancer cell-specific cytotoxic activity.

The pharmaceutical compositions of the present invention can be used to treat and/or prevent cancer, and/or prevent postoperative recurrence thereof in human subjects or patients. The pharmaceutical compositions of the present invention can be used preferably to a subject positive for at least one HLA selected from among HLA-A11, HLA-A33 and HLA-A03. Further, the pharmaceutical compositions of the present invention can be used preferably to treat and/or prevent cancers expressing CDCA1 and at least one HLA selected from among HLA-A11, HLA-A33 and HLA-A03, and/or prevent postoperative recurrence thereof.

In another embodiment, the present invention provides use of an active ingredient selected from below in the manufacture of a pharmaceutical composition for treating or preventing cancer:

(a) a peptide of the present invention;

(b) a polynucleotide encoding a peptide of the present invention in an expressible form;

(c) an APC that presents a peptide of the present invention on its surface;

(d) an exosome that presents a peptide of the present invention on its surface; and

(e) a CTL of the present invention.

(c) an APC that presents on its surface a peptide of the present invention;
(d) an exosome that presents on its surface a peptide of the present invention; and
(e) a CTL of the present invention.

Alternatively, the present invention also provides use of an active ingredient selected from below in the manufacture of pharmaceutical compositions or vaccines for inducing an immune response against CDCA1-expressing cancer cells:
(a) a peptide of the present invention;
(b) a polynucleotide encoding a peptide of the present invention in an expressible form;
(c) an APC that presents on its surface a peptide of the present invention;
(d) an exosome that presents on its surface a peptide of the present invention; and
(e) a CTL of the present invention.

Alternatively, the present invention further provides use of an active ingredient selected from below in the manufacture of pharmaceutical compositions or vaccines for inhibiting proliferation of CDCA1-expressing cancer cells:
(a) a peptide of the present invention;
(b) a polynucleotide encoding a peptide of the present invention in an expressible form;
(c) an APC that presents on its surface a peptide of the present invention;
(d) an exosome that presents on its surface a peptide of the present invention; and
(e) a CTL of the present invention.

The present invention further provides methods or processes for manufacturing pharmaceutical compositions that induce an immune response against CDCA1-expressing cancers, which is a method that may comprise a step of mixing or formulating a peptide or polynucleotide of the present invention with a pharmaceutically acceptable carrier.

Alternatively, the present invention provides methods for inhibiting proliferation of CDCA1-expressing cancer cells or methods of inducing an immune response against CDCA1-expressing cancers, which comprises a step of administering to a subject vaccines or pharmaceutical compositions comprising an active ingredient selected from below:
(a) a peptide of the present invention;
(b) a polynucleotide encoding a peptide of the present invention in an expressible form;
(c) an APC that presents a peptide of the present invention on its surface;
(d) an exosome that presents a peptide of the present invention on its surface; and
(e) a CTL of the present invention.

In the context of the present invention, CDCA1-expressing cancers can be treated by administering a peptide, a polypnucleotide, an APC, an exosome and/or a CTL of the present invention. Alternatively, an immune response against CDCA1-expressing cancers can be induced by administering a peptide, a polynucleotide, an APC, an exosome and/or a CTL of the

present invention. Examples of such cancers include bladder cancer, breast cancer, cervical cancer, cholangiocellular cancer, chronic myeloid leukemia (CML), esophagus cancer, gastric cancer, non-small-cell lung cancer, lymphoma, osteosarcoma, prostate cancer, kidney cancer, small-cell lung cancer, head and neck cancer, soft tissue tumor, colon cancer and such, but are not limited thereto. Further, an immune response against CDCA1-expressing cancer cells can be induced by administering a peptide, a polynucleotide, an APC, an exosome and/or a CTL of the present invention. Therefore, before administering a vaccine or pharmaceutical composition comprising an active ingredient described above, it is preferable to confirm whether the level of CDCA1 expression at a diseased site in the subject to be treated is augmented or not.

Thus, in one embodiment, the present invention provides a method of treating a CDCA1-expressing cancer in a patient in need of the cancer treatment, wherein the method comprises the steps below:

(i) measuring the level of CDCA1 expression in a biological sample collected from the diseased site of a subject with cancer;

(ii) identifying a subject with CDCA1-expressing cancer based on the CDCA1 expression level measured in (i); and

(iii) administering to the subject with CDCA1-overexpressing cancer as compared to normal control at least one ingredient selected from the group consisting of (a) to (e) above.

Alternatively, the present invention further provides vaccines and pharmaceutical compositions comprising at least one active ingredient selected from the group consisting of (a) to (e) above for administration to a subject with CDCA1-expressing cancer. The present invention further provides a method of identifying or selecting a subject to be treated with at least one active ingredient selected from the group consisting of (a) to (e) above, wherein the method comprises the steps below:

(i) measuring the level of CDCA1 expression in a biological sample collected from the diseased site of a subject with cancer;

(ii) identifying a subject with CDCA1-expressing cancer based on the CDCA1 expression level measured in (i); and

(iii) identifying or selecting the subject identified in (ii) as a subject who may be treated with at least one active ingredient selected from the group consisting of (a) to (e) above.

Biological samples collected from a subject for measuring the CDCA1 expression level in the above-described methods are not particularly limited, and for example, tissue samples containing cancer cells collected by biopsy or such can be preferably used.

The CDCA1 expression level in a biological sample can be measured by known methods, and for example, methods that detect transcription products of the CDCA1 gene by probes or PCR methods (for example, cDNA microarray method, Northern blot method, RT-

PCR method or such), methods that detect translation products of the CDCA1 gene by antibodies or such (for example, Western blot method, immunostaining method or such), and such can be used. Further, biological samples may be blood samples, and in this case, the blood level of an antibody against CDCA1 or a fragment thereof is measured, and the CDCA1 expression level at a diseased site may be assessed based on the blood level. The blood level of an antibody against CDCA1 can be measured using known methods, and for example, enzyme immunoassay (EIA), enzyme-linked immunosorbent assay (ELISA), radioimmunoassay (RIA) and such using the CDCA1 protein or a peptide of the present invention as an antigen can be used.

Normally, in tissues and cells that do not express CDCA1, there is almost no detection of CDCA1 transcription products and translation products. Thus, when a transcription product or a translation product of CDCA1 is detected in cancer cells or a tissue sample containing cancer cells collected from a subject, one can determine that the subject's cancer expresses CDCA1. In blood samples of a subject that does not have CDCA1-expressing cancer, there is almost no detection of antibodies against CDCA1 or fragments thereof. Thus, when antibodies against CDCA1 or fragments thereof are detected in a blood sample collected from a subject, one can determine that the subject's cancer expresses CDCA1. Whether a subject's cancer expresses CDCA1 or not may also be determined by comparison with the measurement results of the same type of biological material collected from a non-cancerous site of the subject or the same type of biological material collected from a subject who does not have cancer (normal control sample). That is, in comparison with the level of the target of measurement in a normal control sample (normal control level), when the level in the biological sample of the test subject is elevated, the subject's cancer is assessed to be expressing CDCA1. For example, when the amount of the target of measurement detected is increased by at least 10% or higher in comparison with the normal control level, the subject's cancer may be assessed to be expressing CDCA1. It is desirable that the amount of the target of measurement detected is increased by preferably 25% or higher, and more preferably 50% or higher than the normal control level. Further, the amount of a transcription product or a translation product of CDCA1 detected may be evaluated by normalizing against the detected amount of a known housekeeping gene such as beta-Actin, glyceraldehyde-3-phosphate dehydrogenase, or ribosomal protein P1.

In a preferred embodiment, it is preferable to confirm the HLA type of the subject before administering at least one active ingredient selected from the group consisting of (a) to (e) above. For example, for the subjects to be administered with an active ingredient in association with a peptide having the amino acid sequence selected from among SEQ ID NOs: 3, 5 to 7, 9, 10, 12 to 14, 17, 19, 21, 30, 35, 38 to 40, 45, 53, 56 and 58, it is preferable to select HLA-A11-positive subjects. For the subjects to be administered with an active ingredient in association with a peptide having the amino acid sequence selected from among SEQ ID NOs: 27, 3, 60, 28,

[23] Use of at least one ingredient selected from the group consisting of (a) to (e) below in the manufacture of a pharmaceutical composition for treating and/or preventing cancer, and/or preventing postoperative recurrence thereof:

(a) one or more types of peptides of any one of [1] to [3];

(b) one or more types of polynucleotides encoding the peptide(s) of any one of [1] to [3] in an expressible form;

(c) an antigen-presenting cell (APC) that presents on its cell surface a complex of the peptide of any one of [1] to [3] and an HLA antigen;

(d) an exosome that presents on its cell surface a complex of the peptide of any one of [1] to [3] and an HLA antigen; and

(e) a CTL that targets the peptide of any one of [1] to [3].

[24] Use of at least one ingredient selected from the group consisting of (a) to (e) below for inducing an immune response against cancer:

(a) one or more types of peptides of any one of [1] to [3];

(b) one or more types of polynucleotides encoding the peptide(s) of any one of [1] to [3] in an expressible form;

(c) an antigen-presenting cell (APC) that presents on its cell surface a complex of the peptide of any one of [1] to [3] and an HLA antigen;

(d) an exosome that presents on its cell surface a complex of the peptide of any one of [1] to [3] and an HLA antigen; and

(e) a CTL that targets the peptide of any one of [1] to [3].

[25] Use of at least one ingredient selected from the group consisting of (a) to (e) below for treating and/or preventing cancer and/or preventing postoperative recurrence thereof:

(a) one or more types of peptides of any one of [1] to [3];

(b) one or more types of polynucleotides encoding the peptide(s) of any one of [1] to [3] in an expressible form;

(c) an antigen-presenting cell (APC) that presents on its cell surface a complex of the peptide of any one of [1] to [3] and an HLA antigen;

(d) an exosome that presents on its cell surface a complex of the peptide of any one of [1] to [3] and an HLA antigen; and

(e) a CTL that targets the peptide of any one of [1] to [3].

[26] A method of inducing cytotoxic activity against a CDCA1-epxressing cell(s), which comprises a step of administering to a subject at least one ingredient selected from the group consisting of (a) to (e) below:

(a) one or more types of peptides of any one of [1] to [3];