

from a patient suspected to have a neoplastic disease associated and/or identifiable by an aberrating MUC17 expression, e.g. a gastrointestinal cancer, pancreatic cancer, etc..

[8] The antibody may also serve as a diagnostic tool in the detection of MUC17 in laboratory animals, for example in previously sacrificed cancer-bearing animals.

[9] Moreover, the disclosure provides a polynucleotide encoding the antibody construct, a vector comprising this polynucleotide, and host cells expressing the construct as well as diagnostic compositions comprising the same and kits comprising the antibody of the present disclosure as diagnostic tool alongside further ingredients comprising, but not limited to, at least one of secondary antibodies, enzymes, buffers, instructions for use, tools for calibration, controls, and to forth.

[9a] In one aspect, the present disclosure provides an antibody that binds to human MUC17 as depicted in SEQ ID NO: 1, wherein said antibody binds cell surface-associated MUC17 protein, wherein said antibody comprises a variable heavy chain comprising a CDR3 region depicted in SEQ ID NO: 4, a heavy chain CDR1 and CDR2 regions as depicted in SEQ ID Nos: 2 and 3 and the light chain CDR1, CDR2 and CDR3 regions depicted in SEQ ID Nos: 6, 7, and 8. In another aspects of the present disclosure provide a polynucleotide encoding an antibody as described herein; a host cell transformed or transfected with the polynucleotide as described herein; a composition comprising an antibody as described herein; a detection system comprising the antibody as described herein.

[9b] Yet other aspects of the present disclosure provide an *in vitro* method of detecting neoplastic growth using the antibody, the composition or the detection system as described herein.

[9c] Another aspect of the present disclosure provides a method for detecting and/or quantifying MUC17 expression in a sample obtained from a subject, comprising the steps of: (a) using an antibody or using a detection system as described herein, for determining the expression quantity of MUC17 in the sample; and (b) comparing the expression quantity of MUC17 determined in step (a) to (i) a pre-defined value for the MUC17 expression quantity, (ii) the expression quantity of MUC17 determined in a control sample, or (iii) the expression quantity of MUC17 determined in a sample obtained from the same source or the subject at a previous time point.

[9d] Another aspect of the present disclosure provides an *in vitro* method for diagnosing a neoplastic disease associated with expression quantity of MUC17, comprising the steps of: (a) using an antibody or a composition, or using a detection system as described herein, for determining the expression quantity of MUC17 in a sample obtained from a subject; and (b) comparing the expression quantity of MUC17 determined in step (a) to

- (i) a pre-defined cut-off value for the expression quantity of MUC17, indicating absence of such disease, or
- (ii) the expression quantity of MUC17 determined in a negative control sample representing absence of such neoplastic disease,

wherein a higher expression quantity of MUC17 determined in step (a) as compared to the pre-defined cut-off value of (i) or the expression quantity of MUC17 determined in the negative control sample of (ii) indicates the presence of a disease associated with increased expression quantity of MUC17; or wherein a lower expression quantity of MUC17 determined in step (a) as compared to the pre-defined cut-off value of (i) or the expression quantity of MUC17 determined in the negative control sample of (ii) indicates the presence of a disease associated with decreased expression quantity of MUC17.

[9e] Another aspect of the present disclosure provides an *in vitro* method for monitoring the progression of a disease associated with expression of MUC17 or for monitoring the response to treatment of a disease associated with expression of MUC17, comprising the steps of: (a) using an antibody, or using a detection system as described herein, for determining the expression quantity of MUC17 at a first time point in a sample obtained from a subject diagnosed with a disease associated with expression of MUC17; (b) using an antibody, or using a detection system as described herein, for determining the expression quantity of MUC17 at a second time point or after treatment in a sample obtained from the subject diagnosed with a disease associated with expression of MUC17; and (c) comparing the expression quantity of MUC17 determined in step (a) to the expression quantity of MUC17 determined in step (b); wherein a higher expression quantity of MUC17 determined in step (a) as compared to the expression quantity of MUC17 determined in step (b) indicates that the disease is progressing, or wherein a lower expression quantity of MUC17 determined in step (a) as compared to the expression quantity of MUC17 determined in step (b) indicates that said disease is entering remission or that said disease is responding to the treatment; or wherein a lower expression quantity of MUC17 determined in step (a) as compared to the expression quantity of MUC17 determined in step (b) indicates that the disease is progressing, or wherein a higher expression quantity of MUC17 determined in step (a) as compared to the expression quantity of MUC17 determined in step (b) indicates that said disease is entering remission or that said disease is responding to the treatment.

[9f] Another aspect of the present disclosure provides use of a drug in the manufacture of a medicament for treating a cancer in a patient, wherein the cancer is selected from the group consisting of esophageal cancer, gastric cancer, gastrointestinal cancer, gastroesophageal cancer, including gastroesophageal junction cancer, and/or pancreas cancer, wherein said patient has an altered expression of MUC17 on a cancer cell, particularly a cell of a colorectal carcinoma, a gastric carcinoma, a pancreatic carcinoma, colon adenocarcinoma, esophageal carcinoma, pancreatic adenocarcinoma, rectum adenocarcinoma, and stomach adenocarcinoma, wherein said altered expression was determined in a method as described

herein, or wherein the use as described herein is comprised; and wherein the drug is an antibody construct as described herein.

[9g] Another aspect of the present disclosure provides a diagnostic kit comprising the antibody or the composition and/or detection system as described herein.

Claims

1. An antibody that binds to human MUC17 as depicted in SEQ ID NO: 1, wherein said antibody binds cell surface-associated MUC17 protein, wherein said antibody comprises a variable heavy chain comprising a CDR3 region depicted in SEQ ID NO: 4, a heavy chain CDR1 and CDR2 regions as depicted in SEQ ID Nos: 2 and 3 and the light chain CDR1, CDR2 and CDR3 regions depicted in SEQ ID Nos: 6, 7, and 8.
2. The antibody according to any one of the preceding claims, wherein the antibody comprises a VH region and/or a VL region as comprised in SEQ ID Nos: 5 and/or 9.
3. A polynucleotide encoding an antibody as defined in any one of the preceding claims.
4. A host cell transformed or transfected with the polynucleotide as defined in claim 3.
5. A composition comprising an antibody as defined in any one of claims 1 and 2.
6. A detection system comprising the antibody as defined in any one of claims 1 and 2, or a composition according to claim 5.
7. An *in vitro* method of detecting neoplastic growth using the antibody as defined in any one of claims 1 to 2, the composition of claim 5 or the detection system of claim 6.
8. The method according to claim 7 further comprising determining the quantity of expression of MUC17 in a sample from a patient suspected to suffer from a cancer and, optionally, in a negative control sample and, further optionally, in a positive control sample.
9. The method according to any one of claims 7 and 8 further comprising determining the quantity of expression of MUC17 in a sample from a patient suspected to suffer from a cancer and in a negative control sample, further comprising comparing the expression quantities of MUC17 between the samples, optionally wherein the expression quantities in the negative control and/or the positive control may be derived from stored data in at least one negative control sample and/or at least one positive control sample obtained in a method of detecting neoplastic growth comprising determining the quantity of expression of MUC17, further optionally, wherein the expression quantities in the negative control sample and/or the positive control sample may be derived from stored data comprising averaged expression quantities of more than one negative control sample and/or more than one positive control sample obtained in a method of detecting neoplastic growth comprising determining the quantity of expression of MUC17.

10. The method according to any one of claims 8 and 9 further comprising determining the quantity of expression of MUC17 in a sample, wherein the sample is either a solid tissue sample or a liquid tissue sample.

11. A method for detecting and/or quantifying MUC17 expression in a sample obtained from a subject, comprising the steps of:

- (a) using an antibody as defined in any one of claims 1 to 2, or using a detection system of claim 6, for determining the expression quantity of MUC17 in the sample; and
- (b) comparing the expression quantity of MUC17 determined in step (a) to
 - (i) a pre-defined value for the MUC17 expression quantity,
 - (ii) the expression quantity of MUC17 determined in a control sample, or
 - (iii) the expression quantity of MUC17 determined in a sample obtained from the same source or the subject at a previous time point.

12. An *in vitro* method for diagnosing a neoplastic disease associated with expression quantity of MUC17, comprising the steps of:

- (a) using an antibody or a composition as defined in any one of claims 1 to 2, or 5, or using a detection system of claim 6, for determining the expression quantity of MUC17 in a sample obtained from a subject; and
- (b) comparing the expression quantity of MUC17 determined in step (a) to
 - (i) a pre-defined cut-off value for the expression quantity of MUC17, indicating absence of such disease, or
 - (ii) the expression quantity of MUC17 determined in a negative control sample representing absence of such neoplastic disease,

wherein a higher expression quantity of MUC17 determined in step (a) as compared to the pre-defined cut-off value of (i) or the expression quantity of MUC17 determined in the negative control sample of (ii) indicates the presence of a disease associated with increased expression quantity of MUC17; or

wherein a lower expression quantity of MUC17 determined in step (a) as compared to the pre-defined cut-off value of (i) or the expression quantity of MUC17 determined in the negative control sample of (ii) indicates the presence of a disease associated with decreased expression quantity of MUC17.

13. An *in vitro* method for monitoring the progression of a disease associated with expression of MUC17 or for monitoring the response to treatment of a disease associated with expression of MUC17, comprising the steps of:

- (a) using an antibody as defined in any one of claims 1 to 2, or using a detection system of claim 6, for determining the expression quantity of MUC17 at a first time point in a sample obtained from a subject diagnosed with a disease associated with expression of MUC17;
- (b) using an antibody as defined in any one of claims 1 to 2, or using a detection system of claim 6, for determining the expression quantity of MUC17 at a second time point or after treatment in a sample obtained from the subject diagnosed with a disease associated with expression of MUC17; and
- (c) comparing the expression quantity of MUC17 determined in step (a) to the expression quantity of MUC17 determined in step (b);

wherein a higher expression quantity of MUC17 determined in step (a) as compared to the expression quantity of MUC17 determined in step (b) indicates that the disease is progressing, or wherein a lower expression quantity of MUC17 determined in step (a) as compared to the expression quantity of MUC17 determined in step (b) indicates that said disease is entering remission or that said disease is responding to the treatment; or

wherein a lower expression quantity of MUC17 determined in step (a) as compared to the expression quantity of MUC17 determined in step (b) indicates that the disease is progressing, or wherein a higher expression quantity of MUC17 determined in step (a) as compared to the expression quantity of MUC17 determined in step (b) indicates that said disease is entering remission or that said disease is responding to the treatment.

14. The method of any one of claims 7 to 10, and 12 to 13, wherein the cancer or disease is selected from the group consisting of: esophageal cancer, gastric cancer, gastrointestinal cancer, gastroesophageal cancer, including gastroesophageal junction cancer, and pancreas cancer.

15. Use of a drug in the manufacture of a medicament for treating a cancer in a patient, wherein the cancer is selected from the group consisting of esophageal cancer, gastric cancer, gastrointestinal cancer, gastroesophageal cancer, including gastroesophageal junction cancer, and/or pancreas cancer, wherein said patient has an altered expression of MUC17 on a cancer cell, particularly a cell of a colorectal carcinoma, a gastric carcinoma, a pancreatic carcinoma, colon adenocarcinoma, esophageal carcinoma, pancreatic adenocarcinoma, rectum adenocarcinoma, and stomach adenocarcinoma, wherein said altered expression was determined in a method according to claim 11; and wherein the drug is an antibody construct as defined in any one of claims 1 to 2.

16. A diagnostic kit comprising the antibody or the composition and/or detection system according to any one of claims 1, 2, 5 and 6.