and/or a C-terminus are selectively cleaved.

The pharmaceutical composition according to the present disclosure may further include one or more selected from pharmaceutically acceptable additives, particularly a buffer, a stabilizer, and a surfactant.

The pharmaceutical composition according to the present disclosure may be used in the form of an injection formulation for subcutaneous injection.

[Summary]

In another aspect, the present disclosure refers to a pharmaceutical composition comprising:

(a) pembrolizumab; and

(b) a hyaluronidase PH20 variant, wherein the amino acid sequence of the PH20 variant consists of the amino acid sequence set forth in SEQ ID NO:44.

In another aspect, the present disclosure refers to the pharmaceutical composition as disclosed herein for use in therapy.

In yet another aspect, the present disclosure refers to a use of the pharmaceutical composition as disclosed herein in the manufacture of a medicament for treating cancer in a subject in need thereof.

【Description of Drawings】

The above and other objects, features and other advantages of the present disclosure will be more clearly understood from the following detailed description taken in conjunction with the accompanying drawings, in which:

【CLAIMS】

1. A pharmaceutical composition comprising:

(a) pembrolizumab; and

(b) a hyaluronidase PH20 variant, wherein the amino acid sequence of the PH20 variant consists of the amino acid sequence set forth in SEQ ID NO:44.

2. The pharmaceutical composition according to claim 1, wherein the pharmaceutical composition is an injection formulation for subcutaneous administration.

3. The pharmaceutical composition according to claim 1, wherein the pharmaceutical composition is for subcutaneous injection.

4. The pharmaceutical composition according to any one of claims 1 to 3, further comprising one or more pharmaceutically acceptable additives.

5. The pharmaceutical composition according to any one of claims 1 to 3, wherein the pharmaceutical composition further includes one or more of a buffer, a stabilizer and a surfactant.

6. The pharmaceutical composition according to any one of claims 1 to 5 for use in therapy.

7. The pharmaceutical composition for use of claim 6, wherein the pharmaceutical composition is formulated for subcutaneous injection.

8. Use of the pharmaceutical composition of any one of claims 1 to 5, in the manufacture of a medicament for treating cancer in a subject in need thereof.

9. The use according to claim 8, wherein the medicament is for administration to the subject by subcutaneous injection.

10. The use of claim 8 or 9, wherein the cancer is skin cancer, liver cancer, hepatocellular carcinoma, gastric cancer, breast cancer, lung cancer, ovarian cancer, bronchial cancer, nasopharyngeal cancer, laryngeal cancer, pancreatic cancer, bladder cancer, colorectal cancer, colon cancer, brain cancer, prostate cancer, bone cancer, thyroid cancer, parathyroid cancer, kidney cancer, esophageal cancer, biliary tract cancer, testicular cancer, rectal cancer, head and neck cancer, cervical cancer, ureteral cancer, osteosarcoma, fibrosarcoma, rhabdomyosarcoma, astrocytoma, neuroblastoma, or glioma.

11. The use according to claim 8 or 9, wherein the cancer is gastric cancer, colorectal cancer, breast cancer, lung cancer, or kidney cancer.