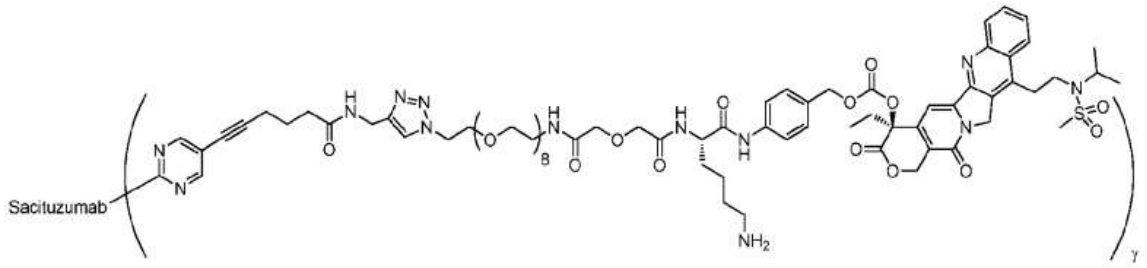
In one aspect, the present disclosure provides use of a biologically active conjugate in the manufacture of a medicament for treating a tumor disease; wherein the biologically active conjugate is

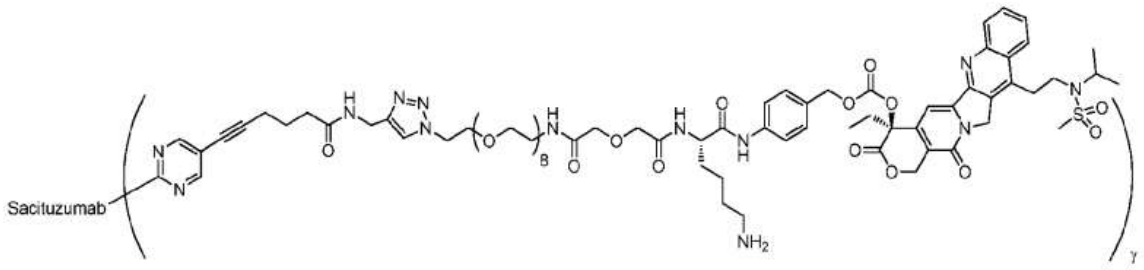


wherein γ is selected from integers from 6 to 8;

wherein the tumor disease is an unresectable locally advanced or metastatic solid tumor that has failed standard treatments, has no standard treatment regimen, or is not suitable for standard treatments at the present stage.

In some examples, the tumor disease is an unresectable locally advanced or metastatic solid tumor that has failed standard treatments, has no standard treatment regimen, or is not suitable for standard treatments at the present stage. In some examples, the standard treatment refers to the

In some technical solutions, the conjugate is conjugate A with a structure represented by the following formula:



Conjugate A

wherein γ is an integer from 1 to 10; preferably, γ is selected from integers from 5 to 8.

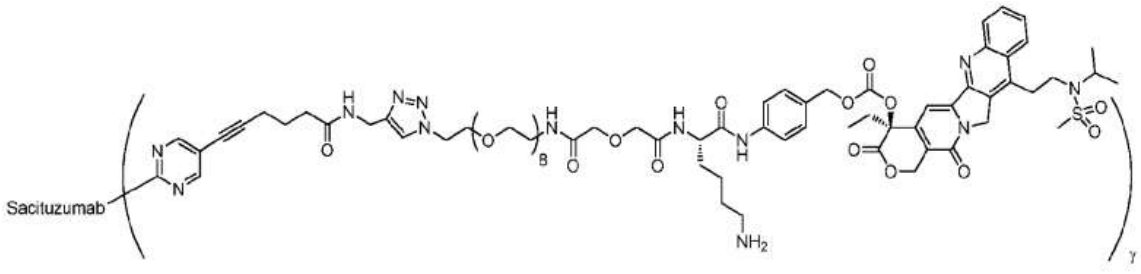
In some examples, the DAR value of the conjugate is 1-12; preferably 1-10; further preferably, the DAR value is 5-8; for example, the DAR value is 6.1, 6.2, 6.3, 6.4, 6.5, 6.6, 6.7, 6.8, 6.9, 7.0, 7.1, 7.2, 7.3, 7.4, 7.5, 7.6, 7.7, 7.8, 7.9 and 8.0.

The present disclosure provides a method for treating a tumor disease, which comprises a step of administering a therapeutically effective amount of the biologically active conjugate of formula (I) as described above and/or a pharmaceutical composition comprising the biologically active conjugate of formula (I) to an individual in need thereof.

In another aspect, the present disclosure provides use of a pharmaceutical composition comprising the biologically active conjugate as described herein in the manufacture of a medicament for the treatment of a tumor disease, wherein the tumor disease is selected from the tumor diseases as described herein, wherein the drug to antibody ratio (DAR) value of the pharmaceutical composition is 6 to 8, and wherein the pharmaceutical composition further comprises a pharmaceutically acceptable carrier and/or excipient.

CLAIMS

1. Use of a biologically active conjugate in the manufacture of a medicament for treating a tumor disease; wherein the biologically active conjugate is



wherein γ is selected from integers from 6 to 8;

wherein the tumor disease is an unresectable locally advanced or metastatic solid tumor that has failed standard treatments, has no standard treatment regimen, or is not suitable for standard treatments at the present stage.

2. The use according to claim 1, wherein the tumor disease is unresectable metastatic triple negative breast cancer, ovarian cancer, Her-2 positive breast cancer, gastric cancer, or pancreatic cancer.

3. The use according to claim 1, wherein the tumor disease comprises breast cancer, gastric cancer, lung cancer, ovarian cancer, urinary tract epithelial cancer, esophageal cancer, liver cancer, colorectal cancer, cervical cancer, endometrial cancer, pancreatic cancer, bladder cancer, or brain tumor.

4. The use according to claim 3, wherein:

(i) the breast cancer is Luminal type A, Luminal type B, Her-2 positive or triple negative type breast cancer;

(ii) the ovarian cancer is an ovarian epithelial cancer, platinum-sensitive ovarian cancer or platinum-resistant ovarian cancer;

(iii) the gastric cancer is gastric adenocarcinoma, gastric adenosquamous carcinoma, gastric squamous cell carcinoma, gastric undifferentiated carcinoma or gastric neuroendocrine tumor;

(iv) the pancreatic cancer is pancreatic epithelial tumor, pancreatic exocrine tumor, pancreatic borderline tumor, pancreatic ductal adenocarcinoma, pancreatic endocrine tumor, pancreatic mature teratoma, pancreatic mesenchymal tumor, pancreatic malignant lymphoma or pancreatic secondary tumor;

(v) the bladder cancer is urothelial carcinoma, bladder squamous cell cancer or bladder adenocarcinoma;

(vi) the urinary tract epithelial cancer is basal type, lumen type or wild type urinary tract epithelial cancer; and

(vii) the lung cancer is small cell lung cancer or non-small cell lung cancer.

5. The use according to claim 1, wherein the tumor disease is triple negative breast cancer.

6. The use according to claim 1, wherein the tumor disease is ovarian cancer.

7. The use according to claim 1, wherein the tumor disease is Her-2 positive breast cancer.

8. The use according to claim 1, wherein the tumor disease is gastric cancer.

9. The use according to claim 1, wherein the tumor disease is pancreatic cancer.

10. Use of a pharmaceutical composition comprising the biologically active conjugate according to claim 1 in the manufacture of a medicament for the treatment of a tumor disease, wherein the tumor disease is selected from the tumor diseases as defined in any one of claims 1 to 9, wherein the drug to antibody ratio (DAR) value of the pharmaceutical composition is 6 to 8, and wherein the pharmaceutical composition further comprises a pharmaceutically acceptable carrier and/or excipient.

11. The use according to claim 10, wherein the DAR value of the composition is 6.1, 6.2, 6.3, 6.4, 6.5, 6.6, 6.7, 6.8, 6.9, 7.0, 7.1, 7.2, 7.3, 7.4, 7.5, 7.6, 7.7, 7.8, 7.9 or 8.0.

12. The use according to claim 10, wherein the DAR value of the composition is 7.3 or 7.4.

13. The use according to any one of claims 10 to 12, wherein the pharmaceutical composition is to be administered once every 7-35 days, or once every 7-28 days, once every 7 days, once every 14 days, once every 21 days, once every 28 days or once every 35 days.

14. The use according to claim 13, wherein the pharmaceutical composition is to be administered once every 14 days.

15. The use according to any one of claims 10 to 14, wherein the pharmaceutical composition is to be administered via an administration route that is oral administration, percutaneous injection, rectal administration, mucosal administration, intramuscular injection, intramedullary injection, intravenous injection, or intraperitoneal injection.

16. The use according to claim 15, wherein the pharmaceutical composition is to be administered via an administration route that is intravenous injection.

17. The use according to any one of claims 10 to 16, wherein the dose of the biologically active conjugate in the pharmaceutical composition each time based on the body weight of a patient is 1 mg/kg to 30 mg/kg, 1 mg/kg to 20 mg/kg, 2 mg/kg to 12 mg/kg, 2 mg/kg to 5 mg/kg, 4 mg/kg to 7 mg/kg, 6 mg/kg to 9 mg/kg, 8 mg/kg to 11 mg/kg, 10 mg/kg to 13 mg/kg, or 12 mg/kg to 15 mg/kg.

18. The use according to claim 17, wherein the dose of the biologically active conjugate each time based on the body weight of a patient is 3 mg/kg.

19. The use according to claim 17, wherein the dose of the biologically active conjugate each time based on the body weight of a patient is 4 mg/kg.

20. The use according to claim 17, wherein the dose of the biologically active conjugate each time based on the body weight of a patient is 5 mg/kg.

21. The use according to any one of claims 10 to 20, wherein the pharmaceutical composition is to be administered via one or more administration stages such as one, two, three or four stages.

22. The use according to claim 21, wherein the pharmaceutical composition is to be administered in one stage.