## SUMMARY

**[0007]** Provided herein is a method of treating cervical cancer in a subject, the method comprising administering to the subject an antibody-drug conjugate that binds to tissue factor (TF), wherein the antibody-drug conjugate is tisotumab vedotin or a biosimilar thereof, and wherein the antibody-drug conjugate is administered at a dose of 2.0 mg/kg once every 3 weeks, wherein the subject has been previously treated with bevacizumab. In some examples, the subject has an ECOG score of 0. In some examples, the subject has an ECOG score of 1. In some examples, the subject is less than 65 years old. In some examples, the subject has been previously treated with:

a) paclitaxel and cisplatin,
b) paclitaxel and carboplatin, or
c) paclitaxel and topotecan.

**[0007a]** In one aspect, the present disclosure refers to use of an antibody-drug conjugate that binds to tissue factor (TF) in the manufacture of a medicament for treating cervical cancer in a subject, wherein the antibody-drug conjugate is tisotumab vedotin or a biosimilar thereof, and wherein the antibody-drug conjugate is to be administered at a dose of 2.0 mg/kg once every 3 weeks, wherein the subject has been previously treated with bevacizumab.

**[0008]** Also provided herein is a method of treating cervical cancer in a subject, the method comprising administering to the subject an antibody-drug conjugate that binds to tissue factor (TF), wherein the antibody-drug conjugate is tisotumab vedotin or a biosimilar thereof, and wherein the antibody-drug conjugate is administered at a dose of 2.0 mg/kg once every 3 weeks, wherein the subject has not been previously treated with bevacizumab. In some examples, the subject has an ECOG score of 0. In some examples, the subject has an ECOG score of 1. In some examples, the subject is less than 65 years old. In some examples, the subject has been previously treated with:

a) paclitaxel and cisplatin,
b) paclitaxel and carboplatin, or
c) paclitaxel and topotecan.

**[0008a]** In another aspect, the present disclosure refers to use of an antibody-drug conjugate that binds to tissue factor (TF) in the manufacture of a medicament for treating cervical cancer in a subject, wherein the antibody-drug conjugate is tisotumab vedotin or a biosimilar thereof, and wherein the antibody-drug conjugate is to be administered at a dose of 2.0 mg/kg once every 3 weeks, wherein the subject has not been previously treated with bevacizumab.

**[0009]** Also provided herein is a method of treating cervical cancer in a subject, the method comprising administering to the subject an antibody-drug conjugate that binds to tissue factor (TF), wherein the antibody-drug conjugate is tisotumab vedotin or a biosimilar thereof, and wherein the antibody-drug conjugate is administered at a dose of 2.0 mg/kg once every 3 weeks, wherein the subject has an Eastern Cooperative Oncology Group (ECOG) score of 0. In some

examples, the subject is less than 65 years old. In some examples, the subject has been previously treated with:

a) paclitaxel and cisplatin,
b) paclitaxel and carboplatin, or
c) paclitaxel and topotecan.

**[0010]** Also provided herein is a method of treating cervical cancer in a subject, the method comprising administering to the subject an antibody-drug conjugate that binds to tissue factor (TF), wherein the antibody-drug conjugate is tisotumab vedotin or a biosimilar thereof, and wherein the antibody-drug conjugate is administered at a dose of 2.0 mg/kg once every 3 weeks, wherein the subject has an Eastern Cooperative Oncology Group (ECOG) score of 1. In some examples, the subject is less than 65 years old. In some examples, the subject has been previously treated with:

a) paclitaxel and cisplatin,
b) paclitaxel and carboplatin, or
c) paclitaxel and topotecan.

**[0011]** Also provided herein is a method of treating cervical cancer in a subject, the method comprising administering to the subject an antibody-drug conjugate that binds to tissue factor (TF), wherein the antibody-drug conjugate is tisotumab vedotin or a biosimilar thereof, and wherein the antibody-drug conjugate is administered at a dose of 2.0 mg/kg once every 3 weeks, wherein the subject is less than 65 years old. In some examples, the subject has an ECOG score of 0. In some examples, the subject has an ECOG score of 1. In some examples, the subject is less than 65 years old. In some examples, the subject has been previously treated with:

a) paclitaxel and cisplatin,
b) paclitaxel and carboplatin, or
c) paclitaxel and topotecan.

**[0012]** In some examples of any of the above methods or examples, the objective response rate is between about 13% and about 35%, optionally, wherein the objective response rate is at least about 14%, about 19%, about 21%, 23.8%, about 24%, about 25%, about 26%,

about 28%, about 30%, or about 33%. In some examples, the subject exhibits progression-free survival of at least about 3 months after administration of the antibody-drug conjugate, optionally, wherein the subject exhibits progression-free survival of at least about 4 months, about 5 months, or about 6 months after administration of the antibody-drug conjugate. In some examples, the subject exhibits overall survival of at least about 10 months after administration of the antibody-drug conjugate, optionally, wherein the subject exhibits overall survival of at least about 11 months, about 12 months, about 13 months, or 14 months after administration of the antibody-drug conjugate. In some examples, the duration of response to the antibody-drug conjugate is at least about 6 months after administration of the antibody-drug conjugate, optionally, wherein the duration of response to the antibody-drug conjugate is at least about 7 months, about 8 months or about 10 months after administration of the antibody-drug conjugate. In some examples, the time to response is less than about 6 months after administration of the antibody-drug conjugate, optionally, wherein the time to response is less than about 4 months, about 2 months, 1.4 months, or about 1.2 months after administration of the antibody-drug conjugate.

**[0013]** Also provided herein is a method of treating cervical cancer in a subject, the method comprising administering to the subject an antibody-drug conjugate that binds to tissue factor (TF), wherein the antibody-drug conjugate is tisotumab vedotin or a biosimilar thereof, and wherein the antibody-drug conjugate is administered at a dose of 2.0 mg/kg once every 3 weeks, wherein the objective response rate is between about 13% and about 35%, optionally, wherein the objective response rate is at least about 14%, about 19%, about 21%, 23.8%, about 24%, about 25%, about 26%, about 28%, about 30%, or about 33%. In some examples, the subject exhibits progression-free survival of at least about 3 months after administration of the antibody-drug conjugate, optionally, wherein the subject exhibits progression-free survival of at least about 4 months, about 5 months, or about 6 months after administration of the antibody-drug conjugate. In some examples, the subject exhibits overall survival of at least about 10 months after administration of the antibody-drug conjugate, optionally, wherein the subject exhibits overall survival of at least about 11 months, about 12 months, about 13 months, or 14 months after administration of the antibody-drug conjugate. In some examples, the duration of response to the antibody-drug conjugate is at least about 6 months after administration of the antibody-drug conjugate, optionally, wherein the duration of response to the antibody-drug

conjugate is at least about 7 months, about 8 months or about 10 months after administration of the antibody-drug conjugate. In some examples, the time to response is less than about 6 months after administration of the antibody-drug conjugate, optionally, wherein the time to response is less than about 4 months, about 2 months, 1.4 months, or about 1.2 months after administration of the antibody-drug conjugate.

**[0014]** Also provided herein is a method of treating cervical cancer in a subject, the method comprising administering to the subject an antibody-drug conjugate that binds to tissue factor (TF), wherein the antibody-drug conjugate is tisotumab vedotin or a biosimilar thereof, and wherein the antibody-drug conjugate is administered at a dose of 2.0 mg/kg once every 3 weeks, wherein the subject exhibits progression-free survival of at least about 3 months after administration of the antibody-drug conjugate, optionally, wherein the subject exhibits progression-free survival of at least about 4 months, about 5 months, or about 6 months after administration of the antibody-drug conjugate. In some examples, the objective response rate is between about 13% and about 35%, optionally, wherein the objective response rate is at least about 14%, about 19%, about 21%, 23.8%, about 24%, about 25%, about 26%, about 28%, about 30%, or about 33%. In some examples, the subject exhibits overall survival of at least about 10 months after administration of the antibody-drug conjugate, optionally, wherein the subject exhibits overall survival of at least about 11 months, about 12 months, about 13 months, or 14 months after administration of the antibody-drug conjugate. In some examples, the duration of response to the antibody-drug conjugate is at least about 6 months after administration of the antibody-drug conjugate, optionally, wherein the duration of response to the antibody-drug conjugate is at least about 7 months, about 8 months or about 10 months after administration of the antibody-drug conjugate. In some examples, the time to response is less than about 6 months after administration of the antibody-drug conjugate, optionally, wherein the time to response is less than about 4 months, about 2 months, 1.4 months, or about 1.2 months after administration of the antibody-drug conjugate.

**[0015]** Also provided herein is a method of treating cervical cancer in a subject, the method comprising administering to the subject an antibody-drug conjugate that binds to tissue factor (TF), wherein the antibody-drug conjugate is tisotumab vedotin or a biosimilar thereof, and wherein the antibody-drug conjugate is administered at a dose of 2.0 mg/kg once every 3 weeks, wherein the subject exhibits overall survival of at least about 10 months after administration of

the antibody-drug conjugate, optionally, wherein the subject exhibits overall survival of at least about 11 months, about 12 months, about 13 months, or 14 months after administration of the antibody-drug conjugate. In some examples, the subject exhibits progression-free survival of at least about 3 months after administration of the antibody-drug conjugate, optionally, wherein the subject exhibits progression-free survival of at least about 4 months, about 5 months, or about 6 months after administration of the antibody-drug conjugate. In some examples, the objective response rate is between about 13% and about 35%, optionally, wherein the objective response rate is at least about 14%, about 19%, about 21%, 23.8%, about 24%, about 25%, about 26%, about 28%, about 30%, or about 33%. In some examples, the subject exhibits overall survival of at least about 10 months after administration of the antibody-drug conjugate, optionally, wherein the subject exhibits overall survival of at least about 11 months, about 12 months, about 13 months, or 14 months after administration of the antibody-drug conjugate. In some examples, the duration of response to the antibody-drug conjugate is at least about 6 months after administration of the antibody-drug conjugate, optionally, wherein the duration of response to the antibody-drug conjugate is at least about 7 months, about 8 months or about 10 months after administration of the antibody-drug conjugate. In some examples, the time to response is less than about 6 months after administration of the antibody-drug conjugate, optionally, wherein the time to response is less than about 4 months, about 2 months, 1.4 months, or about 1.2 months after administration of the antibody-drug conjugate.

**[0016]** Also provided herein is a method of treating cervical cancer in a subject, the method comprising administering to the subject an antibody-drug conjugate that binds to tissue factor (TF), wherein the antibody-drug conjugate is tisotumab vedotin or a biosimilar thereof, and wherein the antibody-drug conjugate is administered at a dose of 2.0 mg/kg once every 3 weeks, wherein the duration of response to the antibody-drug conjugate is at least about 6 months after administration of the antibody-drug conjugate, optionally, wherein the duration of response to the antibody-drug conjugate is at least about 7 months, about 8 months or about 10 months after administration of the antibody-drug conjugate. In some examples, the subject exhibits progression-free survival of at least about 3 months after administration of the antibody-drug conjugate, optionally, wherein the subject exhibits progression-free survival of at least about 4 months, about 5 months, or about 6 months after administration of the antibody-drug conjugate. In some examples, the subject exhibits overall survival of at least about 10 months after

administration of the antibody-drug conjugate, optionally, wherein the subject exhibits overall survival of at least about 11 months, about 12 months, about 13 months, or 14 months after administration of the antibody-drug conjugate. In some examples, the objective response rate is between about 13% and about 35%, optionally, wherein the objective response rate is at least about 14%, about 19%, about 21%, 23.8%, about 24%, about 25%, about 26%, about 28%, about 30%, or about 33%. In some examples, the time to response is less than about 6 months after administration of the antibody-drug conjugate, optionally, wherein the time to response is less than about 4 months, about 2 months, 1.4 months, or about 1.2 months after administration of the antibody-drug conjugate.

**[0017]** Also provided herein is a method of treating cervical cancer in a subject, the method comprising administering to the subject an antibody-drug conjugate that binds to tissue factor (TF), wherein the antibody-drug conjugate is tisotumab vedotin or a biosimilar thereof, and wherein the antibody-drug conjugate is administered at a dose of 2.0 mg/kg once every 3 weeks, wherein the time to response is less than about 6 months after administration of the antibody-drug conjugate, optionally, wherein the time to response is less than about 4 months, about 2 months, 1.4 months, or about 1.2 months after administration of the antibody-drug conjugate. In some examples, the subject exhibits progression-free survival of at least about 3 months after administration of the antibody-drug conjugate, optionally, wherein the subject exhibits progression-free survival of at least about 4 months, about 5 months, or about 6 months after administration of the antibody-drug conjugate. In some examples, the subject exhibits overall survival of at least about 10 months after administration of the antibody-drug conjugate, optionally, wherein the subject exhibits overall survival of at least about 11 months, about 12 months, about 13 months, or 14 months after administration of the antibody-drug conjugate. In some examples, the duration of response to the antibody-drug conjugate is at least about 6 months after administration of the antibody-drug conjugate, optionally, wherein the duration of response to the antibody-drug conjugate is at least about 7 months, about 8 months or about 10 months after administration of the antibody-drug conjugate. In some examples, the objective response rate is at least about between about 13% and about 35%, optionally, wherein the objective response rate is at least about 14%, about 19%, about 21%, 23.8%, about 24%, about 25%, about 26%, about 28%, about 30%, or about 33%.

**[0018]** In some examples of any of the above methods or examples, the subject has been previously treated with bevacizumab. In some examples, the subject has not been previously treated with bevacizumab. In some examples, the subject has experienced disease progression during or after treatment with:

a) paclitaxel and cisplatin,

b) paclitaxel and carboplatin,

c) paclitaxel and topotecan,

d) bevacizumab, paclitaxel, and cisplatin,

e) bevacizumab, paclitaxel, and carboplatin, or

f) bevacizumab, paclitaxel, and topotecan. In some examples, the subject is less than 65 years old. In some examples, the subject has an ECOG score of 0. In some examples, the subject has an ECOG score of 1. In some examples, the cervical cancer is an adenocarcinoma. In some examples, the cervical cancer is an adenosquamous carcinoma. In some examples, the cervical cancer is a squamous cell carcinoma. In some examples, the cervical cancer is a non-squamous cell carcinoma. In some examples, the cervical cancer is recurrent or metastatic cervical cancer. In some examples, the subject has been previously treated with one or more therapeutic agents and did not respond to the treatment, wherein the one or more therapeutic agents is not the antibody-drug conjugate. In some examples, the subject has been previously treated with one or more therapeutic agents and relapsed after the treatment, wherein the one or more therapeutic agents is not the antibody-drug conjugate. In some examples, the subject has been previously treated with one or more therapeutic agents and has experienced disease progression during treatment, wherein the one or more therapeutic agents is not the antibody-drug conjugate. In some examples, the one or more therapeutic agents is a platinum-based therapeutic agent. In some examples, the one or more therapeutic agents is selected from the group consisting of: paclitaxel, cisplatin, carboplatin, topotecan, gemcitabine, fluorouracil, ixabepilone, imatinib mesylate, docetaxel, gefitinib, nab-paclitaxel, pemetrexed, vinorelbine, doxil, cetuximab, pembrolizumab, nivolumab and bevacizumab. In some examples, the subject is not a candidate for curative therapy. In some examples, the curative therapy comprises radiotherapy and/or exenterative surgery. In some examples, the subject has received prior radiation to the pelvis. In some examples, the subject has not received prior radiation to the pelvis. In some examples, the subject has received one prior

line of systemic therapy for relapsed, recurrent or metastatic cancer. In some examples, the subject has received two prior lines of systemic therapy for relapsed, recurrent or metastatic cancer. In some examples, the subject did not respond to treatment with the prior systemic therapy. In some examples, the subject relapsed after treatment with the prior systemic therapy. In some examples, the cervical cancer is an advanced stage cervical cancer, such as a stage 3 or stage 4 cervical cancer, such as metastatic cervical cancer. In some examples, the cervical cancer is recurrent cervical cancer. In some examples, the route of administration for the antibody-drug conjugate is intravenous. In some examples, at least about 0.1%, at least about 1%, at least about 2%, at least about 3%, at least about 4%, at least about 5%, at least about 6%, at least about 7%, at least about 8%, at least about 9%, at least about 10%, at least about 15%, at least about 20%, at least about 25%, at least about 30%, at least about 35%, at least about 40%, at least about 45%, at least about 50%, at least about 60%, at least about 70%, or at least about 80% of the cervical cancer cells express TF. In some examples, the subject has a TF histology score (H-score) of at least 1. In some examples, the subject has one or more adverse events and is further administered an additional therapeutic agent to eliminate or reduce the severity of the one or more adverse events. In some examples, the subject is at risk of developing one or more adverse events and is further administered an additional therapeutic agent to prevent or reduce the severity of the one or more adverse events. In some examples, the subject has one or more adverse events and the dose of the antibody drug conjugate is reduced following the one or more adverse events. In some examples, the dose is reduced from 2.0 mg/kg to 1.3 mg/kg. In some examples, the dose is reduced from 1.3 mg/kg to 0.9 mg/kg. In some examples, the one or more adverse events is anemia, abdominal pain, hypokalemia, hyponatremia, epistaxis, fatigue, nausea, alopecia, conjunctivitis, constipation, decreased appetite, diarrhea, vomiting, peripheral neuropathy, or general physical health deterioration. In some examples, the one or more adverse events is a grade 3 or greater adverse event. In some examples, the one or more adverse events is a serious adverse event. In some examples, the one or more adverse events is conjunctivitis and/or keratitis and the additional agent is a preservative-free lubricating eye drop, an ocular vasoconstrictor and/or a steroid eye drop. In some examples, the antibody-drug conjugate is administered as a monotherapy. In some examples, the subject is a human. In some examples, the

antibody-drug conjugate is in a pharmaceutical composition comprising the antibody-drug conjugate and a pharmaceutical acceptable carrier.

**[0019]** Also provided herein is an antibody-drug conjugate that binds to TF for use in any of the methods or examples provided herein.

**[0020]** Also provided herein is the use of an antibody-drug conjugate that binds to TF for the manufacture of a medicament for use in any of the methods or examples provided herein.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0021]** **FIG. 1** is a diagram showing the mechanism of action (MOA) of the antibody-drug conjugate tisotumab vedotin.

**[0022]** **FIG. 2** is a diagram showing the Phase II study design for treatment with tisotumab vedotin in patients with previously treated, recurrent or metastatic cancer who have received at least one prior line of systemic therapy. [a] indicates tisotumab vedotin 2.0 mg/kg infusion on day 1 of each cycle until disease progression. Each treatment cycle was 3 weeks (Q3W). [b] indicates CT or MRI scan every 6 weeks (± 7 days) for the first 30 weeks of treatment and every 12 weeks (± 7 days) thereafter regardless of treatment delays.

**[0023]** **FIG. 3** is a patient flowchart and disposition of the Phase II study.

**[0024]** **FIG. 4** is a diagram showing target lesion response in each subject. Bars indicates the best percent change in lesion size relative to baseline for each subject.

**[0025]** **FIG. 5** is a graph showing the percent of subjects remaining in response over time.

**[0026]** **FIG. 6** is a graph showing the percent of subjects exhibiting progression free survival over time.

**[0027]** **FIG. 7** is a graph showing the percent of subjects surviving over time.

## DETAILED DESCRIPTION

### I. Definitions

**[0028]** In order that the present disclosure can be more readily understood, certain terms are first defined. As used in this application, except as otherwise expressly provided herein, each of

## CLAIMS

**WHAT IS CLAIMED IS:**

1. Use of an antibody-drug conjugate that binds to tissue factor (TF) in the manufacture of a medicament for treating cervical cancer in a subject, wherein the antibody-drug conjugate is tisotumab vedotin or a biosimilar thereof, and wherein the antibody-drug conjugate is to be administered at a dose of 2.0 mg/kg once every 3 weeks, wherein the subject has been previously treated with bevacizumab.

2. The use of claim 1, wherein the subject has an ECOG score of 0.

3. The use of claim 1, wherein the subject has an ECOG score of 1.

4. The use of any one of claims 1-3, wherein the subject is less than 65 years old.

5. The use of any one of claims 1-4, wherein the subject has been previously treated with:

a) paclitaxel and cisplatin,

b) paclitaxel and carboplatin, or

c) paclitaxel and topotecan.

6. Use of an antibody-drug conjugate that binds to tissue factor (TF) in the manufacture of a medicament for treating cervical cancer in a subject, wherein the antibody-drug conjugate is tisotumab vedotin or a biosimilar thereof, and wherein the antibody-drug conjugate is to be administered at a dose of 2.0 mg/kg once every 3 weeks, wherein the subject has not been previously treated with bevacizumab.

7. The use of claim 6, wherein the subject has an ECOG score of 0.

8. The use of claim 6, wherein the subject has an ECOG score of 1.

9. The use of any one of claims 6-8, wherein the subject is less than 65 years old.

10. The use of any one of claims 6-9, wherein the subject has been previously treated with:

a) paclitaxel and cisplatin,

b) paclitaxel and carboplatin, or

c) paclitaxel and topotecan.

11. The use of any one of claims 1-10, wherein the subject:

a. exhibits progression-free survival of at least about 3 months after administration of the antibody-drug conjugate, optionally, wherein the subject exhibits progression-free survival of at least about 4 months, about 5 months, or about 6 months after administration of the antibody-drug conjugate, and/or

b. exhibits overall survival of at least about 10 months after administration of the antibody-drug conjugate, optionally, wherein the subject exhibits overall survival of at least about 11 months, about 12 months, about 13 months, or 14 months after administration of the antibody-drug conjugate, and/or

c. exhibits duration of response to the antibody-drug conjugate that is at least about 6 months after administration of the antibody-drug conjugate, optionally, wherein the duration of response to the antibody-drug conjugate is at least about 7 months, about 8 months or about 10 months after administration of the antibody-drug conjugate, and/or

d. exhibits a time to response that is less than about 6 months after administration of the antibody-drug conjugate, optionally, wherein the time to response is less than about 4 months, about 2 months, 1.4 months, or about 1.2 months after administration of the antibody-drug conjugate.

12. The use of any one of claims 1-11, wherein the cervical cancer is an adenocarcinoma, an adenosquamous carcinoma, a squamous cell carcinoma, or a non-squamous cell carcinoma.

13. The use of any one of claims 1-12, wherein the cervical cancer is recurrent or metastatic cervical cancer.

14. The use of any one of claims 1-13, wherein the subject has been previously treated with one or more therapeutic agents and did not respond to the treatment or has experienced disease progression during treatment or has relapsed after the treatment wherein the one or more therapeutic agents is not the antibody-drug conjugate.

15. The use of claim 14, wherein the one or more therapeutic agents is a platinum-based therapeutic agent.

16. The use of claim 14, wherein the one or more therapeutic agents is selected from the group consisting of: paclitaxel, cisplatin, carboplatin, topotecan, gemcitabine, fluorouracil, ixabepilone, imatinib mesylate, docetaxel, gefitinib, nab-paclitaxel, pemetrexed, vinorelbine, doxil, cetuximab, pembrolizumab, nivolumab and bevacizumab.

17. The use of any one of claims 1-16, wherein the subject is not a candidate for curative therapy.

18. The use of claim 17, wherein the curative therapy comprises radiotherapy and/or exenterative surgery.

19. The use of any one of claims 1-16, wherein the subject has received prior radiation to the pelvis.

20. The use of any one of claims 1-16, wherein the subject has not received prior radiation to the pelvis.

21. The use of any one of claims 1-20, wherein the subject has received one or two prior lines of systemic therapy for relapsed, recurrent or metastatic cancer.

22. The use of claim 21, wherein the subject did not respond to treatment or relapsed after treatment with the prior systemic therapy.

23. The use of any one of claims 1-22, wherein the cervical cancer is an advanced stage cervical cancer, such as a stage 3 or stage 4 cervical cancer, such as metastatic cervical cancer.

24. The use of any one of claims 1-23, wherein the cervical cancer is recurrent cervical cancer.

25. The use of any one of claims 1-24, wherein the route of administration for the antibody-drug conjugate is intravenous.

26. The use of any one of claims 1-25, wherein the subject has one or more adverse events and is to be further administered an additional therapeutic agent to eliminate or reduce the severity of the one or more adverse events.

27. The use of any one of claims 1-26, wherein the subject is at risk of developing one or more adverse events and is to be further administered an additional therapeutic agent to prevent or reduce the severity of the one or more adverse events.

28. The use of any one of claims 1-27, wherein the subject has one or more adverse events, and the dose of the antibody drug conjugate is reduced following the one or more adverse events.

29. The use of claim 28, wherein the dose is reduced from 2.0 mg/kg to 1.3 mg/kg.

30. The use of claim 29, wherein the dose is reduced from 1.3 mg/kg to 0.9 mg/kg.

31. The use of claim 26 or claim 27, wherein the one or more adverse events is conjunctivitis and/or keratitis and the additional agent is a preservative-free lubricating eye drop, an ocular vasoconstrictor and/or a steroid eye drop.

32. The use of any one of claims 1-31, wherein the antibody-drug conjugate is to be administered as a monotherapy.

33. The use of any one of claims 1-32, wherein the subject is a human.

34. The use of any one of claims 1-33, wherein the antibody-drug conjugate is in a pharmaceutical composition comprising the antibody-drug conjugate and a pharmaceutical acceptable carrier.