SUMMARY

[0017] In one aspect, the present disclosure refers to use of an antibody-drug conjugate that binds to tissue factor (TF) for the manufacture of a medicament for treating cancer in a subject, wherein the antibody-drug conjugate comprises an anti-TF antibody or an antigen-binding fragment thereof conjugated to an auristatin or a functional analog thereof or a functional derivative thereof, wherein the antibody-drug conjugate is to be administered at a dose ranging from about 0.9 mg/kg to about 2.1 mg/kg, and wherein the cancer is selected from the group consisting of colorectal cancer, non-small cell lung cancer, pancreatic cancer, head and neck cancer, bladder cancer, endometrial cancer, esophageal cancer and prostate cancer. Provided herein are methods of treating 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 comprises an anti-TF antibody or an antigen-binding fragment thereof conjugated to a monomethyl auristatin or a functional analog thereof or a functional derivative thereof, wherein the antibody-drug conjugate is administered at a dose ranging from about 1.5 mg/kg to about 2.1 mg/kg, and wherein the cancer is selected from the group consisting of colorectal cancer, non-small cell lung cancer, pancreatic cancer, head and neck cancer, bladder cancer, endometrial cancer, esophageal cancer and prostate cancer. In some examples, the antibody-drug conjugate is administered at a dose of about 2.0 mg/kg. In some examples, the antibody-drug conjugate is administered at a dose of 2.0 mg/kg. In some of any of the examples herein, the antibody-drug conjugate is administered once about every 1 week, 2 weeks, 3 weeks or 4 weeks. In some of any of the examples herein, the antibody-drug conjugate is administered once about every 3 weeks. In some of any of the examples herein, 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 of any of the examples herein, 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 of any of the examples herein, 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 of any of the examples herein, the cancer is colorectal cancer. In some of any of the examples herein, the subject received prior systemic therapy and experienced

disease progression on or after the systemic therapy. In some of any of the examples herein, the subject received 1, 2 or 3 rounds of prior systemic therapy. In some of any of the examples herein, the colorectal cancer is non-operable. In some of any of the examples herein, the subject has been previously treated with one or more agents selected from the group consisting of fluoropyrimidine, oxaliplatin, irinotecan and bevacizumab. In some of any of the examples herein, the subject has been previously treated with one or more agents selected from the group consisting of cetuximab, panitumab and a checkpoint inhibitor. In some of any of the examples herein, the cancer is non-small cell lung cancer. In some of any of the

examples herein, the non-small cell lung cancer is squamous cell carcinoma. In some of any of the examples herein, the non-small cell lung cancer has predominant squamous histology. In some of any of the examples herein, greater than 85% of the non-small cell lung cancer cells have squamous histology. In some of any of the examples herein, the non-small cell lung cancer is adenocarcinoma. In some of any of the examples herein, the subject received prior systemic therapy and experienced disease progression on or after the systemic therapy. In some of any of the examples herein, the subject received 1 or 2 rounds of prior systemic therapy. In some of any of the examples herein, the subject has been previously treated with one or more agents selected from the group consisting of a platinum-based therapy and a checkpoint inhibitor. In some of any of the examples herein, the cancer is pancreatic cancer. In some of any of the examples herein, the pancreatic cancer is exocrine pancreatic adenocarcinoma. In some of any of the examples herein, the pancreatic cancer has predominant adenocarcinoma histology. In some of any of the examples herein, greater than 85% of the pancreatic cancer cells have adenocarcinoma histology. In some of any of the examples herein, the subject received prior systemic therapy and experienced disease progression on or after the systemic therapy. In some of any of the examples herein, the subject received 1 round of prior systemic therapy. In some of any of the examples herein, the subject has been previously treated with one or more agents selected from the group consisting of gemcitabine and 5-fluorouracil. In some of any of the examples herein, the pancreatic cancer is not resectable. In some of any of the examples herein, the cancer is head and neck cancer. In some of any of the examples herein, the head and neck cancer is squamous cell carcinoma. In some of any of the examples herein, the subject received prior systemic therapy and experienced disease progression on or after the systemic therapy. In some of any of the examples herein, the subject received 1 or 2 rounds of prior systemic therapy. In some of any of the examples herein, the subject has been previously treated with one or more agents selected from the group consisting of a platinum-based therapy and a checkpoint inhibitor. In some of any of the examples herein, the subject has been previously treated with an anti-epithelial growth factor receptor therapy. In some of any of the examples herein, the cancer is bladder cancer. In some of any of the examples herein, the subject received prior systemic therapy and experienced disease progression on or after the systemic therapy. In some of any of the examples herein, the subject received 1, 2 or 3 rounds of prior systemic therapy. In some of any of the examples herein, the

subject has been previously treated with a platinum-based therapy. In some of any of the examples herein, the subject has previously undergone surgery or radiation therapy for the bladder cancer. In some of any of the examples herein, the cancer is endometrial cancer. In some of any of the examples herein, the subject received prior systemic therapy and experienced disease progression on or after the systemic therapy. In some of any of the examples herein, the subject received 1, 2 or 3 rounds of prior systemic therapy. In some of any of the examples herein, the subject has been previously treated with one or more agents selected from the group consisting of a platinum-based therapy, hormone therapy, and a checkpoint inhibitor. In some of any of the examples herein, the subject has previously been treated with doxorubicin. In some of any of the examples herein, the subject has previously been treated with paclitaxel. In some of any of the examples herein, the subject has previously undergone surgery or radiation therapy for the endometrial cancer. In some of any of the examples herein, the cancer is esophageal cancer. In some of any of the examples herein, the subject received prior systemic therapy and experienced disease progression on or after the systemic therapy. In some of any of the examples herein, the subject received 1, 2 or 3 rounds of prior systemic therapy. In some of any of the examples herein, the subject has been previously treated with one or more agents selected from the group consisting of a platinum-based therapy and a checkpoint inhibitor. In some of any of the examples herein, the subject has been previously treated with one or more agents selected from the group consisting of ramucirumab, paclitaxel, 5-fluorouracil, docetaxel, irinotecan, capecitabine and trastuzumab. In some of any of the examples herein, the subject has previously undergone surgery, radiation therapy or endoscopic mucosal resection for the esophageal cancer. In some of any of the examples herein, the cancer is prostate cancer. In some of any of the examples herein, the subject received prior systemic therapy and experienced disease progression on or after the systemic therapy. In some of any of the examples herein, the subject received 1, 2 or 3 rounds of prior systemic therapy. In some of any of the examples herein, the prostate cancer is castration-resistant prostate cancer. In some of any of the examples herein, the subject experienced bone metastases. In some of any of the examples herein, the subject has been previously treated with one or more agents selected from the group consisting of androgen deprivation therapy, a luteinizing hormone-releasing hormone agonist, a luteinizing hormone-releasing hormone antagonist, a CYP17 inhibitor, and an anti-androgen. In some of any of the examples herein, the subject has been previously treated with one or more

agents selected from the group consisting of docetaxel, prednisone and cabazitaxel. In some of any of the examples herein, the subject has previously undergone surgery or radiation therapy for the prostate cancer. In some of any of the examples herein, the cancer is an advanced stage cancer. In some of any of the examples herein, the advanced stage cancer is a stage 3 or stage 4 cancer. In some of any of the examples herein, the advanced stage cancer is metastatic cancer. In some of any of the examples herein, the cancer is recurrent cancer. In some of any of the examples herein, the subject received prior treatment with standard of care therapy for the cancer and failed the prior treatment. In some of any of the examples herein, the monomethyl auristatin is monomethyl auristatin E (MMAE). In some of any of the examples herein, the anti-TF antibody or antigen-binding fragment thereof of the antibody-drug conjugate is a monoclonal antibody or a monoclonal antigen-binding fragment thereof. In some of any of the examples herein, the anti-TF antibody or antigen-binding fragment thereof of the antibody-drug conjugate comprises a heavy chain variable region and a light chain variable region, wherein the heavy chain variable region comprises:

(i) a CDR-H1 comprising the amino acid sequence of SEQ ID NO:1;

(ii) a CDR-H2 comprising the amino acid sequence of SEQ ID NO:2; and

(iii) a CDR-H3 comprising the amino acid sequence of SEQ ID NO:3; and

wherein the light chain variable region comprises:

(i) a CDR-L1 comprising the amino acid sequence of SEQ ID NO:4;

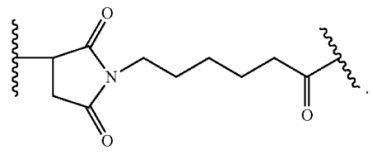
(ii) a CDR-L2 comprising the amino acid sequence of SEQ ID NO:5; and

(iii) a CDR-L3 comprising the amino acid sequence of SEQ ID NO:6.

In some of any of the examples herein, the anti-TF antibody or antigen-binding fragment thereof of the antibody-drug conjugate comprises a heavy chain variable region comprising an amino acid sequence at least 85% identical to the amino acid sequence of SEQ ID NO:7 and a light chain variable region comprising an amino acid sequence at least 85% identical to the amino acid sequence of SEQ ID NO:8. In some of any of the examples herein, the anti-TF antibody or antigen-binding fragment thereof of the antibody-drug conjugate comprises a heavy chain variable region comprising the amino acid sequence of SEQ ID NO:7 and a light chain variable region comprising the amino acid sequence of SEQ ID NO:8. In some of any of the examples herein, the anti-TF antibody of the antibody-drug

conjugate is tisotumab. In some of any of the examples herein, the antibody-drug conjugate further comprises a linker between the anti-TF antibody or antigen-binding fragment thereof and the monomethyl auristatin. In some of any of the examples herein, the linker is a cleavable peptide linker. In some of any of the examples herein, the cleavable peptide linker has a formula: -MC-vc-PAB-, wherein:

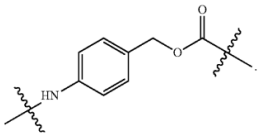
a) MC is:



,

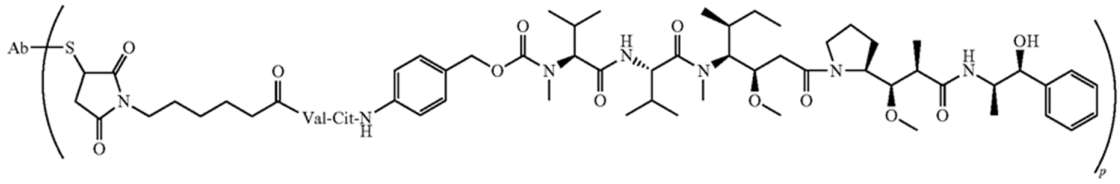
b) vc is the dipeptide valine-citrulline, and

c) PAB is:



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In some of any of the examples herein, the linker is attached to sulphydryl residues of the anti-TF antibody obtained by partial reduction or full reduction of the anti-TF antibody or antigen-binding fragment thereof. In some of any of the examples herein, the linker is attached to monomethyl auristatin E (MMAE), wherein the antibody-drug conjugate has the following structure:



Ab-MC-vc-PAB-MMAE

wherein p denotes a number from 1 to 8, S represents a sulphydryl residue of the anti-TF antibody, and Ab designates the anti-TF antibody or antigen-binding fragment thereof. In some of any of the examples herein, the average value of p in a population of the antibody-drug conjugates is about 4. In some of any of the examples herein, the antibody-

drug conjugate is tisotumab vedotin. In some of any of the examples herein, the route of administration for the antibody-drug conjugate is intravenous. In some of any of the examples herein, 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 cancer cells express TF. In some of any of the examples herein, the one or more therapeutic effects in the subject is improved after administration of the antibody-drug conjugate relative to a baseline. In some of any of the examples herein, the one or more therapeutic effects is selected from the group consisting of: size of a tumor derived from the cancer, objective response rate, duration of response, time to response, progression free survival, overall survival and prostate-specific antigen (PSA) level. In some of any of the examples herein, the subject exhibits a reduction in PSA level in a blood sample from the subject by at least about 5%, 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% relative to the PSA level in a blood sample obtained from the subject before administration of the antibody-drug conjugate. In some of any of the examples herein, the size of a tumor derived from the cancer is reduced by 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% relative to the size of the tumor derived from the cancer before administration of the antibody-drug conjugate. In some of any of the examples herein, the objective response rate is 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%. In some of any of the examples herein, the subject exhibits progression-free survival of at least about 1 month, at least about 2 months, at least about 3 months, at least about 4 months, at least about 5 months, at least about 6 months, at least about 7 months, at least about 8 months, at least about 9 months, at least about 10 months, at least about 11 months, at least about 12 months, at least about eighteen months, at least about two years, at least about three years, at least about four years, or at least about five years after administration of the antibody-drug conjugate. In some of any of the examples herein, the subject exhibits

overall survival of at least about 1 month, at least about 2 months, at least about 3 months, at least about 4 months, at least about 5 months, at least about 6 months, at least about 7 months, at least about 8 months, at least about 9 months, at least about 10 months, at least about 11 months, at least about 12 months, at least about eighteen months, at least about two years, at least about three years, at least about four years, or at least about five years after administration of the antibody-drug conjugate. In some of any of the examples herein, the duration of response to the antibody-drug conjugate is at least about 1 month, at least about 2 months, at least about 3 months, at least about 4 months, at least about 5 months, at least about 6 months, at least about 7 months, at least about 8 months, at least about 9 months, at least about 10 months, at least about 11 months, at least about 12 months, at least about eighteen months, at least about two years, at least about three years, at least about four years, or at least about five years after administration of the antibody-drug conjugate. In some of any of the examples herein, 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 of any of the examples herein, 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 of any of the examples herein, 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 of any of the examples herein, the one or more adverse events is a grade 3 or greater adverse event. In some of any of the examples herein, the one or more adverse events is a serious adverse event. In some of any of the examples herein, 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 of any of the examples herein, the antibody-drug conjugate is administered as a monotherapy. In some of any of the examples herein, the subject is a human. In some of any of the examples herein, the antibody-drug conjugate is in a pharmaceutical composition comprising the antibody-drug conjugate and a pharmaceutical acceptable carrier.

[0018] Also provided herein are kits comprising:

(a) a dosage ranging from about 0.9 mg/kg to about 2.1 mg/kg of an antibody-drug conjugate that binds to tissue factor (TF), wherein the antibody-drug conjugate comprises an

anti-TF antibody or an antigen-binding fragment thereof conjugated to a monomethyl auristatin or a functional analog thereof or a functional derivative thereof; and

(b) instructions for using the antibody drug conjugate according to some of any of the examples herein.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] FIG. 1 is a diagram showing the mechanism of action (MOA) of the antibody-drug conjugate tisotumab vedotin.

[0020] FIG. 2A-2B show dose-dependent anti-tumor effects of single-dose tisotumab vedotin treatment in a NCI-H441 cell line-derived (CDX) mouse xenograft model. FIG. 2A shows tumor growth of the NCI-H441 xenografts after treatment with different doses of tisotumab vedotin, isotype control antibody (IgG1-b12), or isotype control ADC (IgG1-b12-vcMMAE). Mean and standard of error of the mean (SEM) of each group is shown at each time point. FIG. 2B shows mean tumor size in each mouse on day 47. Mean and SEM of each group are indicated. Differences among the groups were analyzed by one-way ANOVA. Statistically significant differences are indicated as follows: *: $p<0.05$; **: $p<0.01$; ***: $p<0.001$.

[0021] FIG. 3 shows anti-tumor effects of tisotumab vedotin treatment in a squamous cell lung carcinoma patient-derived xenograft (PDX) mouse model LXFE 690. Mean and SEM of tumor size of the LXFE 690 xenografts at each time point in groups treated with two doses of tisotumab vedotin at 4 mg/kg, IgG1-b12 or IgG1b12-vcMMAE are shown.

[0022] FIG. 4A-4B show dose-dependent anti-tumor effects of tisotumab vedotin treatment in a HPAF II CDX mouse model. FIG. 4A shows tumor growth of the HPAF II xenografts after treatment with tisotumab vedotin, or IgG1-b12. Mean and SEM of each group is shown at each time point. FIG. 4B shows mean tumor size in each mouse on day 25. Mean and SEM of each group are indicated. Differences among the groups were analyzed by one-way ANOVA. Statistically significant differences versus the IgG1-b12 group are indicated as follows: *: $p<0.05$; **: $p<0.01$; ***: $p<0.001$.

[0023] FIG. 5 shows anti-tumor effects of tisotumab vedotin treatment in a pancreatic cancer PDX mouse model PAXF 1657. Mean and SEM of tumor size of the PAXF 1657 xenografts at each time point in groups treated with two doses of tisotumab vedotin at 4 mg/kg, IgG1-b12 or IgG1b12-vcMMAE are shown.

CLAIMS

WHAT IS CLAIMED IS:

1. Use of an antibody-drug conjugate that binds to tissue factor (TF) for the manufacture of a medicament for treating cancer in a subject, wherein the antibody-drug conjugate comprises an anti-TF antibody or an antigen-binding fragment thereof conjugated to an auristatin or a functional analog thereof or a functional derivative thereof, wherein the antibody-drug conjugate is to be administered at a dose ranging from about 0.9 mg/kg to about 2.1 mg/kg, and wherein the cancer is selected from the group consisting of colorectal cancer, non-small cell lung cancer, pancreatic cancer, head and neck cancer, bladder cancer, endometrial cancer, esophageal cancer and prostate cancer.

2. The use of claim 1, wherein the dose is about 2.0 mg/kg.

3. The use of any one of claims 1-2, wherein the antibody-drug conjugate is to be administered once about every 1 week, 2 weeks, 3 weeks or 4 weeks.

4. The use of any one of claims 1-3, wherein the cancer is colorectal cancer.

5. The use of any one of claims 1-3, wherein the cancer is non-small cell lung cancer.

6. The use of any one of claims 1-3, wherein the cancer is pancreatic cancer.

7. The use of any one of claims 1-3, wherein the cancer is head and neck cancer.

8. The use of any one of claims 1-3, wherein the cancer is bladder cancer.

9. The use of any one of claims 1-3, wherein the cancer is endometrial cancer.

10. The use of any one of claims 1-3, wherein the cancer is esophageal cancer.

11. The use of any one of claims 1-3, wherein the cancer is prostate cancer.

12. The use of any one of claims 1-11, wherein the auristatin is a monomethyl auristatin.

13. The use of any one of claims 12, wherein the monomethyl auristatin is monomethyl auristatin E (MMAE).

14. The use of any one of claims 1-13, wherein the anti-TF antibody or antigen-binding fragment thereof of the antibody-drug conjugate comprises a heavy chain variable region and a light chain variable region, wherein the heavy chain variable region comprises:

(i) a CDR-H1 comprising the amino acid sequence of SEQ ID NO:1;

(ii) a CDR-H2 comprising the amino acid sequence of SEQ ID NO:2; and

(iii) a CDR-H3 comprising the amino acid sequence of SEQ ID NO:3; and

wherein the light chain variable region comprises:

(i) a CDR-L1 comprising the amino acid sequence of SEQ ID NO:4;

(ii) a CDR-L2 comprising the amino acid sequence of SEQ ID NO:5; and

(iii) a CDR-L3 comprising the amino acid sequence of SEQ ID NO:6.

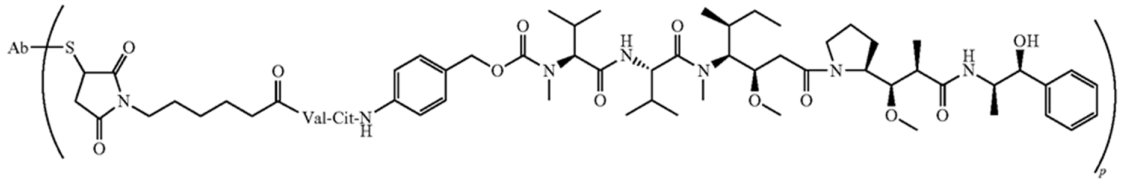
15. The use of any one of claims 1-14, wherein the anti-TF antibody or antigen-binding fragment thereof of the antibody-drug conjugate comprises a heavy chain variable region comprising the amino acid sequence of SEQ ID NO:7 and a light chain variable region comprising the amino acid sequence of SEQ ID NO:8.

16. The use of any one of claims 1-15, wherein the anti-TF antibody of the antibody-drug conjugate is tisotumab.

17. The use of any one of claims 1-16, wherein the antibody-drug conjugate further comprises a linker between the anti-TF antibody or antigen-binding fragment thereof and the monomethyl auristatin.

18. The use of claim 17, wherein the linker is attached to sulphydryl residues of the anti-TF antibody obtained by partial reduction or full reduction of the anti-TF antibody or antigen-binding fragment thereof.

19. The use of any one of claims 17 or 18, wherein the linker is attached to monomethyl auristatin E (MMAE), wherein the antibody-drug conjugate has the following structure:



Ab-MC-vc-PAB-MMAE

wherein p denotes a number from 1 to 8, S represents a sulphydryl residue of the anti-TF antibody, and Ab designates the anti-TF antibody or antigen-binding fragment thereof.

20. The use of any one of claims 1-19, wherein the antibody-drug conjugate is tisotumab vedotin.

21. The use of any one of claims 1-20, wherein 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 cancer cells express TF.

22. The use of any one of claims 1-21, wherein one or more therapeutic effects in the subject is improved after administration of the antibody-drug conjugate relative to a baseline.

23. The use of claim 22, wherein the one or more therapeutic effects is selected from the group consisting of: size of a tumor derived from the cancer, objective response rate, duration of response, time to response, progression free survival, overall survival and prostate specific antigen (PSA) level.

24. The use of any one of claims 1-23, wherein the size of a tumor derived from the cancer is reduced by 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% relative to the size of the tumor derived from the cancer before administration of the antibody-drug conjugate.

25. The use of any one of claims 1-24, wherein the objective response rate is 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%.

26. The use of any one of claims 1-25, wherein the subject exhibits progression-free survival of at least about 1 month, at least about 2 months, at least about 3 months, at least about 4 months, at least about 5 months, at least about 6 months, at least about 7 months, at least about 8 months, at least about 9 months, at least about 10 months, at least about 11 months, at least about 12 months, at least about eighteen months, at least about two years, at least about three years, at least about four years, or at least about five years after administration of the antibody-drug conjugate.

27. The use of any one of claims 1-26, wherein the subject exhibits overall survival of at least about 1 month, at least about 2 months, at least about 3 months, at least about 4 months, at least about 5 months, at least about 6 months, at least about 7 months, at least about 8 months, at least about 9 months, at least about 10 months, at least about 11 months, at least about 12 months, at least about eighteen months, at least about two years, at least about three years, at least about four years, or at least about five years after administration of the antibody-drug conjugate.

28. The use of any one of claims 1-27, wherein the duration of response to the antibody-drug conjugate is at least about 1 month, at least about 2 months, at least about 3 months, at least about 4 months, at least about 5 months, at least about 6 months, at least about 7 months, at least about 8 months, at least about 9 months, at least about 10 months, at least about 11 months, at least about 12 months, at least about eighteen months, at least about two years, at least about three years, at least about four years, or at least about five years after administration of the antibody-drug conjugate.

29. The use of any one of claims 1-28, 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.

30. The use of claim 29, wherein 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.

31. The use of claim 29 or claim 30, 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.