formulations comprising the bispecific antibody construct at a pH outside of this range (e.g., pH 4.2 or pH 7.4), when under the same storage conditions.

[0008a] In one aspect, described herein is a stable aqueous pharmaceutical formulation comprising (a) a bispecific antibody construct in a single-chain variable fragment (scFv) format comprising a first binding domain that binds to a target cell surface antigen and a second binding domain that binds to human CD3 on the surface of a T cell, (b) a saccharide, (c) a surfactant, and (d) a buffer, wherein the pH of the formulation is 5.2.

[0008b] In another aspect, described herein is a use of the formulation as described herein in the manufacture of a medicament for treating cancer in a subject in need thereof.

[0009] **[0008c]** In another aspect, described herein is a formulation as described herein for use in therapy. In one example, described herein is a stable, aqueous pharmaceutical formulation comprising a bispecific antibody construct described herein, a buffer, a saccharide, and a surfactant, wherein the pH of the pharmaceutical formulation ranges from 4.8 to 5.5. In some examples, the pH of the formulation ranges from 4.5 to 5.3. In some examples, the pH of the formulation is 5.2.

[0010] In some examples, the formulation comprises less than about 10% (e.g., 9%, 8%, 7%, 6%, 5%, 4%, 3% or less) of low molecule weight (LMW) species of the bispecific antibody construct after storage at about 40˚C for one month.

[0011] In some examples, the formulation comprises less than about 10% (e.g., 9%, 8%, 7%, 6%, 5%, 4%, 3% or less) of low molecule weight (LMW) species of the bispecific antibody construct after storage at about 2-8˚C for one month.

[0012] In some examples, the formulation comprises less than about 5% (e.g., 4%, 3%, 2%, 1% or less) of high molecule weight (HMW) species of the bispecific antibody construct after storage at about 40˚C for one month.

[0013] In some examples, the formulation comprises less than about 5% (e.g., 4%, 3%, 2%, 1% or less) of high molecule weight (HMW) species of the bispecific antibody construct after storage at about 2-8˚C for one month.

[0014] In some examples, the relative potency of the bispecific antibody construct in the formulation is greater than about 30% (e.g., about 35%, 40%, 50%, 55%, 60% or more after storage at one month at about 40˚C.

[0015] In some examples, the percent of intact BiTE® molecule (i.e., main peak species) in the formulation is greater than 95% of the total protein content in the formulation.

[0016] In some examples, the bispecific antibody construct comprises a first binding domain that binds to a target cell surface antigen, a second binding domain that binds to human CD3 on the surface of a T cell. In some examples, the bispecific antibody construct further comprises a third domain comprising, in an amino to carboxyl order, hinge-CH2 domain-CH3 domain-linker-hinge-CH2 domain-CH3 domain. In some examples, each of the first and second binding domains of the bispecific antibody construct comprises a VH region and a VL region.

[0017] In some examples, the bispecific antibody construct is a single chain antibody construct.

[0018] In some examples, the bispecific antibody construct binds to a target cell surface antigen, such as, CDH19, MSLN, DLL3, FLT3, EGFRvlll, BCMA, PSMA, CD33, CD19, CD70, CLDN18.2 or MUC17.

[0019] In some examples, the first binding domain of the bispecific antibody construct comprises a set of 6 CDRs set forth in (a) SEQ ID NOs: 24-29, (b) SEQ ID NOs: 34-39, (c) SEQ ID NOs: 78-83, (d) SEQ ID NOs: 10-15, (e) SEQ ID NOs: 46-51, (f) SEQ ID NOs: 88-93, (g) SEQ ID NOs: 67-72, (h) SEQ ID NOs: 56-61, (i) SEQ ID NOs: 112-117, (j) SEQ ID NOs: 100-105**,** (k) SEQ ID NOs:148-153, SEQ ID NOs: 157-162, or SEQ ID NOs: 166-171, or SEQ ID NOs: 175-180, (l) SEQ ID NOs:132-137, or (m) SEQ ID NOs: 123-128.

[0020] In some examples, the first binding domain of the bispecific antibody construct comprises a VH region comprising an amino acid sequence at least 90% identical (e.g., 91%, 92%, 93%, 94%, 95%, 96%, 97%, 98%, 99%, or 100% identical) to the amino acid sequence set forth in SEQ ID NO: 30, 40, 84, 16, 17, 52, 94, 73**,** 62, 118, 154, 163, 172, 181, 106, 138, 143, or 129. In some examples, the first binding domain of the bispecific antibody construct comprises a VH comprising the amino acid sequence set forth in SEQ ID NO: 30, 40, 84, 16, 17, 52, 94, 73, 62, 118, 154, 163, 172, 181, 106, 138 or 143, or 129.

[0021] In some examples, the first binding domain of the bispecific antibody construct comprises a VL region comprising an amino acid sequence at least 90% identical (e.g., 91%, 92%, 93%, 94%, 95%, 96%, 97%, 98%, 99%, or 100% identical) to the amino acid sequence set forth in SEQ ID NO: 31, 41, 85, 18, 19, 53, 95, 74, 63, 119, 155, 164, 173, 182, 107, 139, 144, or 130. In some examples, the first binding domain of the bispecific antibody construct comprises a VL comprising the amino acid sequence set forth in SEQ ID NO: 31, 41, 85, 18, 19, 53, 95, 74, 63, 119, 155, 164, 173, 182, 107, 139, 144, or 130.

[0022] In some examples, wherein the first binding domain comprises (a) a VH region comprising an amino acid sequence set forth in SEQ ID NO: 30 and a VL region comprising an amino acid sequence set forth in SEQ ID NO: 31; (b) a VH region comprising an amino acid sequence set forth in SEQ ID NO: 40 and a VL region comprising an amino acid sequence set forth in SEQ ID NO: 41; (c) a VH region comprising an amino acid sequence set forth in SEQ ID NO: 84 and a VL region comprising an amino acid sequence set forth in SEQ ID NO: 85; (d) a VH region comprising an amino acid sequence set forth in SEQ ID

NO: 16 or 17 and a VL region comprising an amino acid sequence set forth in SEQ ID NO: 18 or 19; (e) a VH region comprising an amino acid sequence set forth in SEQ ID NO: 52 and a VL region comprising an amino acid sequence set forth in SEQ ID NO: 53; (f) a VH region comprising an amino acid sequence set forth in SEQ ID NO: 94 and a VL region comprising an amino acid sequence set forth in SEQ ID NO: 95; (g) a VH region comprising an amino acid sequence set forth in SEQ ID NO: 73 and a VL region comprising an amino acid sequence set forth in SEQ ID NO: 74; (h) a VH region comprising an amino acid sequence set forth in SEQ ID NO: 62 and a VL region comprising an amino acid sequence set forth in SEQ ID NO: 63; (i) a VH region comprising an amino acid sequence set forth in SEQ ID NO: 118 and a VL region comprising an amino acid sequence set forth in SEQ ID NO: 119; (j) a VH region comprising an amino acid sequence set forth in SEQ ID NO: 154, 163, 172 or 181, and a VL region comprising an amino acid sequence set forth in SEQ ID NO: 155, 164,173, or 182 **;** (k) a VH region comprising an amino acid sequence set forth in SEQ ID NO: 106 and a VL region comprising an amino acid sequence set forth in SEQ ID NO: 107; (l) a VH region comprising an amino acid sequence set forth in SEQ ID NO: 138 or 143, and a VL region comprising an amino acid sequence set forth in SEQ ID NO: 139 or 144; or (m) a VH region comprising an amino acid sequence set forth in SEQ ID NO: 129 and a VL region comprising an amino acid sequence set forth in SEQ ID NO: 130.

[0023] In some examples, the second binding domain of the bispecific antibody construct comprises a set of 6 CDRs set forth in SEQ ID NOs: 1-6.

[0024] In some examples, the second binding domain of the bispecific antibody construct comprises a VH region comprising an amino acid sequence at least 90% identical (e.g., 91%, 92%, 93%, 94%, 95%, 96%, 97%, 98%, 99%, or 100% identical) to the amino acid sequence set forth in SEQ ID NO: 7. In some examples, the second binding domain of the bispecific antibody construct comprises a VH comprising the amino acid sequence set forth in SEQ ID NO: 7.

[0025] In some examples, the second binding domain of the bispecific antibody construct comprises a VL region comprising an amino acid sequence at least 90% identical (e.g., 91%, 92%, 93%, 94%, 95%, 96%, 97%, 98%, 99%, or 100% identical) to the amino acid sequence set forth in SEQ ID NO: 8. In some examples, the second binding domain of the bispecific antibody construct comprises a VL comprising the amino acid sequence set forth in SEQ ID NO: 8.

[0026] In some examples, wherein the second binding domain comprises (a) a VH region comprising an amino acid sequence set forth in SEQ ID NO: 7 and a VL region comprising an amino acid sequence set forth in SEQ ID NO: 8.

[0027] In some examples, the bispecific antibody construct comprises a first binding domain that binds CD19 comprising an anti-CD19 variable light domain comprising the amino acid sequence of SEQ ID NO: 85 and an anti-CD19 variable heavy domain comprising the amino acid sequence of SEQ ID NO: 84, a second binding domain comprising an anti-CD3 variable heavy domain comprising the amino acid sequence of SEQ ID NO: 7, and an anti-CD3 variable light domain comprising the amino acid sequence of SEQ ID NO: 8. For example, in one example, the bispecific antibody construct comprises a first binding domain comprising the amino acid sequence of SEQ ID NO: 86 a second binding domain comprising the amino acid sequence of SEQ ID NO: 9. In some examples, the bispecific antibody construct comprises the amino acid sequence set forth in SEQ ID NO: 87.

[0028] In some examples, the bispecific antibody construct comprises a first binding domain that binds MSLN comprising an anti-MSLN variable light domain comprising the amino acid sequence of SEQ ID NO: 41 and an anti-MSLN variable heavy domain comprising the amino acid sequence of SEQ ID NO: 40, a second binding domain comprising an anti-CD3 variable heavy domain comprising the amino acid sequence of SEQ ID NO: 7, and an anti-CD3 variable light domain comprising the amino acid sequence of SEQ ID NO: 8. For example, in one example, the bispecific antibody construct comprises a first binding domain comprising the amino acid sequence of SEQ ID NO: 42, and a second binding domain comprising the amino acid sequence of SEQ ID NO: 9. In some examples, the bispecific antibody construct comprises an amino acid sequence set forth in SEQ ID NO: 43, 44 or 45.

[0029] In some examples, the bispecific antibody construct comprises a first binding domain that binds DLL3 comprising an anti-DLL3 variable light domain comprising the amino acid sequence of SEQ ID NO: 74 and an anti-DLL3 variable heavy domain comprising the amino acid sequence of SEQ ID NO: 73, a second binding domain comprising an anti-CD3 variable heavy domain comprising the amino acid sequence of SEQ ID NO: 7, and an anti-CD3 variable light domain comprising the amino acid sequence of SEQ ID NO: 8. For example, in one example, the bispecific antibody construct comprises a first binding domain comprising the amino acid sequence of SEQ ID NO: 75, and a second binding domain comprising the amino acid sequence of SEQ ID NO: 9. In some examples, the

bispecific antibody construct comprises an amino acid sequence set forth in SEQ ID NO: 76 or 77.

[0030] In some examples, the bispecific antibody construct comprises a first binding domain that binds FLT3 comprising an anti-FLT3 variable light domain comprising the amino acid sequence of SEQ ID NO: 63 and an anti-FLT3 variable heavy domain comprising the amino acid sequence of SEQ ID NO: 62, a second binding domain comprising an anti-CD3 variable heavy domain comprising the amino acid sequence of SEQ ID NO: 7, and an anti-CD3 variable light domain comprising the amino acid sequence of SEQ ID NO: 8. For example, in one example, the bispecific antibody construct comprises a first binding domain comprising the amino acid sequence of SEQ ID NO: 64, a second binding domain comprising the amino acid sequence of SEQ ID NO: 9. In some examples, the bispecific antibody construct comprises an amino acid sequence set forth in SEQ ID NO: 65 or 66.

[0031] In some examples, the bispecific antibody construct comprises a first binding domain that binds EGFRvIII comprising an anti-EGFRvIII variable light domain comprising the amino acid sequence of SEQ ID NO: 31 and an anti-EGFRvIII variable heavy domain comprising the amino acid sequence of SEQ ID NO: 30, a second binding domain comprising an anti-CD3 variable heavy domain comprising the amino acid sequence of SEQ ID NO: 7, and an anti-CD3 variable light domain comprising the amino acid sequence of SEQ ID NO: 8. For example, in one example, the bispecific antibody construct comprises a first binding domain comprising the amino acid sequence of SEQ ID NO: 32, a second binding domain comprising the amino acid sequence of SEQ ID NO: 9. In some examples, the bispecific antibody construct comprises an amino acid sequence set forth in SEQ ID NO: 33.

[0032] In some examples, the bispecific antibody construct comprises a first binding domain that binds BCMA comprising an anti-BCMA variable light domain comprising the amino acid sequence of SEQ ID NO: 95 and an anti-BCMA variable heavy domain comprising the amino acid sequence of SEQ ID NO: 94, a second binding domain comprising an anti-CD3 variable heavy domain comprising the amino acid sequence of SEQ ID NO: 7, and an anti-CD3 variable light domain comprising the amino acid sequence of SEQ ID NO: 8. For example, in one example, the bispecific antibody construct comprises a first binding domain comprising the amino acid sequence of SEQ ID NO: 96, a second binding domain comprising the amino acid sequence of SEQ ID NO: 9. In some examples, the bispecific antibody construct comprises an amino acid sequence set forth in SEQ ID NO: 98 or SEQ ID NO: 97.

[0033] In some examples, the bispecific antibody construct comprises a first binding domain that binds PSMA comprising an anti-PSMA variable light domain comprising the amino acid sequence of SEQ ID NO: 119 or 107 and an anti-PSMA variable heavy domain comprising the amino acid sequence of SEQ ID NO: 118 or 106, a second binding domain comprising an anti-CD3 variable heavy domain comprising the amino acid sequence of SEQ ID NO: 7, and an anti-CD3 variable light domain comprising the amino acid sequence of SEQ ID NO: 8. For example, in one example, the bispecific antibody construct comprises a first binding domain comprising the amino acid sequence of SEQ ID NO: 120 or 108, a second binding domain comprising the amino acid sequence of SEQ ID NO: 9. In some examples, the bispecific antibody construct comprises an amino acid sequence set forth in SEQ ID NO: 121, 122, 109, 110 or 111.

[0034] In some examples, the bispecific antibody construct comprises a first binding domain that binds CD33 comprising an anti-CD33 variable light domain comprising the amino acid sequence of SEQ ID NO: 18 or 19 and an anti-CD33 variable heavy domain comprising the amino acid sequence of SEQ ID NO: 16 or 17, a second binding domain comprising an anti-CD3 variable heavy domain comprising the amino acid sequence of SEQ ID NO: 7, and an anti-CD3 variable light domain comprising the amino acid sequence of SEQ ID NO: 8. For example, in one example, the bispecific antibody construct comprises a first binding domain comprising the amino acid sequence of SEQ ID NO: 189 or 190, a second binding domain comprising the amino acid sequence of SEQ ID NO: 9. In some examples, the bispecific antibody construct comprises the amino acid sequence set forth in SEQ ID NO: 20, 21, 22 or 23.

[0035] In some examples, the bispecific antibody construct comprises a first binding domain that binds CDH19 comprising an anti-CDH19 variable light domain comprising the amino acid sequence of SEQ ID NO: 53 and an anti-CDH19 variable heavy domain comprising the amino acid sequence of SEQ ID NO: 52, a second binding domain comprising an anti-CD3 variable heavy domain comprising the amino acid sequence of SEQ ID NO: 7, and an anti-CD3 variable light domain comprising the amino acid sequence of SEQ ID NO: 8. For example, in one example, the bispecific antibody construct comprises a first binding domain comprising the amino acid sequence of SEQ ID NO: 54, a second binding domain comprising the amino acid sequence of SEQ ID NO: 9. In some examples, the bispecific antibody construct comprises the amino acid sequence set forth in SEQ ID NO: 55.

[0036] In some examples, the bispecific antibody construct comprises a first binding domain that binds MUC17 comprising an anti-MUC17 variable light domain comprising the amino acid sequence of SEQ ID NO: 155, 164, 173, or 182 and an anti-MUC17 variable heavy domain comprising the amino acid sequence of SEQ ID NO: 154, 163, 172, or 181 a second binding domain comprising an anti-CD3 variable heavy domain comprising the amino acid sequence of SEQ ID NO: 7, and an anti-CD3 variable light domain comprising the amino acid sequence of SEQ ID NO: 8. In some examples, the bispecific antibody construct comprises the amino acid sequence set forth in SEQ ID NO: 156, 165, 174 or 183.

[0037] In some examples, the bispecific antibody construct comprises a first binding domain that binds cldn18.2 comprising an anti-cldn18.2 variable light domain comprising the amino acid sequence of SEQ ID NO: 139 or 144 and an anti-cldn18.2 variable heavy domain comprising the amino acid sequence of SEQ ID NO: 138 or 143, a second binding domain comprising an anti-CD3 variable heavy domain comprising the amino acid sequence of SEQ ID NO: 7, and an anti-CD3 variable light domain comprising the amino acid sequence of SEQ ID NO: 8. For example, in one example, the bispecific antibody construct comprises a first binding domain comprising the amino acid sequence of SEQ ID NO: 140 or 145, and a second binding domain comprising the amino acid sequence of SEQ ID NO: 9. In some examples, the bispecific antibody construct comprises the amino acid sequence set forth in SEQ ID NO: 141, 142, 146 or 147.

[0038] In some examples, the bispecific antibody construct comprises a first binding domain that binds CD70 comprising an anti-CD70 variable light domain comprising the amino acid sequence of SEQ ID NO: 130 and an anti-CD70 variable heavy domain comprising the amino acid sequence of SEQ ID NO: 129, a second binding domain comprising an anti-CD3 variable heavy domain comprising the amino acid sequence of SEQ ID NO: 7, and an anti-CD3 variable light domain comprising the amino acid sequence of SEQ ID NO: 8. In some examples, the bispecific antibody construct comprises an amino acid sequence set forth in SEQ ID NO: 131.

[0039] The pharmaceutical formulation of the disclosure comprises a buffer. In some examples, the buffer acetate, glutamate, citrate, succinate, tartrate, fumarate, maleate, histidine, phosphate, and 2-(N-morpholino)ethanesulfonate or a combination thereof. In some examples, the buffer is present in the formulation at a concentration ranging from about 5 mM to about 200 mM (or about 10 mM to about 50 mM). In some examples, the buffer is present in the formulation at a concentration of 10 mM.

[0040] The pharmaceutical formulation of the disclosure comprises a saccharide. In some examples, the saccharide is monosaccharide or a disaccharide. In some examples, the saccharide is a sugar alcohol (e.g., sorbitol). In some examples, the saccharide is sucrose, trehalose, mannitol, sorbitol or a combination thereof. In some examples, the saccharide is present in the formulation at a concentration ranging from about 1 to about 15% (w/V) (or about 9 to about 12% (w/V) or about 5% to about 12% (w/V) or about 7% to about 12% (w/V)).

[0041] The pharmaceutical formulation of the disclosure comprises a surfactant. In some examples, the surfactant is polysorbate 20, polysorbate 40, polysorbate 60, polysorbate 80, poloxamer 188, poloxamer 407, triton X-100, polyoxyethylene, PEG 3350, PEG 4000, or a combination thereof. In some examples, the surfactant is present in the formulation at a concentration ranging from 0.004 to about 0.5% (w/V) (or about 0.001 to about 0.01% (w/V), or about 0.001 to about 0.5% (w/V) or about 0.004 to about 0.01% (w/V)).

[0042] In some examples, the formulation has an osmolarity in the range of about 150 to about 500 mOsm. In some examples, the formulation has an osmolarity of no greater than 500 mOsm/L, 450 mOsm/L, 400 mOsm/L, or 350 mOsm/L. In some examples, the formulation is close to isotonic, e.g. 250-350 mOsm/L.

[0043] The pharmaceutical formulation, in some examples, comprises 10 mM glutamate, 9% (w/V) sucrose and 0.01% (w/V) polysorbate 80, and wherein the pH of the liquid pharmaceutical formulation is 5.2. In some examples, the bispecific antibody construct is present in the formulation at a concentration ranging from about 0.1 mg/mL to about 20 mg/mL. In some examples, the bispecific antibody construct is present in the formulation at a concentration of 1 mg/mL, 5 mg/mL, 10 mg/mL or 20 mg/mL. In some examples, the bispecific antibody is present in the formulation in an amount ranging from about 1000 µg to about 200 mg.

[0044] In some examples, the pharmaceutical formulation of the disclosure is a liquid formulation.

[0045] In another example, described herein is a method of treating cancer in a subject in need thereof comprising administering a formulation of the disclosure to the subject.

[0046] It should be understood that while various examples in the specification are presented using “comprising” language, under various circumstances, a related example may also be described using “consisting of” or “consisting essentially of” language. The

disclosure contemplates examples described as “comprising” a feature to include examples which “consist of” the feature. It is to be noted that the term “a” or “an” refers to one or more, for example, “an immunoglobulin molecule,” is understood to represent one or more immunoglobulin molecules. As such, the terms “a” (or “an”), “one or more,” and “at least one” can be used interchangeably herein.

[0047] It should also be understood that when describing a range of values, the characteristic being described could be an individual value found within the range. For example, “a pH from about pH 4.8 to about pH 5.5,” could be, but is not limited to, pH 4.6, 5.2, 5.5 etc. and any value in between such values. Additionally, “a pH from about pH 4.8 to about pH 5.5,” should not be construed to mean that the pH of a formulation in question varies 2 pH units in the range from pH 4.8 to pH 5.5 during storage, but rather a value may be picked in that range for the pH of the solution, and the pH remains buffered at about that pH.

[0048] When the term “about” is used, it means the recited number plus or minus 5%, 10%, 15% or more of that recited number. The actual variation intended is determinable from the context.

[0049] In any of the ranges described herein, the endpoints of the range are included in the range. However, the description also contemplates the same ranges in which the lower and/or the higher endpoint is excluded. Additional features and variations of the disclosure will be apparent to those skilled in the art from the entirety of this application, including the drawing and detailed description, and all such features are intended as examples of the disclosure. Likewise, features of the disclosure described herein can be re-combined into additional examples that also are intended as examples of the disclosure, irrespective of whether the combination of features is specifically mentioned above as an example or example of the disclosure. Also, only such limitations which are described herein as critical to the disclosure should be viewed as such; variations of the disclosure lacking limitations which have not been described herein as critical are intended as examples of the disclosure.

[0050] All references cited herein are hereby incorporated by reference in their entireties.

BRIEF DESCRIPTION OF THE FIGURES

[0051] Figure 1 is a graph showing the % low molecular weight (LMW) by reduced Capillary electrophoresis sodium dodecyl sulfate (rCE-SDS), for BiTE-I, BiTE-C, BiTE-D, and BiTE-G) from accelerated stability studies at higher pH formulations.

What is claimed is:

1. A stable aqueous pharmaceutical formulation comprising

(a) a bispecific antibody construct in a single-chain variable fragment (scFv) format comprising a first binding domain that binds to a target cell surface antigen and a second binding domain that binds to human CD3 on the surface of a T cell,

(b) a saccharide,

(c) a surfactant, and

(d) a buffer,

wherein the pH of the formulation is 5.2.

2. The formulation of claim 1, wherein the saccharide is a monosaccharide or a disaccharide.

3. The formulation of claim 1 or claim 2, wherein the saccharide is glucose, galactose, fructose, xylose, sucrose, lactose, maltose, trehalose, sorbitol, mannitol, or xylitol.

4. The formulation of any one of claims 1-3, wherein the surfactant is a nonionic surfactant.

5. The formulation of any one of claims 1-4, wherein the surfactant is polysorbate 20, polysorbate 40, polysorbate 60, polysorbate 80, poloxamer 188, poloxamer 407, or triton x-100.

6. The formulation of claim 5, wherein the surfactant is polysorbate 20, polysorbate 40, polysorbate 60, or polysorbate 80.

7. The formulation of claim 5, wherein the surfactant is poloxamer 188 or poloxamer 407.

8. The formulation of any one of claims 1-7, wherein the buffer is an acetate buffer, a glutamate buffer, a citrate buffer, a lactic buffer, a succinate buffer, a tartrate buffer, a fumarate buffer, a maleate buffer, a histidine buffer, or a phosphate buffer.

9. The formulation of any one of claims 1-8, wherein the formulation comprises the bispecific antibody construct at a concentration of from 0.1 mg/ml to 20 mg/ml.

10. The formulation of any one of claims 1-9, further comprising a third domain comprising, in an amino to carboxyl order, hinge-CH2 domain-CH3 domain-linker-hinge-CH2 domain-CH3 domain.

11. The formulation of claim 10, wherein each of the first and second binding domains comprise a VH region and a VL region.

12. The formulation of claim 10 or claim 11, wherein the bispecific antibody construct is a single chain antibody construct.

13. The formulation of any one of claims 10-12, wherein the target cell surface antigen is CDH19, MSLN, DLL3, FLT3, EGFR, EGFRvlll, BCMA, PSMA, CD33, CD19, CD70, MUC17 or CLDN18.2.

14. The formulation of any one of claims 10-13, wherein the first binding domain of the bispecific antibody construct comprises a set of 6 CDRs set forth in (a) SEQ ID NOs: 24-29, (b) SEQ ID NOs: 34-39, (c) SEQ ID NOs: 78-83, (d) SEQ ID NOs: 10-15, (e) SEQ ID NOs: 46-51, (f) SEQ ID NOs: 88-93, (g) SEQ ID NOs: 67-72, (h) SEQ ID NOs: 56-61, (i) SEQ ID NOs: 112-117, (j) SEQ ID NOs: 100-105, (k) SEQ ID NOs:148-153, SEQ ID NOs: 157-162, or SEQ ID NOs: 166-171, or SEQ ID NOs: 175-180, (l) SEQ ID NOs:132-137, or (m) 123-128.

15. The formulation of any one of claims 10-14, wherein the second binding domain of the bispecific antibody construct comprises a set of 6 CDRs set forth in SEQ ID NOs: 1-6.

16. The formulation of any one of claims 10-15, wherein the first binding domain comprises:

(a) a VH region comprising an amino acid sequence set forth in SEQ ID NO: 30 and a VL region comprising an amino acid sequence set forth in SEQ ID NO: 31;

(b) a VH region comprising an amino acid sequence set forth in SEQ ID NO: 40 and a VL region comprising an amino acid sequence set forth in SEQ ID NO: 41;

(c) a VH region comprising an amino acid sequence set forth in SEQ ID NO: 84 and a VL region comprising an amino acid sequence set forth in SEQ ID NO: 85;

(d) a VH region comprising an amino acid sequence set forth in SEQ ID NO: 16 or 17 and a VL region comprising an amino acid sequence set forth in SEQ ID NO: 18 or 19;

(e) a VH region comprising an amino acid sequence set forth in SEQ ID NO: 52 and a VL region comprising an amino acid sequence set forth in SEQ ID NO: 53;

(f) a VH region comprising an amino acid sequence set forth in SEQ ID NO: 94 and a VL region comprising an amino acid sequence set forth in SEQ ID NO: 95;

(g) a VH region comprising an amino acid sequence set forth in SEQ ID NO: 73 and a VL region comprising an amino acid sequence set forth in SEQ ID NO: 74;

(h) a VH region comprising an amino acid sequence set forth in SEQ ID NO: 62 and a VL region comprising an amino acid sequence set forth in SEQ ID NO: 63;

(i) a VH region comprising an amino acid sequence set forth in SEQ ID NO: 118 and a VL region comprising an amino acid sequence set forth in SEQ ID NO: 119;

(j) a VH region comprising an amino acid sequence set forth in SEQ ID NO: 154, 163,172, or 181 and a VL region comprising an amino acid sequence set forth in SEQ ID NO: 155, 164, 173, or 182;

(k) a VH region comprising an amino acid sequence set forth in SEQ ID NO: 106 and a VL region comprising an amino acid sequence set forth in SEQ ID NO: 107;

(l) a VH region comprising an amino acid sequence set forth in SEQ ID NO: 138 or 143 and a VL region comprising an amino acid sequence set forth in SEQ ID NO: 139 or 144; or

(m) a VH region comprising an amino acid sequence set forth in SEQ ID NO: 129 and a VL region comprising an amino acid sequence set forth in SEQ ID NO: 130.

17. The formulation of any one of claims 10-16, wherein the second binding domain comprises a VH region comprising an amino acid sequence set forth in SEQ ID NO: 7 and a VL region comprising an amino acid sequence set forth in SEQ ID NO: 8.

18. The formulation of any one of claims 10-17, wherein the bispecific antibody construct comprises amino acid sequence set forth in SEQ ID NO: 20, SEQ ID NO: 21, SEQ ID NO: 22, SEQ ID NO: 23, SEQ ID NO: 33, SEQ ID NO: 43, SEQ ID NO: 44, SEQ ID NO: 45, SEQ ID NO: 55, SEQ ID NO: 65, SEQ ID NO: 66, SEQ ID NO: 76, SEQ ID NO: 77, SEQ ID NO: 87, SEQ ID NO: 97, SEQ ID NO: 98, SEQ ID NO: 99, SEQ ID NO: 109, SEQ ID NO: 110, SEQ ID NO: 111, SEQ ID NO: 121, SEQ ID NO: 122, SEQ ID NO: 131, SEQ ID NO: 141, SEQ ID NO: 142, SEQ ID NO: 146, SEQ ID NO: 147, SEQ ID NO: 156,

SEQ ID NO: 165, SEQ ID NO: 174, SEQ ID NO: 183, SEQ ID NO: 184, SEQ ID NO: 185, SEQ ID NO: 186, SEQ ID NO: 187, or SEQ ID NO: 188.

19. The formulation of any one of claims 1-18, wherein the formulation comprises less than 10% of low molecule weight (LMW) clipping product of the bispecific antibody construct after storage at 40˚C for one month.

20. The formulation of claim 19, wherein the formulation comprises less than 8% of low molecule weight (LMW) clipping product of the bispecific antibody construct after storage at 40˚C for one month.

21. The formulation of claim 19 or 20, wherein the formulation comprises less than 5% of low molecule weight (LMW) clipping product of the bispecific antibody construct after storage at 40˚C for one month.

22. The formulation of any one of claims 19-21, wherein the formulation comprises less than 3% of low molecule weight (LMW) clipping product of the bispecific antibody construct after storage at 40˚C for one month.

23. The formulation of any one of claims 19-22, wherein the formulation comprises less than 5% of high molecule weight (HMW) aggregates of the bispecific antibody construct after one month's storage at 40˚C.

24. The formulation of any one of claims 19-23, wherein the relative potency of the bispecific antibody construct is greater than 30% after one month at 40˚C.

25. The formulation of any one of claims 19-23, wherein the relative potency of the bispecific antibody construct is greater than 50% after one month at 40˚C.

26. The formulation of any one of claims 19-23, wherein the relative potency of the bispecific antibody construct is greater than 60% after one month at 40˚C.

27. Use of the formulation of any one of claims 1-26 in the manufacture of a medicament for treating cancer in a subject in need thereof.

28. The use of claim 27, wherein the use further comprises diluting the formulation with a pharmaceutically acceptable liquid before administration to the subject.

29. The use of claim 27 or 28, wherein the formulation is to be administered by intravenous administration.

30. A formulation of any one of claims 1-26 for use in therapy.