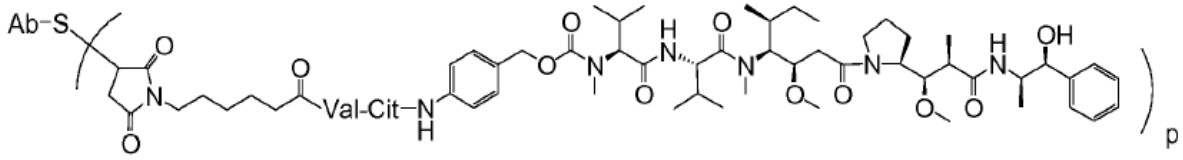
[0022] In a specific example, the sugar is sucrose. In one example of the present disclosure, sucrose is at a concentration of about 120 mM. In another example, sucrose is at a concentration of 120 mM.

[0023] In some examples, the composition of the present disclosure is lyophilized (such as a lyophilized cake). In some examples, the lyophilized composition is contained in a vial, e.g., a 20-ml glass vial.

[0023a] In one aspect, the present disclosure refers to a liquid composition comprising an anti-CD79b immunoconjugate, a buffering agent, a sugar, and a surfactant, wherein:

the anti-CD79b immunoconjugate is at a concentration between 5 mg/ml and 60 mg/ml;
the buffering agent is at a concentration between 10 mM and 200 mM;
the sugar is at a concentration between 100 mM and 260 mM;
the surfactant is polysorbate 20 at a concentration between 1.0 mg/ml and 1.4 mg/ml,
wherein the pH of the liquid composition is between 5.0 and 6.0, and
wherein the anti-CD79b immunoconjugate comprises the formula:

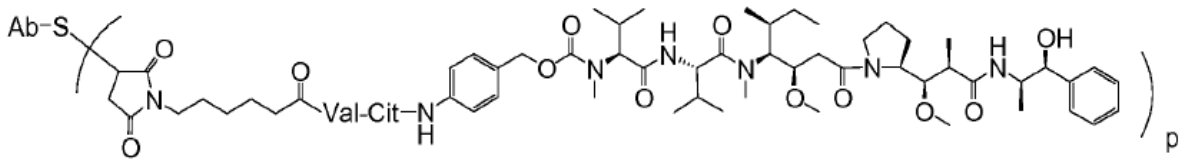


wherein:

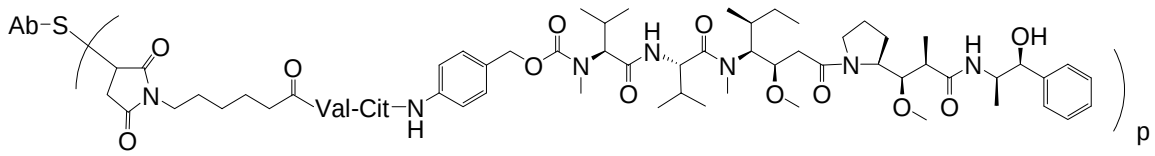
Ab is an anti-CD79b antibody, wherein the anti-CD79b antibody comprises a heavy chain and a light chain, wherein the light chain comprises (a) an HVR-L1 sequence of KASQSVDYEGDSFLN (SEQ ID NO: 1); (b) an HVR-L2 sequence of AASNLES (SEQ ID NO: 2); and (c) an HVR-L3 sequence of QQSNEDPLT (SEQ ID NO: 3); wherein the heavy chain comprises (a) an HVR-H1 sequence of GYTFSSYWIE (SEQ ID NO: 4); (b) an HVR-H2 sequence of GEILPGGGDTNYNEIFKG (SEQ ID NO: 5); and (c) an HVR-H3 sequence of TRRVPIRLDY (SEQ ID NO: 6); Val is valine; Cit is citrulline; and

p is a value from 1 to 8.

[0023b] In one aspect, the present disclosure refers to a lyophilized composition comprising: (a) 140-150 mg of an anti-CD79b immunoconjugate, 8.4-9.0 mg polysorbate 20, 8.27-8.88 mg succinic acid, 3.80-4.08 mg sodium hydroxide, and 288-309 mg sucrose, or (b) 30 mg of an anti-CD79b immunoconjugate, 1.8 mg polysorbate 20, 1.77 mg succinic acid, 0.816 mg sodium hydroxide, and 61.8 mg sucrose,
wherein the anti-CD79b immunoconjugate comprises the formula:

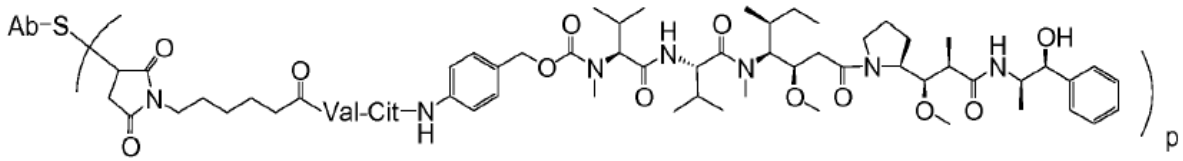


wherein:



wherein Ab is an anti-CD79b antibody, wherein the anti-CD79b antibody comprises a heavy chain and a light chain, wherein the heavy chain comprises the amino acid sequence of SEQ ID NO: 9, the light chain comprises the amino acid sequence of SEQ ID NO: 10; Val is valine; Cit is citrulline; and p is a value from about 2 to about 5 (such as about 3.5).

[0031a] In one aspect, the present disclosure refers to a liquid composition for intravenous administration comprising: a) between 0.72 and 2.7 mg/ml of an anti-CD79b immunoconjugate; b) between 0.36 and 1.35 mM sodium succinate; c) between 0.51 and 16.24 mM sucrose; and d) between 0.0432 and 0.162 mg/ml polysorbate 20, wherein the pH of the liquid composition is between 5 and 5.7, and wherein the anti-CD79b immunoconjugate comprises the formula:



wherein:

Ab is an anti-CD79b antibody, wherein the anti-CD79b antibody comprises a heavy chain and a light chain, wherein the light chain comprises (a) an HVR-L1 sequence of KASQSVDYEGDSFLN (SEQ ID NO: 1); (b) an HVR-L2 sequence of AASNLES (SEQ ID NO: 2); and (c) an HVR-L3 sequence of QQSNEDPLT (SEQ ID NO: 3); wherein the heavy chain comprises (a) an HVR-H1 sequence of GYTFSSYWIE (SEQ ID NO: 4); (b) an HVR-H2 sequence of GEILPGGGDTNYNEIFKG (SEQ ID NO: 5); and (c) an HVR-H3 sequence of TRRVPIRLDY (SEQ ID NO: 6); Val is valine; Cit is citrulline; and

p is a value from 1 to 8.

[0031b] In one aspect, the present disclosure refers to a liquid composition for intravenous administration obtained by diluting the liquid composition as described above in an isotonic buffer.

CLAIMS

What is claimed is:

1. A liquid composition comprising an anti-CD79b immunoconjugate, a buffering agent, a sugar, and a surfactant, wherein:

the anti-CD79b immunoconjugate is at a concentration between 5 mg/ml and 60 mg/ml;

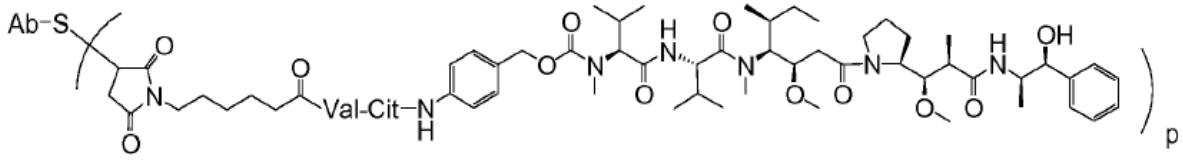
the buffering agent is at a concentration between 10 mM and 200 mM;

the sugar is at a concentration between 100 mM and 260 mM;

the surfactant is polysorbate 20 at a concentration between 1.0 mg/ml and 1.4 mg/ml,

wherein the pH of the liquid composition is between 5.0 and 6.0, and

wherein the anti-CD79b immunoconjugate comprises the formula:



wherein:

Ab is an anti-CD79b antibody, wherein the anti-CD79b antibody comprises a heavy chain and a light chain, wherein the light chain comprises (a) an HVR-L1 sequence of KASQSVDYEGDSFLN (SEQ ID NO: 1); (b) an HVR-L2 sequence of AASNLES (SEQ ID NO: 2); and (c) an HVR-L3 sequence of QQSNEDPLT (SEQ ID NO: 3); wherein the heavy chain comprises (a) an HVR-H1 sequence of GYTFSSYWIE (SEQ ID NO: 4); (b) an HVR-H2 sequence of GEILPGGGDTNYNEIFKG (SEQ ID NO: 5); and (c) an HVR-H3 sequence of TRRVPIRLDY (SEQ ID NO: 6); Val is valine; Cit is citrulline; and

p is a value from 1 to 8.

2. The liquid composition of claim 1, wherein the anti-CD79b immunoconjugate is at a concentration of 10 mg/ml to 20 mg/ml.

3. The liquid composition of claim 1 or claim 2, wherein the anti-CD79b immunoconjugate is at a concentration of 20 mg/ml.

4. The liquid composition of any one of claims 1-3, wherein the buffering agent is a histidine buffer or a succinate buffer.

5. The liquid composition of any one of claims 1-4, wherein the buffering agent is a histidine buffer.

6. The liquid composition of any one of claims 1-4, wherein the buffering agent is a succinate buffer.

7. The liquid composition of claim 6, wherein the succinate buffer is a sodium succinate buffer.

8. The liquid composition of claim 7, wherein the sodium succinate buffer is at a concentration of 10 mM.

9. The liquid composition of any one of claims 1-8, wherein the liquid composition has a pH of 5.3.

10. The liquid composition of any one of claims 1-9, wherein the sugar is selected from the group consisting of: sucrose, mannitol, sorbitol, glycerol, dextran 40, and trehalose.

11. The liquid composition of any one of claims 1-10, wherein the sugar is sucrose.

12. The liquid composition of claim 11, wherein the sucrose is at a concentration of 120 mM.

13. The liquid composition of any one of claims 1-12, wherein the surfactant is polysorbate 20 at a concentration of 0.12% w/v or 1.2 mg/ml.

14. The liquid composition of any one of claims 1-4 and 6-13, wherein the anti-CD79b immunoconjugate is at a concentration of 20 mg/ml, the buffering agent is a sodium succinate buffer at a concentration of 10 mM, the surfactant is polysorbate 20 at a concentration of 0.12% w/v or 1.2 mg/ml, and the sugar is sucrose at a concentration of 120 mM, and wherein the liquid composition has a pH of 5.3.

15. The liquid composition of any one of claims 1-14, wherein the liquid composition has been reconstituted from a lyophilized composition.

16. The liquid composition of claim 15, wherein the lyophilized composition is a lyophilized cake.

17. The liquid composition of claim 15 or claim 16, wherein the liquid composition has been reconstituted with sterile water for injection (SWFI).

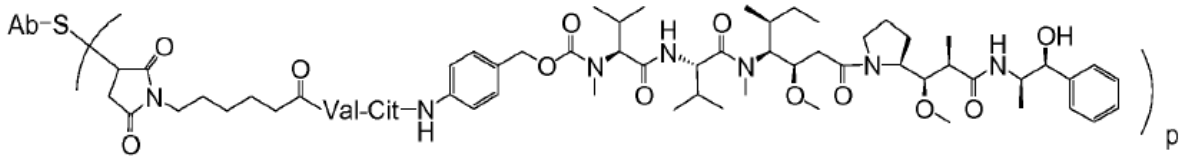
18. The liquid composition of any one of claims 15-17, wherein the liquid composition has been reconstituted with 7.2 ml SWFI.

19. The liquid composition of any one of claims 1-18, wherein the liquid composition is stable for at least 24 hours upon storage at 30°C.

20. The liquid composition of any one of claims 1-19, wherein the liquid composition is stable for at least 72 hours upon storage at 2°C to 8°C.

21. A lyophilized composition comprising: (a) 140-150 mg of an anti-CD79b immunoconjugate, 8.4-9.0 mg polysorbate 20, 8.27-8.88 mg succinic acid, 3.80-4.08 mg sodium hydroxide, and 288-309 mg sucrose, or (b) 30 mg of an anti-CD79b immunoconjugate, 1.8 mg polysorbate 20, 1.77 mg succinic acid, 0.816 mg sodium hydroxide, and 61.8 mg sucrose,

wherein the anti-CD79b immunoconjugate comprises the formula:



wherein:

Ab is an anti-CD79b antibody, wherein the anti-CD79b antibody comprises a heavy chain and a light chain, wherein the light chain comprises (a) an HVR-L1 sequence of KASQSVDYEGDSFLN (SEQ ID NO: 1); (b) an HVR-L2 sequence of AASNLES (SEQ ID NO: 2); and (c) an HVR-L3 sequence of QQSNEDPLT (SEQ ID NO: 3); wherein the heavy chain comprises (a) an HVR-H1 sequence of GYTFSSYWIE (SEQ ID NO: 4); (b) an HVR-

H2 sequence of GEILPGGGDTNYNEIFKG (SEQ ID NO: 5); and (c) an HVR-H3 sequence of TRRVPIRLDY (SEQ ID NO: 6); Val is valine; Cit is citrulline; and

p is a value from 1 to 8.

22. The lyophilized composition of claim 21, wherein the lyophilized composition comprises 150 mg of the anti-CD79b immunoconjugate, 9.0 mg polysorbate 20, 8.88 mg succinic acid, 4.08 mg sodium hydroxide, and 309 mg sucrose.

23. The lyophilized composition of claim 21, wherein the lyophilized composition comprises 140 mg of the anti-CD79b immunoconjugate, 8.4 mg polysorbate 20, 8.27 mg succinic acid, 3.80 mg sodium hydroxide, and 288 mg sucrose.

24. The lyophilized composition of claim 21, wherein the lyophilized composition comprises 30 mg of the anti-CD79b immunoconjugate, 1.8 mg polysorbate 20, 1.77 mg succinic acid, 0.816 mg sodium hydroxide, and 61.8 mg sucrose.

25. The lyophilized composition of any one of claims 21-24, wherein the lyophilized composition is stable for at least 6 months upon storage at 2°C to 8°C.

26. The lyophilized composition of any one of claims 21-25, wherein the lyophilized composition is stable for at least 7 months upon storage at 25°C over a residual moisture content range of 0.3% (w/w) to 3.2% (w/w).

27. The lyophilized composition of any one of claims 21-26, wherein the lyophilized composition is a lyophilized cake.

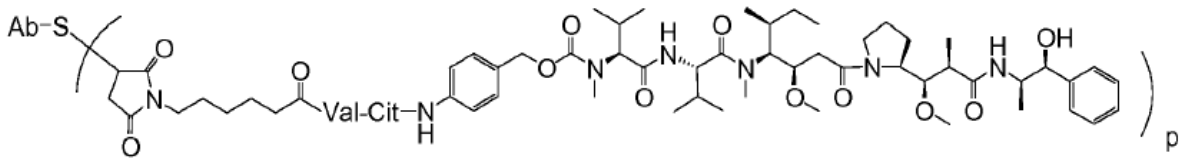
28. A liquid composition produced by reconstituting the lyophilized composition of any one of claims 21-27.

29. The liquid composition of claim 28, wherein the lyophilized composition is reconstituted with sterile water for injection (SWFI).

30. The liquid composition of claim 28 or claim 29, wherein the lyophilized composition is reconstituted with 7.2 ml SWFI.

31. A glass vial containing the liquid composition of any one of claims 1-20 and 28-30, or the lyophilized composition of any one of claims 21-27.

32. A liquid composition for intravenous administration comprising: a) between 0.72 and 2.7 mg/ml of an anti-CD79b immunoconjugate; b) between 0.36 and 1.35 mM sodium succinate; c) between 0.51 and 16.24 mM sucrose; and d) between 0.0432 and 0.162 mg/ml polysorbate 20, wherein the pH of the liquid composition is between 5 and 5.7, and wherein the anti-CD79b immunoconjugate comprises the formula:



wherein:

Ab is an anti-CD79b antibody, wherein the anti-CD79b antibody comprises a heavy chain and a light chain, wherein the light chain comprises (a) an HVR-L1 sequence of KASQSVDYEGDSFLN (SEQ ID NO: 1); (b) an HVR-L2 sequence of AASNLES (SEQ ID NO: 2); and (c) an HVR-L3 sequence of QQSNEDPLT (SEQ ID NO: 3); wherein the heavy chain comprises (a) an HVR-H1 sequence of GYTFSSYWIE (SEQ ID NO: 4); (b) an HVR-H2 sequence of GEILPGGGDTNYNEIFKG (SEQ ID NO: 5); and (c) an HVR-H3 sequence of TRRVPIRLDY (SEQ ID NO: 6); Val is valine; Cit is citrulline; and

p is a value from 1 to 8.

33. The liquid composition of claim 32, comprising: a) 0.72 mg/ml of the anti-CD79b immunoconjugate; b) 0.36 mM sodium succinate; c) 0.51 mM sucrose; and d) 0.0432 mg/ml polysorbate 20, wherein the pH of the liquid composition is between 5.1 and 5.4.

34. The liquid composition of claim 32, comprising: a) 2.7 mg/ml of the anti-CD79b immunoconjugate; b) 1.35 mM sodium succinate; c) 16.24 mM sucrose; and d) 0.162 mg/ml polysorbate 20, wherein the pH of the liquid composition is between 5.1 and 5.4.

35. The liquid composition of any one of claims 32-34, wherein the pH of the liquid composition is 5.3.

36. The liquid composition of any one of claims 32-35, wherein the ratio of the anti-CD79b immunoconjugate to the polysorbate 20 in the composition is 0.72 mg/ml:0.0432 mg/ml.

37. A liquid composition for intravenous administration obtained by diluting the liquid composition of any one of claims 1-20 and 28-30 in an isotonic buffer.

38. The liquid composition of claim 37, wherein the isotonic buffer is a 0.9% sodium chloride solution, a 0.45% sodium chloride solution, or a 5% dextrose solution.

39. The liquid composition of claim 37 or claim 38, wherein the surfactant concentration following dilution is at least 0.004% w/v.

40. The liquid composition of any one of claims 32-39, wherein the volume of the liquid composition is between 50 ml and 100 ml.

41. The liquid composition of claim 40, wherein the volume of the liquid composition is 50 ml.

42. The liquid composition of claim 40, wherein the volume of the liquid composition is 100 ml.

43. The liquid composition of any one of claims 32-42, wherein the liquid composition is in an intravenous (IV) bag.

44. An intravenous (IV) bag containing the liquid composition of any one of claims 32-42.

45. The liquid composition of any one of claims 1-20 and 28-30, the lyophilized composition of any one of claims 21-27, or the liquid composition for intravenous

administration of any one of claims 32-43, wherein the anti-CD79b antibody comprises a heavy chain variable domain (VH) comprising the amino acid sequence of SEQ ID NO: 7 and a light chain variable domain (VL) comprising the amino acid sequence of SEQ ID NO: 8.

46. The liquid composition of any one of claims 1-20, 28-30, and 45, the lyophilized composition of any one of claims 21-27 and 45, or the liquid composition for intravenous administration of any one of claims 32-43 and 45, wherein the heavy chain of the anti-CD79b antibody comprises the amino acid sequence of SEQ ID NO: 9, and wherein the light chain of the anti-CD79b antibody comprises the amino acid sequence of SEQ ID NO: 10.

47. The liquid composition of any one of claims 1-20, 28-30, and 45-46, the lyophilized composition of any one of claims 21-27 and 45-46, or the liquid composition for intravenous administration of any one of claims 32-43 and 45-46, wherein p is a value from 2 to 5.

48. The liquid composition of any one of claims 1-20, 28-30, and 45-47, the lyophilized composition of any one of claims 21-27 and 45-47, or the liquid composition for intravenous administration of any one of claims 32-43 and 45-47, wherein p is about 3.5.

49. The liquid composition of any one of claims 1-20, 28-30, and 45-48, the lyophilized composition of any one of claims 21-27 and 45-48, or the liquid composition for intravenous administration of any one of claims 32-43 and 45-48, wherein the anti-CD79b immunoconjugate is polatuzumab vedotin.

50. The liquid composition of claim 1, wherein a) the immunoconjugate is polatuzumab vedotin; b) the buffering agent is sodium succinate; and c) the sugar is sucrose, wherein the ratio of said polatuzumab vedotin : sodium succinate : sucrose : polysorbate 20 is 20 mg/ml : 10 mM : 120 mM : 1.2 mg/ml, wherein the pH of the liquid composition is between 5.1 and 5.4.

51. The liquid composition of claim 50, wherein said polatuzumab vedotin is at a concentration between 5 mg/ml and 60 mg/ml.

52. Use of the liquid composition of any one of claims 1-20, 28-30, and 45-51, the lyophilized composition of any one of claims 21-27 and 45-49, or the liquid composition for intravenous administration of any one of claims 32-43 and 45-49 in the manufacture of a medicament for treating a B cell proliferative disorder in a patient in need thereof.

53. The use of claim 52, wherein the B cell proliferative disorder is selected from the group consisting of: lymphoma, myeloma, non-Hodgkin's lymphoma (NHL), diffuse large B-cell lymphoma (DLBCL), aggressive NHL, indolent lymphoma, follicular lymphoma (FL), relapsed aggressive NHL, relapsed indolent NHL, relapsed NHL, refractory NHL, refractory indolent NHL, chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma, leukemia, hairy cell leukemia (HCL), acute lymphocytic leukemia (ALL), and mantle cell lymphoma.

54. The use of claim 53, wherein the B cell proliferative disorder is non-Hodgkin's lymphoma (NHL).

55. The use of claim 53, wherein the B cell proliferative disorder is diffuse large B-cell lymphoma (DLBCL).

56. The use of claim 53, wherein the B cell proliferative disorder is relapsed NHL or refractory NHL.

57. The use of claim 53, wherein the B cell proliferative disorder is follicular lymphoma (FL).

58. The use of claim 53, wherein the B cell proliferative disorder is relapsed/refractory diffuse large B-cell lymphoma (DLBCL).