

WHAT IS CLAIMED IS:

1. A composition comprising greater than about 100 mg/mL of an anti-TSLP antibody, a surfactant, proline, and a buffer,
wherein the anti-TSLP antibody comprises
 - (A) a light chain variable domain comprising: (i) a light chain CDR1 sequence comprising the amino acid sequence set forth in SEQ ID NO:3; (ii) a light chain CDR2 sequence comprising the amino acid sequence set forth in SEQ ID NO:4; and (iii) a light chain CDR3 sequence comprising the amino acid sequence set forth in SEQ ID NO:5; and
 - (B) a heavy chain variable domain comprising: (i) a heavy chain CDR1 sequence comprising the amino acid sequence set forth in SEQ ID NO:6; (ii) a heavy chain CDR2 sequence comprising the amino acid sequence set forth in SEQ ID NO:7, and (iii) a heavy chain CDR3 sequence comprising the amino acid sequence set forth in SEQ ID NO:8.
2. The composition of claim 1, wherein the anti-TSLP antibody comprises:
 - (A) a light chain variable domain selected from the group consisting of:
 - i. a sequence of amino acids at least 80% identical to SEQ ID NO:12;
 - ii. a sequence of amino acids encoded by a polynucleotide sequence that is at least 80% identical to SEQ ID NO:11; or
 - iii. a sequence of amino acids encoded by a polynucleotide that hybridizes under moderately stringent conditions to the complement of a polynucleotide consisting of SEQ ID NO:11; or
 - (B) a heavy chain variable domain selected from the group consisting of:
 - i. a sequence of amino acids that is at least 80% identical to SEQ ID NO:10;
 - ii. a sequence of amino acids encoded by a polynucleotide sequence that is at least 80% identical to SEQ ID NO:9; or
 - iii. a sequence of amino acids encoded by a polynucleotide that hybridizes under moderately stringent conditions to the complement of a polynucleotide consisting of SEQ ID NO:9; or
 - (C) a light chain variable domain of (A) and a heavy chain variable domain of (B).
3. The composition of claim 1 or 2, wherein the anti-TSLP antibody is an IgG2 antibody.

4. The composition of any one of claims 1 to 3, wherein the anti-TSLP antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO: 13, a light chain comprising the amino acid sequence of SEQ ID NO: 14, or a heavy chain comprising the amino acid sequence of SEQ ID NO: 13 and a light chain comprising the amino acid sequence of SEQ ID NO: 14.
5. The composition of any one of claims 1 to 4, wherein the anti-TSLP antibody specifically binds to a TSLP polypeptide as set forth in amino acids 29-159 of SEQ ID NO: 2.
6. The composition of any one of claims 1 to 5, wherein both binding sites of the anti-TSLP antibody have identical binding to TSLP.
7. The composition of any one of claims 1 to 6, wherein the anti-TSLP antibody is present in the composition at a concentration less than about 200 mg/mL.
8. The composition of claim 7, wherein the anti-TSLP antibody is present in the composition at a concentration less than about 150 mg/mL.
9. The composition of claim 8, wherein the anti-TSLP antibody is present in the composition at a concentration of about 110 mg/mL to about 140 mg/mL.
10. The composition of claim 9, wherein the anti-TSLP antibody is present in the composition at a concentration about 110 mg/mL $\pm$ 10%.
11. The composition of claim 9, wherein the anti-TSLP antibody is present in the composition at a concentration about 140 mg/mL $\pm$ 10%.
12. The composition of any one of the preceding claims, wherein the surfactant is amphipathic and nonionic.
13. The composition of claim 12, wherein the surfactant is a polysorbate.
14. The composition of claim 13, wherein the surfactant is polysorbate 20 or polysorbate 80 or a mixture thereof.
15. The composition of any one of claims 12 to 14, comprising a surfactant at a concentration less than or about 0.005% (w/v) to about 0.015% (w/v).
16. The composition of claim 15, comprising about 0.010% (w/v) $\pm$ 0.0025% (w/v) surfactant.
17. The composition of claim 15, comprising about 0.005% (w/v), 0.010% (w/v), or 0.015% (w/v) surfactant.

18. The composition of any one of the preceding claims, comprising less than about 3.0% (w/v) proline.
19. The composition of any one of the preceding claims, comprising about 2.4% (w/v) to about 2.8% (w/v) proline or about 2.5% (w/v) to about 2.8% (w/v) proline.
20. The composition of any one of the preceding claims, wherein the proline is L-proline.
21. The composition of any one of the preceding claims, wherein proline is the only amino acid present in the composition.
22. The composition of any one of the preceding claims, wherein the buffer is selected from the group consisting of: succinate, glutamate, histidine, and acetate.
23. The composition of claim 22, wherein the buffer is acetate.
24. The composition of any one of the preceding claims, comprising about 10 mM to about 30 mM buffer.
25. The composition of claim 24, comprising about 20 mM to about 28 mM buffer, optionally, about 23 mM to about 28 mM or about 24 mM to about 28 mM.
26. The composition of claim 25, comprising about 24 mM to about 26 mM buffer.
27. The composition of any one of the preceding claims, comprising not more than 0.001% (w/v) of a sugar or citrate, optionally, wherein the sugar is a disaccharide, e.g., trehalose and sucrose.
28. The composition of any one of the preceding claims, wherein the composition is a liquid.
29. The composition of claim 28, wherein the pH is less than about 6.0, optionally, less than about 5.5.
30. The composition of claim 29, wherein the pH is about 4.5 to about 5.5.
31. The composition of claim 30, wherein the pH is about 4.8 to about 5.4.
32. The composition of claim 31, wherein the pH is about 4.9, 5.2, or 5.4.
33. The composition of any one of claims 28 to 32, characterized by a reduced viscosity, relative to liquid composition not comprising proline.

34. The composition of any one of claims 28 to 33, characterized by a viscosity of less than about 24 cP at about 20 °C to about 25 °C when the concentration of the anti-TSLP antibody is less than 155 mg/mL, optionally, ~6 cP when the concentration of the anti-TSLP antibody is about 110 mg/mL or about 15 cP when the concentration of the anti-TSLP antibody is about 140 mg/mL.

35. The composition of claim 29, characterized by a viscosity of about 5 cP to about 20 cP, optionally about 15 cP.

36. The composition of any one of claims 28 to 35, wherein the composition is isotonic or has an osmolality in a range of about 200 mOsm/kg to about 500 mOsm/kg, or about 225 mOsm/kg to about 400 mOsm/kg, or about 250 mOsm/kg to about 350 mOsm/kg.

37. The composition of any one of the previous claims, wherein less than 5% of the antibody is degraded after about 24 months to about 36 months of storage at 2°C to 8°C as determined by Size Exclusion Chromatography (SEC), optionally, wherein less than 2% of the antibody is degraded after 24 months or 36 months of storage at 2°C to 8°C.

38. The composition of any one of the previous claims, wherein less than 5% of the antibody is degraded after at least 2 weeks (optionally, after at least 1 month, after at least 2 months, after at least 3 months, after at least 4 months, after at least 5 months or after at least 6 months) of storage at about 25°C, as determined by SEC.

39. The composition of any one of the previous claims, wherein less than 5% of the antibody is degraded after about 24 months to about 36 months of storage at 2°C to 8°C followed by at least 2 weeks or at least 1 month or at least 2 months of storage at about 25°C, as determined by SEC.

40. A composition comprising, about 110 mg/mL to about 140 mg/mL tezepelumab, about 0.01% (w/v) $\pm$ 0.005% (w/v) polysorbate 80, about 2.4% (w/v) to about 2.8% (w/v) L-proline, and about 20 mM to about 28 mM acetate, wherein the viscosity of the composition is less than about 20 cP and the pH is less than about 5.5.

41. The composition of claim 40, wherein the pH is 5.2, optionally, wherein the viscosity is about 15 cP at 20 °C to about 25 °C.

42. A composition comprising about 110 mg/mL of an anti-TSLP antibody, 0.01% (w/v) polysorbate 80, about 2.4% (w/v) to about 2.8% (w/v) L-proline, and about 20 mM to about 28 mM acetate, wherein the composition has a pH of about 5.2.

43. The composition of claim 42, comprising about 22 mM to about 26 mM.
44. The composition of claim 43, comprising about 24 mM to about 26 mM acetate.
45. The composition of any one of claims 42 to 44, comprising 110 mg/mL anti-TSLP antibody, 24 mM acetate, 2.5% (w/v) L proline, and 0.01% (w/v) polysorbate 80 at pH 5.2.
46. The composition of claim 1, comprising 110 mg/mL anti-TSLP antibody, 10 mM acetate, 3.0% (w/v) L-proline, and 0.01% (w/v) polysorbate 80, at pH 5.2.
47. A composition comprising about 140 mg/mL of an anti-TSLP antibody, 0.01% (w/v) polysorbate 80, about 2.5% (w/v) to about 2.8% (w/v) L-proline, and about 20 mM to about 28 mM acetate, wherein the composition has a pH of about 5.2.
48. The composition of claim 47, comprising about 25 mM to about 26 mM acetate.
49. An article of manufacture comprising the composition of any one of the preceding claims optionally, comprising about 0.5 mL to about 5 mL of the composition.
50. The article of manufacture of claim 49, comprising about 1 mL to about 3 mL of the composition.
51. A prefilled syringe comprising the composition of any one of the preceding claims optionally, comprising about 0.5 mL to about 5 mL of the composition.
52. The prefilled syringe of claim 51, comprising about 1 mL to about 3 mL of the composition.
53. A vial comprising the composition of any one of the preceding claims, optionally, comprising about 0.5 mL to about 5 mL of the composition.
54. The vial of claim 53, comprising about 1 mL to about 3 mL of the composition.
55. An autoinjector comprising the composition of any one of the preceding claims, optionally, comprising about 0.5 mL to about 5 mL.
56. The autoinjector of claim 55, comprising about 1 mL to about 3 mL of the composition.
57. The autoinjector of claim 55 or 56, wherein the auto-injector is an Ypsomed YpsoMate®.
58. The autoinjector of any one of claims 55 to 57, wherein the auto-injector is disclosed in WO 2018/226565, WO 2019/094138, WO 2019/178151, WO 20120/072577,

WO2020/081479, WO 2020/081480, PCT/US20/70590, PCT/US20/70591, PCT/US20/53180, PCT/US20/53179, PCT/US20/53178, or PCT/US20/53176.

59. A method for treating an inflammatory disease in a subject comprising administering to the subject a therapeutically effective amount of the composition of any one of the preceding claims.

60. The method of claim 59, wherein the inflammatory disease is selected from the group consisting of: asthma, atopic dermatitis, chronic obstructive pulmonary disease (COPD), eosinophilic esophagitis (EoE), nasal polyps, chronic spontaneous urticaria, Ig-driven disease, IgA nephropathy, lupus nephritis, eosinophilic gastritis, chronic sinusitis without nasal polyps and idiopathic pulmonary fibrosis (IPF).

61. The method of claim 60 wherein the inflammatory disease is asthma.

62. The method of claim 59 or 60, comprising administering the composition at an interval of every 2 weeks.

63. The method of claim 59 or 60, comprising administering the composition every 4 weeks.

64. The method of any one of claims 59 to 63, wherein the composition is administered for a period of at least 4 months, 6 months, 9 months, 1 year or more.

65. The method of any one of claims 59 to 64, wherein the composition is administered subcutaneously.

66. The method of any one of claims 61 to 65, wherein the asthma is severe asthma.

67. The method of any one of claims 61 to 66, wherein the asthma is eosinophilic or non-eosinophilic asthma.

68. The method any one of claims 61 to 67, wherein the asthma is low eosinophil asthma.

69. The method of any one of claims 59 to 68, wherein the subject is an adult.

70. The method any one of claims 59 to 68, wherein the subject is a child or adolescent.

71. The method any one of claims 59 to 70, wherein the administration decreases eosinophils in blood, sputum, bronchoalveolar fluid, or lungs of the subject.

72. The method any one of claims 59 to 71, wherein the administration shifts cell counts in the subject from a Th2 high population to a Th2 low population.

73. The method any one of claims 59 to 72, wherein the administration improves one or more measures of asthma in a subject selected from the group consisting of forced expiratory volume (FEV), FEV1 reversibility, forced vital capacity (FCV), FeNO, Asthma Control Questionnaire-6 score and AQLQ(S)+12 score.

74. The method any one of claims 59 to 73, wherein the administration improves one or more symptoms of asthma as measured by an asthma symptom diary.

75. A method of making a stable, liquid antibody composition having a viscosity of less than about 24 cP and comprising less than about 200 mg/mL an anti-TSLP antibody, a surfactant and a buffer, said method comprising: (i) combining a first solution comprising the antibody at a first concentration, acetate and proline with a buffer comprising acetate and proline, to obtain a solution comprising about 110 mg/mL to about 140 mg/mL tezepelumab, proline, and acetate, and (ii) adding a surfactant to achieve a final concentration of about 0.01% (w/v) $\pm$ 0.005% (w/v) surfactant.

76. The method of claim 75, wherein the stable, liquid composition comprises about 140 mg/mL of an anti-TSLP antibody.

77. The method of claim 75 or 76, wherein the viscosity of the stable, liquid composition with the proline is reduced relative to the stable, liquid composition without the proline.

78. The method of any one of claims 75 to 77, wherein the viscosity of the stable, liquid composition is less than about 20 cP.

79. The method of any one of claims 75 to 78, wherein a solution comprising about 200 mM to about 300 mM proline is combined with the first solution.

80. The method of any one of claims 75 to 79, wherein the proline is L-proline.

81. The method of any one of claims 75 to 80, wherein the surfactant is polysorbate 80 or polysorbate 20.

82. The method of claim 81, wherein the surfactant is polysorbate 80.

83. The method of any one of claims 75 to 82, wherein the buffer is made with glacial acetic acid.

84. The method of any one of claims 75 to 83, wherein the buffer composition comprises about 1 mM to about 30 mM acetate, optionally, about 5 mM to about 15 mM acetate.

85. The method of any one of claims 75 to 84, wherein the pH of the stable, liquid antibody composition is about 5.2.

86. The method of any one of claims 75 to 85, wherein the anti-TSLP antibody comprises:

(A) a light chain variable domain selected from the group consisting of:

- iv. a sequence of amino acids at least 80% identical to SEQ ID NO:12;
- v. a sequence of amino acids encoded by a polynucleotide sequence that is at least 80% identical to SEQ ID NO:11; or
- vi. a sequence of amino acids encoded by a polynucleotide that hybridizes under moderately stringent conditions to the complement of a polynucleotide consisting of SEQ ID NO:11; or

(B) a heavy chain variable domain selected from the group consisting of:

- iv. a sequence of amino acids that is at least 80% identical to SEQ ID NO:10;
- v. a sequence of amino acids encoded by a polynucleotide sequence that is at least 80% identical to SEQ ID NO:9; or
- vi. a sequence of amino acids encoded by a polynucleotide that hybridizes under moderately stringent conditions to the complement of a polynucleotide consisting of SEQ ID NO:9; or

(C) a light chain variable domain of (A) and a heavy chain variable domain of (B).

87. The method of claim 86, wherein the anti-TSLP antibody is an IgG2 antibody.

88. The method of claim 86 or 87, wherein the anti-TSLP antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO: 13, a light chain comprising the amino acid sequence of SEQ ID NO: 14, or a heavy chain comprising the amino acid sequence of SEQ ID NO: 13 and a light chain comprising the amino acid sequence of SEQ ID NO: 14.

89. A method of making a stable, liquid antibody composition having a viscosity of less than about 24 cP and comprising less than about 200 mg/mL an anti-TSLP antibody, a

surfactant and a buffer, said method comprising formulating the anti-TSLP antibody with a buffer comprising about 10 mM to about 20 mM acetate and about 2.7% (w/v) to about 3.3% (w/v) having a pH of about 4.9 to about 5.5, and (ii) adding a surfactant to achieve a final concentration of about 0.005% (w/v) $\pm$ 0.015% (w/v) surfactant.

90. The method of claim 89, wherein the buffer is made using glacial acetic acid.

91. The method of claim 89 or 90, wherein the buffer is titrated to pH 5.2 using sodium hydroxide.

92. A solution for injection (i) comprising about 110 mg/mL to about 115 mg/mL tezepelumab, about 24 mM to about 26 mM acetate made using glacial acetic acid, about 2.4% to about 2.6% (w/v) L-proline, about 0.01% polysorbate 80, sodium hydroxide, and water for injection, (ii) having a pH of about 5.2 and a shelf-life of about 3 years.

93. A prefilled syringe comprising about 1.91 mL of the stable, liquid antibody composition of claim 92.