

What is claimed is:

1. Use of an agent that reduces the expression or activity of a Thymic Stromal Lymphopoietin (TSLP) polypeptide in the manufacture of a medicament for the treatment of a subject having atopic dermatitis, wherein the medicament is to be administered to the subject, wherein the subject is identified as having an increase in the level of Brain Derived Neurotrophin (BDNF) polypeptide in circulation or an increase in the level of Brain Derived Neurotrophin (BDNF) polynucleotide in a skin sample derived from the subject relative to a reference.
2. The use of claim 1, wherein BDNF polypeptide in circulation is measured in blood, plasma, or serum sample derived from the subject.
3. The use of claim 1, wherein the use further comprises detecting an increase in Ciliary Neurotrophic Factor (CNTF) polynucleotide or Ciliary Neurotrophic Factor Receptor (CNTFR) polynucleotide in circulation.
4. The use of claim 1, wherein BDNF polynucleotide in skin is increased in a skin biopsy of lesional or non-lesional skin.
5. The use of any one of claims 1-4, wherein the use further comprises detecting an increase in amphiregulin polynucleotide in lesional and non-lesional skin biopsies.
6. The use of any one of claims 1-5, wherein the use further comprises detecting an increase in a polynucleotide biomarker selected from the group consisting of Neurotrophic Tyrosine Kinase Receptor Type 2 (NTRK2), Neurotrophic Tyrosine Kinase Receptor Type 3 (NTRK3), and Neurotrophin Factor 3 (NTF3).
7. The use of any one of claims 1-5, wherein the polypeptide is detected in an immunological assay.

8. The use of any one of claims 1-5, wherein the polynucleotide is detected by hybridization to a microarray or by gene expression analysis.
- 5 9. Use of an agent that reduces the expression or activity of a Thymic Stromal Lymphopoietin (TSLP) polypeptide in the manufacture of a medicament for treating a subject having atopic dermatitis, wherein the medicament is to be administered to the subject, wherein the subject is identified as having an increase in the level of Brain Derived Neurotrophin (BDNF) polynucleotide and Amphiregulin polynucleotide in a skin sample derived from the subject relative to a reference.
- 10 10. Use of an agent that reduces the expression or activity of a Thymic stromal lymphopoietin (TSLP) polypeptide in the manufacture of a medicament for treating a subject having atopic dermatitis, wherein the medicament is to be administered to the subject, wherein the subject is identified as having an increase in the level of Brain Derived Neurotrophin (BDNF) polynucleotide, Amphiregulin polynucleotide, and one or more of NTRK2, NTRK3, or NTF3 polynucleotides in a skin sample derived from the subject relative to a reference.
- 15 11. The use of claim 9 or 10, wherein the polynucleotide is detected by hybridization to a microarray.
- 20 12. Use of an agent that reduces the expression or activity of a Thymic stromal lymphopoietin (TSLP) polypeptide in the manufacture of a medicament for treating a subject having atopic dermatitis, wherein the medicament is to be administered to the subject, wherein the subject is identified as having an increase in the level of Brain Derived Neurotrophin (BDNF) polypeptide and an increase in Ciliary Neurotrophic Factor (CNTF) and/or Ciliary Neurotrophic Factor Receptor (CNTFR) in blood, plasma, or sera derived from the subject relative to a reference.
- 25 13. The use of claim 12, wherein the polypeptide is detected in an immunological assay.
- 30 14. Use of an agent that reduces the expression or activity of a Thymic stromal lymphopoietin (TSLP) polypeptide in the manufacture of a medicament, for the treatment of a subject having atopic dermatitis, wherein the medicament is to be administered to the subject, wherein the subject is identified as having an alteration in a

biomarker polypeptide selected from the group consisting of Amphiregulin (AREG), Brain Derived Neurotrophin (BDNF), Ciliary Neurotrophic Factor (CNTF), Ciliary Neurotrophic Factor Receptor (CNTFR), Neurotrophin 3 (NTF3), Neurotrophin 4 (NTF4), Nerve Growth Factor (NGF), Neurotrophic Tyrosine Kinase Receptor Type 1 (NTRK1), Neurotrophic Tyrosine Kinase Receptor Type 2 (NTRK2), and Neurotrophic Tyrosine Kinase Receptor Type 3 (NTRK3) in a blood, plasma, or sera sample of the subject relative to a reference.

15. Use of an agent that reduces the expression or activity of a Thymic stromal lymphopoietin (TSLP) polypeptide in the manufacture of a medicament for the treatment of a subject having atopic dermatitis, wherein the medicament is to be administered to the subject, wherein the subject is identified as having an alteration in a biomarker polynucleotide selected from the group consisting of Amphiregulin (AREG), Brain Derived Neurotrophin (BDNF), Ciliary Neurotrophic Factor (CNTF), Ciliary Neurotrophic Factor Receptor (CNTFR), Neurotrophin 3 (NTF3), Neurotrophin 4 (NTF4), Nerve Growth Factor (NGF), Neurotrophic Tyrosine Kinase Receptor Type 1 (NTRK1), Neurotrophic Tyrosine Kinase Receptor Type 2 (NTRK2), and Neurotrophic Tyrosine Kinase Receptor Type 3 (NTRK3) in a skin sample of the subject relative to a reference.

16. The use of any one of claims 1-15, wherein the atopic dermatitis is responsive to treatment with the agent that reduces the expression or activity of a Thymic stromal lymphopoietin (TSLP) polypeptide.

17. The use of any one of claims 1-15, wherein the agent that reduces the expression or activity of the TSLP polypeptide is an anti-TSLP antibody, or antigen binding portion thereof.

18. The use of any one of claims 1-15, wherein the agent that reduces the expression or activity of the TSLP polypeptide is an antibody, or antigen binding portion thereof, wherein the antibody, or antigen binding portion thereof comprises:

(a) a heavy chain variable region CDR1 comprising the amino acid sequence of SEQ ID NO:

6;

(b) a heavy chain variable region CDR2 comprising the amino acid sequence of SEQ ID NO: 7;

(c) a heavy chain variable region CDR3 comprising the amino acid sequence of SEQ ID NO: 8;

5 (d) a light chain variable region CDR1 comprising the amino acid sequence of SEQ ID NO: 3;

(e) a light chain variable region CDR2 comprising the amino acid sequence of SEQ ID NO: 4; and

10 5 (f) a light chain variable region CDR3 comprising the amino acid sequence of SEQ ID NO:

19. The use of any one of claims 1-15, wherein the agent that reduces the expression or activity of the TSLP polypeptide is an antibody, or antigen binding portion thereof, wherein the antibody, or antigen binding portion thereof comprises the heavy chain sequence of SEQ ID NO: 10 and the light chain sequence of SEQ ID NO 12.

20. The use of any one of claims 1-15, wherein the agent that reduces the expression or activity of the TSLP polypeptide is an antibody, wherein the antibody is Tezepelumab.

20 21. The use of any one of claims 1-20, wherein the subject is human.

22. The use of any one of claims 1-21, wherein the reference is the level, expression, or activity of the corresponding polypeptide or nucleic acid molecule biomarker present in a control sample.

25 23. The use of claim 22 wherein the control sample is derived from a subject having atopic dermatitis that is not responsive to anti-TSLP therapy.

24. The use of claim 22 or 23 wherein the control sample is derived from a healthy subject.

30 25. A method of identifying a subject as having atopic dermatitis (AD) responsive to an anti-TSLP therapy, the method comprising detecting an increase in the level of Brain Derived Neurotrophic Factor (BDNF) polypeptide in circulation or an increase in the level of Brain

Derived Neurotrophic Factor (BDNF) polynucleotide in a skin sample derived from the subject relative to a reference, thereby identifying the subject as having atopic dermatitis that is responsive to anti-TSLP therapy.

- 5 26. A method of identifying a subject as having atopic dermatitis (AD) responsive to an anti-TSLP therapy, the method comprising detecting an increase in the level of Brain Derived Neurotrophic Factor (BDNF) polynucleotide and Amphiregulin polynucleotide in a skin sample derived from the subject relative to a reference, thereby identifying the subject as having atopic dermatitis that is responsive to anti-TSLP therapy.

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27. A method of identifying a subject as having atopic dermatitis (AD) responsive to an anti-TSLP therapy, the method comprising detecting an increase in the level of Brain Derived Neurotrophic Factor (BDNF) polynucleotide, Amphiregulin polynucleotide, and one or more of NTRK2, NTRK3, or NTF3 polynucleotides in a skin sample derived from the subject, thereby
15 identifying the subject as having atopic dermatitis that is responsive to anti-TSLP therapy.

28. A method of identifying a subject as having atopic dermatitis (AD) responsive to an anti-TSLP therapy, the method comprising detecting an increase in the level of Brain Derived Neurotrophic Factor (BDNF) polypeptide and an increase in CNTF and/or CNTFR in blood,
20 plasma, or sera derived from the subject, thereby identifying the subject as having atopic dermatitis that is responsive to anti-TSLP therapy.

29. A method of identifying a subject as having atopic dermatitis (AD) responsive to an anti-TSLP therapy, the method comprising

- 25 (a) detecting an antibody binding to a circulating polypeptide marker selected from the group consisting of Amphiregulin (AREG), Brain Derived Neurotrophin (BDNF), Ciliary Neurotrophic Factor (CNTF), Ciliary Neurotrophic Factor Receptor (CNTFR), Neurotrophin 3 (NTF3), Neurotrophin 4 (NTF4), Nerve Growth Factor (NGF), Neurotrophic Tyrosine Kinase Receptor Type 1 (NTRK1), Neurotrophic Tyrosine Kinase Receptor Type 2 (NTRK2), and
30 Neurotrophic Tyrosine Kinase Receptor Type 3 (NTRK3) in a blood, plasma, or sera sample of the subject; and

(b) detecting an alteration in the level of said marker in the sample relative to a reference, thereby identifying the subject as having atopic dermatitis (AD) responsive to an anti-TSLP therapy.

5 30. A method of identifying a subject as having atopic dermatitis (AD) responsive to an anti-TSLP therapy, the method comprising

(a) detecting a probe binding to a polynucleotide marker selected from the group consisting of Amphiregulin (AREG), Brain Derived Neurotrophin (BDNF), Ciliary Neurotrophic Factor (CNTF), Ciliary Neurotrophic Factor Receptor (CNTFR), Neurotrophin 3 (NTF3),
10 Neurotrophin 4 (NTF4), Nerve Growth Factor (NGF), Neurotrophic Tyrosine Kinase Receptor Type 1 (NTRK1), Neurotrophic Tyrosine Kinase Receptor Type 2 (NTRK2), and Neurotrophic Tyrosine Kinase Receptor Type 3 (NTRK3) in a skin sample of the subject; and

(b) detecting an alteration in the level of said marker in the sample relative to a reference, thereby identifying the subject as having atopic dermatitis (AD) responsive to an anti-TSLP
15 therapy.

31. A method of monitoring the efficacy of therapy in a subject, the method comprising

(a) administering an anti-TSLP therapy to the subject; and

(b) detecting the level of Brain Derived Neurotrophic Factor polynucleotide in a skin
20 sample derived from the subject relative to the level of Brain Derived Neurotrophic Factor polynucleotide in a skin sample obtained from the subject at an earlier point in time, wherein a decrease in the level of BDNF over time indicates that the anti-TSLP therapy is effective.

32. The method of claim 31, wherein the method further comprises detecting the level of
25 amphiregulin polypeptide in the sera of the subject relative to the level present in the sera of the subject at an earlier point in time, wherein an increase in said level over time indicates that the anti-TSLP therapy is effective.

33. A kit for the treatment of atopic dermatitis (AD), the kit comprising an agent that reduces the
30 expression or activity of a Thymic stromal lymphopoietin (TSLP) polypeptide, and one or more of a capture molecule or probe that specifically binds a polypeptide or polynucleotide biomarker

selected from the group consisting of Amphiregulin (AREG), Ciliary Neurotrophic Factor (CNTF), Ciliary Neurotrophic Factor Receptor (CNTFR), Brain Derived Neurotrophin (BDNF), Neurotrophin 3 (NTF3), Neurotrophin 4 (NTF4), Nerve Growth Factor (NGF), Neurotrophic Tyrosine Kinase Receptor Type 1 (NTRK1), Neurotrophic Tyrosine Kinase Receptor Type 2 (NTRK2), Neurotrophic Tyrosine Kinase Receptor Type 3 (NTRK3).