when administered to atopic dermatitis patients using the dosing regimens provided herein, including patients using topical corticosteroids concomitantly, as assessed by several efficacy outcome measures. Accordingly, provided herein are uses of IL-13 antagonists, including anti-IL-13 antibodies such as lebrikizumab, in treating atopic dermatitis and methods of treating atopic dermatitis with IL-13 antagonists, including anti-IL-13 antibodies such as lebrikizumab.

[0023] Accordingly, in one aspect, there is provided use of a pharmaceutical composition comprising 125 mg or 250 mg or 500 mg of an anti-IL-13 antibody, in the manufacture of a medicament for treating atopic dermatitis in a patient, wherein the pharmaceutical composition reduces disease severity in the patient and wherein disease severity is assessed by an Atopic Dermatitis Disease Severity Outcome Measure, wherein the anti-IL-13 antibody is an antibody comprising a VH comprising HVR-H1, HVR-H2, and HVR-H3, wherein the respective VH HVRs have the amino acid sequence of SEQ ID NO: 5, SEQ ID NO: 6, and SEQ ID NO: 7, and comprising a VL comprising HVR-L1, HVR-L2, and HVR-L3, wherein the respective VL HVRs have the amino acid sequence of SEQ ID NO: 8, SEQ ID NO: 9, and SEQ ID NO: 10. Also provided are methods of treating atopic dermatitis in a patient comprising administering to the patient a pharmaceutical composition comprising a therapeutically effective amount of an IL-13 antagonist, wherein the pharmaceutical composition reduces disease severity in the patient and wherein disease severity is assessed by an Atopic Dermatitis Disease Severity Outcome Measure (ADDSOM). In some embodiments, the atopic dermatitis is moderate to severe as determined by Rajka/Langeland criteria score and wherein the Rajka/Langeland criteria score is determined to be between 4.5 and 9. In some embodiments, the use or method further comprises administration of one or more topical corticosteroids. In some embodiments, the one or more topical corticosteroids is administered before administration of the IL-13 antagonist, at the same time as administration of the IL-13 antagonist, or after administration of the IL-13 antagonist. In some embodiments, the one or more topical corticosteroids is selected from triamcinolone acetonide, hydrocortisone, and a combination of triamcinolone acetonide and hydrocortisone. In some embodiments, the patient is aged 12 years and over. In some embodiments, the patient is inadequately controlled on topical corticosteroids. In some embodiments, the IL-13 antagonist is a monoclonal anti-IL-13 antibody. In some embodiments, the anti-IL-13 antibody is an antibody comprising a VH comprising HVR-H1, HVR-H2, and HVR-H3, wherein the respective VH HVRs have the amino acid sequence of SEQ ID NO: 5, SEQ ID NO: 6, and SEQ ID NO: 7, and comprising a VL comprising HVR-L1, HVR-L2, and HVR-L3, wherein the respective VL HVRs have the amino acid sequence of SEQ ID NO: 8, SEQ ID NO: 9, and SEQ ID NO: 10. In certain embodiments, the anti-IL-13 antibody is an IgG1, IgG2, IgG3, or IgG4. In certain embodiments, the anti-IL-13 antibody is a human, humanized, or chimeric antibody. In some embodiments, the anti-IL-13 antibody is an antibody comprising a VH comprising a sequence selected from SEQ ID NO: 1 and SEQ ID NO: 3, and comprising a VL comprising a sequence selected from SEQ ID NO: 2 and SEQ ID NO: 4. In certain embodiments, the anti-IL-13 antibody is a full-length antibody or a fragment thereof that binds human IL-13. In some embodiments, the anti-IL-13 antibody is IgG4. In

the IL-13 antagonist is a monoclonal anti-IL-13 antibody. In some embodiments, the anti-IL-13 antibody is an antibody comprising a VH comprising HVR-H1, HVR-H2, and HVR-H3, wherein the respective VH HVRs have the amino acid sequence of SEQ ID NO: 5, SEQ ID NO: 6, and SEQ ID NO: 7, and comprising a VL comprising HVR-L1, HVR-L2, and HVR-L3, wherein the respective VL HVRs have the amino acid sequence of SEQ ID NO: 8, SEQ ID NO: 9, and SEQ ID NO: 10. In certain embodiments, the anti-IL-13 antibody is an IgG1, IgG2, IgG3, or IgG4. In certain embodiments, the anti-IL-13 antibody is a human, humanized, or chimeric antibody. In some embodiments, the anti-IL-13 antibody is an antibody comprising a VH comprising a sequence selected from SEQ ID NO: 1 and SEQ ID NO: 3, and comprising a VL comprising a sequence selected from SEQ ID NO: 2 and SEQ ID NO: 4. In certain embodiments, the anti-IL-13 antibody is a full-length antibody or a fragment thereof that binds human IL-13. In some embodiments, the anti-IL-13 antibody is IgG4. In one embodiment, the anti-IL-13 antibody is lebrikizumab. In one embodiment, the anti-IL-13 antibody comprises a heavy chain having the amino acid sequence of SEQ ID NO: 11 and a light chain having the amino acid sequence of SEQ ID NO: 12. In some embodiments, the IL-13 antagonist is administered to the patient using a subcutaneous administration device. In certain such embodiments, the subcutaneous administration device is selected from a prefilled syringe, disposable pen injection device, microneedle device, microinfuser device, needle-free injection device, and autoinjector device. In one embodiment, the IL-13 antagonist is lebrikizumab and lebrikizumab is administered to the patient using a prefilled syringe. In one embodiment, the IL-13 antagonist is lebrikizumab and lebrikizumab is administered to the patient using an autoinjector device.

[0026] In another aspect, there is provided use of 125mg or 250 mg of an anti-IL-13 antibody, in the manufacture of a medicament for treating atopic dermatitis in a patient, wherein the anti-IL-13 antibody is to be administered subcutaneously once every four weeks or once every eight weeks, wherein the anti-IL-13 antibody is an antibody comprising a VH comprising HVR-H1, HVR-H2, and HVR-H3, wherein the respective VH HVRs have the amino acid sequence of SEQ ID NO: 5, SEQ ID NO: 6, and SEQ ID NO: 7, and comprising a VL comprising HVR-L1, HVR-L2, and HVR-L3, wherein the respective VL HVRs have the amino acid sequence of SEQ ID NO: 8, SEQ ID NO: 9, and SEQ ID NO: 10. Also provided are methods comprising administering to a patient a therapeutically effective amount of an IL-13 antagonist, wherein the therapeutically effective amount is selected from 125 mg and 250 mg and wherein the IL-13 antagonist is administered subcutaneously once every four weeks. In some embodiments, the therapeutically effective amount is about 125 mg or between 110 mg and 140 mg of an anti-IL-13 antibody or between 120 mg and 130 mg of an anti-IL-13 antibody. In some embodiments, the therapeutically effective amount is about 250 mg or between 225 mg and 275 mg of an anti-IL-13 antibody or between 240 mg and 260 mg of an anti-IL-13 antibody. In some embodiments, the IL-13 antagonist is a monoclonal anti-IL-13 antibody. In some embodiments, the anti-IL-13 antibody is an antibody comprising a VH comprising HVR-H1, HVR-H2, and HVR-H3, wherein the respective VH HVRs have the amino acid sequence of

Outcome (PRO). In some embodiments, the ADDSOM is EASI and the therapeutically effective amount reduces the EASI by 50% or 75% or 90% compared to the EASI determined prior to administration of a first dose of the IL-13 antagonist. In some embodiments, the EASI is determined 12 weeks after administration of the first dose or 20 weeks after administration of the first dose or 24 weeks after administration of the first dose. In some embodiments, the ADDSOM is SCORAD and the therapeutically effective amount reduces the SCORAD by 50% compared to the SCORAD determined prior to administration of a first dose of the IL-13 antagonist. In some embodiments, the ADDSOM is SCORAD and the therapeutically effective amount reduces the SCORAD by 75% compared to the SCORAD determined prior to administration of a first dose of the IL-13 antagonist. In some embodiments, the SCORAD is determined 12 weeks after administration of the first dose. In some embodiments, the ADDSOM is IGA and the therapeutically effective amount reduces the IGA to zero or one. In some embodiments, the IGA is determined 12 weeks after administration of a first dose of the IL-13 antagonist. In some embodiments, the ADDSOM is PRO and the PRO is pruritus visual analogue scale (VAS), sleep loss VAS, or Atopic Dermatitis Impact Questionnaire (ADIQ) score. In some embodiments, the PRO is determined 12 weeks after administration of a first dose of the IL-13 antagonist. In some embodiments, the PRO is pruritus VAS and the therapeutically effective amount reduces the pruritus VAS by 40% to 55%. In some embodiments, the PRO is sleep loss VAS and the therapeutically effective amount reduces the sleep loss VAS by 53% to 61%. In some embodiments, the PRO is ADIQ and the therapeutically effective amount reduces the ADIQ score by 54% to 65%.

[0027] In another aspect, there is provided use of an anti-IL-13 antibody, in the manufacture of a medicament for treating atopic dermatitis in a patient, wherein the anti-IL-13 antibody is to be administered at aloading dose that is 250 mg or 500 mg, and a subsequent maintenance dose that is 125 mg or 250 mg, wherein the anti-IL-13 antibody is an antibody comprising a VH comprising HVR-H1, HVR-H2, and HVR-H3, wherein the respective VH HVRs have the amino acid sequence of SEQ ID NO: 5, SEQ ID NO: 6, and SEQ ID NO: 7, and comprising a VL comprising HVR-L1, HVR-L2, and HVR-L3, wherein the respective VL HVRs have the amino acid sequence of SEQ ID NO: 8, SEQ ID NO: 9, and SEQ ID NO: 10. Also provided are methods of treating atopic dermatitis in a patient by administering to the patient a therapeutically effective amount of an IL-13 antagonist, where the administration comprises administration of at least one loading dose and administration of at least one subsequent maintenance dose, and where each of the at least one loading dose and each of the at least one maintenance dose is administered subcutaneously at a flat dose. In some embodiments, the atopic dermatitis is moderate to severe as determined by Rajka/Langeland criteria score and wherein the Rajka/Langeland criteria score is determined to be between 4.5 and 9. In some embodiments, the use or method further comprises administration of one or more topical corticosteroids. In some embodiments, the one or more topical corticosteroids is administered before administration of the IL-13 antagonist, at the same time as administration of the IL-13 antagonist, or after administration of the IL-13 antagonist. In some embodiments, the one or more topical corticosteroids is selected from triamcinolone

CLAIMS:

1. Use of a pharmaceutical composition comprising 125 mg or 250 mg or 500 mg of an anti-IL-13 antibody, in the manufacture of a medicament for treating atopic dermatitis in a patient, wherein the pharmaceutical composition reduces disease severity in the patient and wherein disease severity is assessed by an Atopic Dermatitis Disease Severity Outcome Measure, wherein the anti-IL-13 antibody is an antibody comprising a VH comprising HVR-H1, HVR-H2, and HVR-H3, wherein the respective VH HVRs have the amino acid sequence of SEQ ID NO: 5, SEQ ID NO: 6, and SEQ ID NO: 7, and comprising a VL comprising HVR-L1, HVR-L2, and HVR-L3, wherein the respective VL HVRs have the amino acid sequence of SEQ ID NO: 8, SEQ ID NO: 9, and SEQ ID NO: 10.

2. The use of claim 1, wherein the anti-IL-13 antibody is an antibody comprising a VH comprising a sequence selected from SEQ ID NO: 1 and SEQ ID NO: 3, and a VL comprising a sequence selected from SEQ ID NO: 2 and SEQ ID NO: 4.

3. The use of claim1 or 2, wherein the anti-IL-13 antibody comprises a heavy chain having the amino acid sequence of SEQ ID NO: 11 and a light chain having the amino acid sequence of SEQ ID NO: 12.

4. The use of any one of claims 1-3, wherein the pharmaceutical composition comprises 125 mg of the anti-IL-13 antibody and wherein the composition is to be administered subcutaneously once every four weeks.

5. The use of claim 4, wherein the pharmaceutical composition is to be administered for a period of 12 weeks or a period of 20 weeks or a period of 24 weeks.

6. The use of any one of claims 1-3, wherein the pharmaceutical composition comprises 250 mg of the anti-IL-13 antibody and wherein the composition is to be administered subcutaneously once every four weeks.

7. The use of any one of claims 1-3, wherein the pharmaceutical composition comprises 250 mg of the anti-IL-13 antibody and wherein the composition is to be administered subcutaneously once every eight weeks.

8. The use of claim6 or 7, wherein the pharmaceutical composition is to be administered for a period of 24 weeks or more.

9. The use of any one of claims 1-8, wherein the Atopic Dermatitis Disease Severity Outcome Measure is Eczema Area and Severity Index (EASI).

10. The use of claim 9, wherein the pharmaceutical composition reduces the EASI by 50% or 75% or 90% compared to the EASI determined prior to administration of a first dose of the pharmaceutical composition,

wherein the EASI is determined 12 weeks after administration of the first dose or 20 weeks after administration of the first dose or 24 weeks after administration of the first dose.

11. The use of any one of claims 1-8, wherein the Atopic Dermatitis Disease Severity Outcome Measure is Severity Scoring of Atopic Dermatitis (SCORAD).

12. The use of claim 11, wherein the pharmaceutical composition reduces the SCORAD by 50% or 75% compared to the SCORAD determined prior to administration of a first dose of the pharmaceutical composition, wherein the SCORAD is determined 12 weeks after administration of the first dose.

13. The use of any one of claims 1-8, wherein the Atopic Dermatitis Disease Severity Outcome Measure is Investigator Global Assessment (IGA).

14. The use of claim 13, wherein the pharmaceutical composition reduces the IGA to zero or one, wherein the IGA is determined 12 weeks after administration of a first dose of the pharmaceutical composition.

15. The use of any one of claims 1-8, wherein the Atopic Dermatitis Disease Severity Outcome Measure is a Patient Reported Outcome (PRO).

16. The use of claim 15, wherein the PRO is pruritus visual analogue scale (VAS), sleep loss VAS, or Atopic Dermatitis Impact Questionnaire (ADIQ) score, wherein the PRO is determined 12 weeks after administration of a first dose of the pharmaceutical composition.

17. The use of claim 15 or 16, wherein the pharmaceutical composition reduces the pruritus VAS by 40% to 55%.

18. The use of claim 15 or 16, wherein the pharmaceutical composition reduces the sleep loss VAS by 53% to 61%.

19. The use of claim15 or 16, wherein the pharmaceutical composition reduces the ADIQ score by 54% to 65%.

20. Use of 125mg or 250 mg of an anti-IL-13 antibody, in the manufacture of a medicament for treating atopic dermatitis in a patient, wherein the anti-IL-13 antibody is to be administered subcutaneously once every four weeks or once every eight weeks, wherein the anti-IL-13 antibody is an antibody comprising a VH comprising HVR-H1, HVR-H2, and HVR-H3, wherein the respective VH HVRs have the amino acid sequence of SEQ ID NO: 5, SEQ ID NO: 6, and SEQ ID NO: 7, and comprising a VL comprising HVR-L1, HVR-L2, and HVR-L3, wherein the respective VL HVRs have the amino acid sequence of SEQ ID NO: 8, SEQ ID NO: 9, and SEQ ID NO: 10.

21. The use of claim 20, wherein the anti-IL-13 antibody is to be administered at 125mg once every four weeks.

22. The use of claim 20, wherein the anti-IL-13 antibody is to be administered at 250mg once every four weeks.

23. The use of any one of claims 20-22, wherein the anti-IL-13 antibody is an antibody comprising a VH comprising a sequence selected from SEQ ID NO: 1 and SEQ ID NO: 3, and comprising a VL comprising a sequence selected from SEQ ID NO: 2 and SEQ ID NO: 4.

24. The use of any one of claims 20-23, wherein the anti-IL-13 antibody comprises a heavy chain having the amino acid sequence of SEQ ID NO: 11 and a light chain having the amino acid sequence of SEQ ID NO: 12.

25. Use of an anti-IL-13 antibody, in the manufacture of a medicament for treating atopic dermatitis in a patient, wherein the anti-IL-13 antibody is to be administered at a loading dose that is 250 mg or 500 mg, and a subsequent maintenance dose that is 125 mg or 250 mg, , wherein the anti-IL-13 antibody is an antibody comprising a VH comprising HVR-H1, HVR-H2, and HVR-H3, wherein the respective VH HVRs have the amino acid sequence of SEQ ID NO: 5, SEQ ID NO: 6, and SEQ ID NO: 7, and comprising a VL comprising HVR-L1, HVR-L2, and HVR-L3, wherein the respective VL HVRs have the amino acid sequence of SEQ ID NO: 8, SEQ ID NO: 9, and SEQ ID NO: 10.

26. The use of claim 25, wherein the anti-IL-13 antibody is an antibody comprising a VH comprising a sequence selected from SEQ ID NO: 1 and SEQ ID NO: 3, and a VL comprising a sequence selected from SEQ ID NO: 2 and SEQ ID NO: 4.

27. The use of claim 25 or 26, wherein the anti-IL-13 antibody comprises a heavy chain having the amino acid sequence of SEQ ID NO: 11 and a light chain having the amino acid sequence of SEQ ID NO: 12.

28. The use of any one of claims 25-27, wherein the loading dose is 250 mg and the maintenance dose is 125 mg.

29. The use of any one of claims 25-27, wherein the loading dose is 500 mg and the maintenance dose is 250 mg.

30. The use of any one of claims 25-29, wherein the maintenance dose is to be administered for 24 weeks or more.

31. The use of any one of claims 20-30, wherein the anti-IL-13 antibody reduces disease severity in the patient and wherein disease severity is assessed by an Atopic Dermatitis Disease Severity Outcome Measure.

32. The use of claim 31, wherein the Atopic Dermatitis Disease Severity Outcome Measure is Eczema Area and Severity Index (EASI).

33. The use of claim 32, wherein the anti-IL-13 antibody reduces the EASI by 50% or 75% or 90% compared to the EASI determined prior to administration of a first dose of the IL-13 antagonist, wherein the EASI is determined 12 weeks after administration of the first dose or 20 weeks after administration of the first dose or 24 weeks after administration of the first dose.

34. The use of claim 31, wherein the Atopic Dermatitis Disease Severity Outcome Measure is Severity Scoring of Atopic Dermatitis (SCORAD).

35. The use of claim 34, wherein the anti-IL-13 antibody reduces the SCORAD by 50% or 75% compared to the SCORAD determined prior to administration of a first dose of the IL-13 antagonist, wherein the SCORAD is determined 12 weeks after administration of the first dose.

36. The use of claim 31, wherein the Atopic Dermatitis Disease Severity Outcome Measure is Investigator Global Assessment (IGA).

37. The use of claim 36, wherein the anti-IL-13 antibody reduces the IGA to zero or one, wherein the IGA is determined 12 weeks after administration of a first dose of the IL-13 antagonist.

38. The use of claim 31, wherein the Atopic Dermatitis Disease Severity Outcome Measure is a Patient Reported Outcome (PRO).

39. The use of claim 38, wherein the PRO is pruritus visual analogue scale (VAS), sleep loss VAS, or Atopic Dermatitis Impact Questionnaire (ADIQ) score, wherein the PRO is determined 12 weeks after administration of a first dose of the IL-13 antagonist.

40. The use of claim39, wherein the anti-IL-13 antibody reduces the pruritus VAS by 40% to 55%.

41. The use of claim 39, wherein the anti-IL-13 antibody reduces the sleep loss VAS by 53% to 61%.

42. The use of claim 39, wherein the anti-IL-13 antibody reduces the ADIQ score by 54% to 65%.

43. The use of any one of claims 1-42, wherein the atopic dermatitis is moderate to severe as determined by Rajka/Langeland criteria score and wherein the Rajka/Langeland criteria score is determined to be between 4.5 and 9.

44. The use of any one of claims 1-43, wherein the anti-IL-13 antibody is to be administered to the patient using a subcutaneous administration device.

45. The use of claim 44, wherein the subcutaneous administration device is selected from a prefilled syringe, disposable pen injection device, microneedle device, microinfuser device, needle-free injection device, and autoinjector device.

46. The use of any one of claims 1-45, wherein one or more topical corticosteroids is/are to be administered.

47. The use of claim 46, wherein the one or more topical corticosteroids is to be administered before administration of the anti-IL-13 antibody, at the same time as administration of the anti-IL-13 antibody, or after administration of the anti-IL-13 antibody.

48. The use of claim 46 or 47, wherein the one or more topical corticosteroids is selected from triamcinolone acetonide, hydrocortisone, and a combination of triamcinolone acetonide and hydrocortisone.

49. The use of any one of claims 1-48, wherein the patient is aged 12 years and over.

50. The use of any one of claims 1-49, wherein the patient is inadequately controlled on topical corticosteroids.