UPADACITINIB FOR TREATING ALOPECIA AREATA

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Application No. 63/531,443, filed August 8, 2023, which is herein incorporated by reference in its entirety

FIELD OF THE DISCLOSURE

[0002] The present disclosure is directed to methods of treating alopecia areata (AA) with the selective JAK1 inhibitor, upadacitinib.

BACKGROUND OF THE DISCLOSURE

[0003] Alopecia areata (AA) is an autoimmune disease characterized by non-scarring partial or total hair loss on the scalp or any other body area. The extent of hair loss can range from single or multiple well-defined patches to the involvement of the whole scalp (alopecia totalis) or the entire body surface.

[0004] A clinical association of alopecia areata with atopic dermatitis (AD) has been reported, with up to one-third of patients with alopecia areata who are also affected by AD. Both AD and alopecia areata are characterized by elevated levels of IgE, high circulating eosinophil count, and increased Th2 cytokine serum levels. Alopecia areata increases the risk of AD, and this risk is greatest for those with early-onset alopecia (before 10–13 years of age) and/or alopecia totalis or universalis. AD also increases the risk of severe forms of alopecia areata, with a 26-fold higher risk of developing alopecia areata in AD patients compared to healthy controls.

[0005] Despite the prevalence of alopecia areata in patients with AD, and the various approved treatments for AD, there are few systemic therapies currently available for the treatment of alopecia areata, which highlights the challenges in treating this disease, especially in severe cases. Thus, the identification of new, effective therapies for alopecia areata represents an unmet clinical need.

SUMMARY OF THE DISCLOSURE

[0006] The present disclosure provides methods for treating alopecia areata (AA) with the selective JAK1 inhibitor, upadacitinib. The treatment methods generally comprise administering to a patient in need thereof a therapeutically effective amount of upadacitinib.

[0007] There is provided a method of treating a human patient having alopecia areata, the method comprising orally administering once daily to the patient 30 mg of upadacitinib.

[0007a] In one aspect, there is provided use of upadacitinib in the manufacture of a medicament for treating a human patient having alopecia areata, wherein 30 mg of the upadacitinib is to be orally administered once daily.

[0008] There is provided a method of treating a human patient having alopecia areata, the method comprising orally administering once daily to the patient 15 mg of upadacitinib.

[0008a] In another aspect, there is provided use of upadacitinib in the manufacture of a medicament for treating a human patient having alopecia areata, wherein 15 mg of the upadacitinib is to be orally administered once daily.

[0009] In some examples, the patient is an adult.

[0010] There is provided a method of treating alopecia areata in a human pediatric patient, the method comprising orally administering a therapeutically effective amount of upadacitinib to the pediatric patient, wherein:

if the pediatric patient has a body weight in a range from about 10 kg to less than about 20 kg:

(i) the upadacitinib is administered twice daily at a dose of 3 mg each (3 mg BID), or

(ii) the upadacitinib is administered twice daily at a dose of 6 mg each (6 mg BID);

if the pediatric patient has a body weight in a range from about 20 kg to less than about 30 kg:

(i) the upadacitinib is administered twice daily at a dose of 4 mg each (4 mg BID), or

(ii) the upadacitinib is administered twice daily at a dose of 8 mg each (8 mg BID); and

if the pediatric patient has a body weight of about 30 kg or greater:

(i) the upadacitinib is administered twice daily at a dose of 6 mg each (6 mg BID),

(ii) the upadacitinib is administered twice daily at a dose of 8 mg each (8 mg BID), or

(ii) the upadacitinib is administered once daily at a dose of 15 mg (15 mg QD).

[0010a] In another aspect, there is provided use of upadacitinib in the manufacture of a medicament for treating alopecia areata in a pediatric human patient, wherein the upadacitinib is to be orally administered, and wherein:

if the pediatric patient has a body weight in a range from about 10 kg to less than about 20 kg:

(i) the upadacitinib is to be administered twice daily at a dose of 3 mg each (3 mg BID), or

(ii) the upadacitinib is to be administered twice daily at a dose of 6 mg each (6 mg BID);

if the pediatric patient has a body weight in a range from about 20 kg to less than about 30 kg:

(i) the upadacitinib is to be administered twice daily at a dose of 4 mg each (4 mg BID), or

(ii) the upadacitinib is to be administered twice daily at a dose of 8 mg each (8 mg BID); and

if the pediatric patient has a body weight of about 30 kg or greater:

(i) the upadacitinib is to be administered twice daily at a dose of 6 mg each (6 mg BID),

(ii) the upadacitinib is to be administered twice daily at a dose of 8 mg each (8 mg BID), or

(iii) the upadacitinib is to be administered once daily at a dose of 15 mg (15 mg QD).

[0011] In some examples, the twice daily dose of upadacitinib is administered to the pediatric patient as a stable oral pharmaceutical solution.

[0012] In some examples, the stable oral pharmaceutical solution comprises upadacitinib, a buffer and/or pH adjusting agent, a preservative, a sweetener, and water.

[0013] In some examples, the oral solution comprises upadacitinib at a concentration of about 0.5 mg/mL or about 1 mg/mL.

[0014] In some examples, the once daily at a dose of 15 mg of upadacitinib is administered to the pediatric patient as an extended-release tablet.

[0015] In some examples, the method results in an AA-IGA score of 0 or 1 at 40 weeks from the first daily administration.

[0016] In some examples, the method results in a Severity of Alopecia Tool (SALT) score of ≤ 20 (less than or equal to 20% scalp hair loss) at 40 weeks from the first daily administration. In some examples, the method results in a SALT score of ≤ 10 at 40 weeks from the first daily administration. In some examples, the method results in a SALT score of 0 at 40 weeks from the first daily administration.

[0017] In some examples, the method results in SALT 50 (at least a 50% improvement [decrease] from Baseline in SALT score) at 40 weeks from the first daily administration. In some examples, the method results in SALT 75 (at least a 75% improvement [decrease] from Baseline in SALT score) at 40 weeks from the first daily administration. In some examples, the method results in a SALT 90 (at least a 90% improvement [decrease] from Baseline in SALT score) at 40 weeks from the first daily administration. In some examples, the method results in a SALT 100 (at least a 100% improvement [decrease] from Baseline in SALT score) at 40 weeks from the first daily administration.

[0018] In some examples, the method results in an AA-IGA score of 0 or 1 at 28 weeks from the first daily administration.

[0019] In some examples, the method results in a Severity of Alopecia Tool (SALT) score of ≤ 20 (less than or equal to 20% scalp hair loss) at 28 weeks from the first daily administration. In some examples, the method results in a SALT score of ≤ 10 at 28 weeks from the first daily administration. In some examples, the method results in a SALT score of 0 at 28 weeks from the first daily administration.

[0020] In some examples, the method results in SALT 50 (at least a 50% improvement [decrease] from Baseline in SALT score) at 28 weeks from the first daily administration. In some examples, the method results in SALT 75 (at least a 75% improvement [decrease] from Baseline in SALT score) at 28 weeks from the first daily administration. In some examples, the method results in a SALT 90 (at least a 90% improvement [decrease] from Baseline in SALT score) at 28 weeks from the first daily administration. In some examples, the method results in a SALT 100 (at least a 100% improvement [decrease] from Baseline in SALT score) at 28 weeks from the first daily administration.

[0021] In some examples, the method results in a Severity of Alopecia Tool (SALT) score of ≤ 20 (less than or equal to 20% scalp hair loss) at 24 weeks from the first daily administration. In some examples, the method results in a SALT score of ≤ 10 at 24 weeks from the first daily administration. In some examples, the method results in a SALT score of 0 at 24 weeks from the first daily administration.

[0022] In some examples, the method results in SALT 50 (at least a 50% improvement [decrease] from Baseline in SALT score) at 24 weeks from the first daily administration. In some examples, the method results in SALT 75 (at least a 75% improvement [decrease] from Baseline in SALT score) at 24 weeks from the first daily administration. In some examples, the method results in a SALT 90 (at least a 90% improvement [decrease] from Baseline in SALT score) at 24 weeks from the first daily administration. In some examples, the method results in a SALT 100 (at least a 100% improvement [decrease] from Baseline in SALT score) at 24 weeks from the first daily administration. In some examples, the method results in a Severity of Alopecia Tool (SALT) score of ≤ 20 (less than or equal to 20% scalp hair loss) at 12 weeks from the first daily administration. In some examples, the method results in a SALT score of ≤ 10 at 12 weeks from the first daily administration. In some examples, the method results in a SALT score of 0 at 12 weeks from the first daily administration.

[0023] In some examples, the method results in SALT 50 (at least a 50% improvement [decrease] from Baseline in SALT score) at 12 weeks from the first daily administration. In some examples, the method results in SALT 75 (at least a 75% improvement [decrease] from Baseline in SALT score) at 12 weeks from the first daily administration. In some examples, the method results in a SALT 90 (at least a 90% improvement [decrease] from Baseline in SALT score) at 12 weeks from the first daily administration. In some examples, the method results in a SALT 100 (at least a 100% improvement [decrease] from Baseline in SALT score) at 12 weeks from the first daily administration. In some examples, the method results in a Severity of Alopecia Tool (SALT) score of ≤ 20 (less than or equal to 20% scalp hair loss) at 8 weeks from the first daily administration. In some examples, the method results in a SALT score of ≤ 10 at 8 weeks from the first daily administration. In some examples, the method results in a SALT score of 0 at 8 weeks from the first daily administration.

[0024] In some examples, the method results in SALT 50 (at least a 50% improvement [decrease] from Baseline in SALT score) at 48 weeks from the first daily administration. In some examples, the method results in SALT 75 (at least a 75% improvement [decrease] from Baseline in SALT score) at 8 weeks from the first daily administration. In some examples, the method results in a SALT 90 (at least a 90% improvement [decrease] from Baseline in SALT score) at 8 weeks from the first daily administration. In some examples, the method results in a SALT 100 (at least a 100% improvement [decrease] from Baseline in SALT score) at 8 weeks from the first daily administration. In some examples, the method results in a Severity of Alopecia Tool (SALT) score of ≤ 20 (less than or equal to 20% scalp

hair loss) at 4 weeks from the first daily administration. In some examples, the method results in a SALT score of ≤ 10 at 4 weeks from the first daily administration. In some examples, the method results in a SALT score of 0 at 4 weeks from the first daily administration.

[0025] In some examples, the method results in SALT 50 (at least a 50% improvement [decrease] from Baseline in SALT score) at 4 weeks from the first daily administration. In some examples, the method results in SALT 75 (at least a 75% improvement [decrease] from Baseline in SALT score) at 4 weeks from the first daily administration. In some examples, the method results in a SALT 90 (at least a 90% improvement [decrease] from Baseline in SALT score) at 4 weeks from the first daily administration. In some examples, the method results in a SALT 100 (at least a 100% improvement [decrease] from Baseline in SALT score) at 4 weeks from the first daily administration. In some examples, the method results in an achievement of ClinRO measure for Eyebrow Hair Loss of 0 or 1 at Week 24 with a ≥ 2 point improvement from Baseline among subjects with Baseline score ≥ 2.

[0026] In some examples, the method results in an achievement of PRO for Scalp Hair Assessment 0/1 with ≥ 2-point improvement (reduction) from Baseline at Week 24 among subjects with Baseline score ≥ 3.

[0027] In some examples, the method results in an achievement of PaGIC score of 1 or 2 at Week 24.

[0028] In some examples, the method results in an achievement of Skindex-16 AA Emotions Domain scores at Week 24.

[0029] In some examples, the method results in a change from Baseline in Skindex-16 AA Functioning Domain scores at Week 24.

[0030] In some examples, the method results in an achievement of of HADS-A < 8 and HADS-D < 8 at Week 24 among subjects with HADS-A ≥ 8 or HADS-D ≥ 8 at Baseline.

[0031] In some examples, the method results in a change in AASIS Interference Subscale score at Week 24.

[0032] In some examples, the method results in a change in AASIS Symptoms Subscale score at Week 24.

[0033] In some examples, the method results in an achievement of ClinRO measure for Eyebrow Hair Loss of 0 or 1 at Week 12 with a ≥ 2 point improvement from Baseline among subjects with Baseline score ≥ 2.

[0034] In some examples, the method results in an achievement of PRO for Scalp Hair Assessment 0/1 with ≥ 2-point improvement (reduction) from Baseline at Week 12 among subjects with Baseline score ≥ 3.

[0035] In some examples, the method results in an achievement of PaGIC score of 1 or 2 at Week 12.

[0036] In some examples, the method results in an achievement of Skindex-16 AA Emotions Domain scores at Week 12.

[0037] In some examples, the method results in a change from Baseline in Skindex-16 AA Functioning Domain scores at Week 12.

[0038] In some examples, the method results in an achievement of of HADS-A < 8 and HADS-D < 8 at Week 12 among subjects with HADS-A ≥ 8 or HADS-D ≥≥ 8 at Baseline.

[0039] In some examples, the method results in a change in AASIS Interference Subscale score at Week 12.

[0040] In some examples, the method results in a change in AASIS Symptoms Subscale score at Week 12.

[0041] In some examples, the method results in an achievement of ClinRO measure for Eyebrow Hair Loss of 0 or 1 at Week 8 with a ≥ 2 point improvement from Baseline among subjects with Baseline score ≥ 2.

[0042] In some examples, the method results in an achievement of PRO for Scalp Hair Assessment 0/1 with ≥ 2-point improvement (reduction) from Baseline at Week 8 among subjects with Baseline score ≥ 3.

[0043] In some examples, the method results in an achievement of PaGIC score of 1 or 2 at Week 8.

[0044] In some examples, the method results in an achievement of Skindex-16 AA Emotions Domain scores at Week 8.

[0045] In some examples, the method results in a change from Baseline in Skindex-16 AA Functioning Domain scores at Week 8.

[0046] In some examples, the method results in an achievement of of HADS-A < 8 and HADS-D < 8 at Week 8 among subjects with HADS-A ≥ 8 or HADS-D ≥ 8 at Baseline.

[0047] In some examples, the method results in a change in AASIS Interference Subscale score at Week 8.

[0048] In some examples, the method results in a change in AASIS Symptoms Subscale score at Week 8.

[0049] In some examples, the method results in an achievement of ClinRO measure for Eyebrow Hair Loss of 0 or 1 at Week 4 with a ≥ 2 point improvement from Baseline among subjects with Baseline score ≥ 2.

[0050] In some examples, the method results in an achievement of PRO for Scalp Hair Assessment 0/1 with ≥ 2-point improvement (reduction) from Baseline at Week 4 among subjects with Baseline score ≥ 3.

[0051] In some examples, the method results in an achievement of PaGIC score of 1 or 2 at Week 4.

[0052] In some examples, the method results in an achievement of Skindex-16 AA Emotions Domain scores at Week 4.

[0053] In some examples, the method results in a change from Baseline in Skindex-16 AA Functioning Domain scores at Week 4.

[0054] In some examples, the method results in an achievement of of HADS-A < 8 and HADS-D < 8 at Week 4 among subjects with HADS-A ≥ 8 or HADS-D ≥ 8 at Baseline.

[0055] In some examples, the method results in a change in AASIS Interference Subscale score at Week 4.

[0056] In some examples, the method results in a change in AASIS Symptoms Subscale score at Week 4.

[0057] In some examples, the method results in an AA-IGA score of 0 or 1 at 16 weeks from the first daily administration.

[0058] In some examples, the method results in a Severity of Alopecia Tool (SALT) score of 50 at 16 weeks from the first daily administration. In some examples, the method results in a SALT 75 at 16 weeks from the first daily administration. In some examples, the method results in a SALT 90 at 16 weeks from the first daily administration. In some examples, the method results in a SALT 100 at 16 weeks from the first daily administration.

[0059] In some examples, the method results in an AA-IGA score of 0 or 1 at 4 weeks from the first daily administration.

[0060] In some examples, the method results in a SALT 50 at 4 weeks from the first daily administration. In some examples, the method results in SALT 75 at 4 weeks from the first daily administration. In some examples, the method results in a SALT 90 at 4 weeks from the first daily administration. In some examples, the method results in a SALT 100 at 4 weeks from the first daily administration.

[0061] In some examples, the patient has moderate alopecia areata. In some examples, the patient has moderate or severe alopecia areata. In some examples, the patient has severe alopecia areata. In some examples, the patient has very severe alopecia areata.

[0062] In some examples, the alopecia areata is localized on the fronto-parietal region of the scalp and the eyebrows.

[0063] In some examples, the patient, prior to initiating treatment, has a serum IgE level >100 IU/ml.

[0064] In some examples, the patient has previously received treatment with a systemic agent for alopecia areata. In some examples, the systemic agent is cyclosporine or dupilumab. In some examples, the systemic agent is baricitinib.

BRIEF DESCRIPTION OF THE DRAWINGS

[0065] **FIG. 1** is a graphical depiction of therapeutic response rate over time with respect to achievement of SALT 50, SALT 75, SALT 90, and SALT 100 improvement in alopecia areata relative to baseline score for patients receiving 30 mg per day upadacitinib.

[0066] **FIG. 2** is a graphical depiction of mean SALT score over time for patients exhibiting high or normal IgE serum level prior to beginning upadacitinib administration for patients receiving 30 mg per day upadacitinib.

DETAILED DESCRIPTION OF THE DISCLOSURE

I. Definitions

[0067] Section headings as used in this section and the entire disclosure are not intended to be limiting.

[0068] Where a numeric range is recited, each intervening number within the range is explicitly contemplated with the same degree of precision. For example, for the range 6 to 9, the numbers 7 and 8 are contemplated in addition to 6 and 9, and for the range 6.0 to 7.0, the numbers 6.0, 6.1, 6.2, 6.3, 6.4, 6.5, 6.6, 6.7, 6.8, 6.9 and 7.0 are explicitly contemplated. In the same manner, all recited ratios also include all sub-ratios falling within the broader ratio.

[0069] The singular forms "a," "an" and "the" include plural referents unless the context clearly dictates otherwise.

[0070] The term "about" generally refers to a range of numbers that one of skill in the art would consider equivalent to the recited value (i.e., having the same function or result). In many instances, the term "about" may include numbers that are rounded to the nearest significant figure.

[0071] Unless the context requires otherwise, the terms "comprise," "comprises," and "comprising" are used on the basis and clear understanding that they are to be interpreted inclusively, rather than exclusively, and that Applicant intends each of those words to be so interpreted in construing this patent, including the claims below.

[0072] The term "AUC" refers to the area under the curve. AUC is the definite integral of a curve that describes the variation of a drug concentration in blood plasma as a function of time.

CLAIMS

What is claimed is:

1. Use of upadacitinib in the manufacture of a medicament for treating a human patient having alopecia areata, wherein 30 mg of the upadacitinib is to be orally administered once daily.

2. Use of upadacitinib in the manufacture of a medicament for treating a human patient having alopecia areata, wherein 15 mg of the upadacitinib is to be orally administered once daily.

3. The use of claim 1 or 2, wherein the patient is an adult.

4. The use of any one of claims 1-3, wherein the use results in an AA-IGA score of 0 or 1 at 40 weeks from the first daily administration.

5. The use of any one of claims 1-4, wherein the use results in a Severity of Alopecia Tool (SALT) 50 at 40 weeks from the first daily administration.

6. The use of any one of claims 1-4, wherein the use results in SALT 75 at 40 weeks from the first daily administration.

7. The use of any one of claims 1-4, wherein the use results in a SALT 90 at 40 weeks from the first daily administration.

8. The use of any one of claims 1-4, wherein the use results in a SALT 100 at 40 weeks from the first daily administration.

9. The use of any one of claims 1-3, wherein the use results in an AA-IGA score of 0 or 1 at 28 weeks from the first daily administration.

10. The use of any one of claims 1-4, wherein the use results in a Severity of Alopecia Tool (SALT) 50 at 28 weeks from the first daily administration.

11. The use of any one of claims 1-4, wherein the use results in SALT 75 at 28 weeks from the first daily administration.

12. The use of any one of claims 1-4, wherein the use results in a SALT 90 at 28 weeks from the first daily administration.

13. The use of any one of claims 1-4, wherein the use results in a SALT 100 at 28 weeks from the first daily administration.

14. The use of any one of claims 1-3, wherein the use results in an AA-IGA score of 0 or 1 at 16 weeks from the first daily administration.

15. The use of any one of claims 1-4, wherein the use results in a Severity of Alopecia Tool (SALT) score of ≤ 20 at 24 weeks from the first daily administration.

16. The use of any one of claims 1-4, wherein the use results in a Severity of Alopecia Tool (SALT) 50 at 16 weeks from the first daily administration.

17. The use of any one of claims 1-4, wherein the use results in a SALT 75 at 16 weeks from the first daily administration.

18. The use of any one of claims 1-4, wherein the use results in a SALT 90 at 16 weeks from the first daily administration.

19. The use of any one of claims 1-4, wherein the use results in a SALT 100 at 16 weeks from the first daily administration.

20. The use of any one of claims 1-3, wherein the use results in an AA-IGA score of 0 or 1 at 4 weeks from the first daily administration.

21. The use of any one of claims 1-4, wherein the use results in a SALT 50 at 4 weeks from the first daily administration.

22. The use of any one of claims 1-4, wherein the use results in SALT 75 at 4 weeks from the first daily administration.

23. The use of any one of claims 1-4, wherein the use results in a SALT 90 at 4 weeks from the first daily administration.

24. The use of any one of claims 1-4, wherein the use results in a SALT 100 at 4 weeks from the first daily administration.

25. The use of any one of claims 1-24, wherein the patient has moderate or severe alopecia areata.

26. The use of any one of claims 1-24, wherein the patient has severe alopecia areata.

27. The use of any one of claims 1-26, wherein the alopecia areata is localized on the fronto-parietal region of the scalp and the eyebrows.

28. The use of any one of claims 1-27, wherein the patient, prior to initiating treatment, has a serum IgE level >100 IU/ml.

29. The use of any one of claims 1-28, wherein the patient has previously received treatment with a systemic agent for alopecia areata.

30. The use of claim 29, wherein the systemic agent is cyclosporine or dupilumab.

31. The use of claim 29, wherein the systemic agent is baricitinib.

32. Use of upadacitinib in the manufacture of a medicament for treating alopecia areata in a pediatric human patient, wherein the upadacitinib is to be orally administered, and wherein:

if the pediatric patient has a body weight in a range from about 10 kg to less than about 20 kg:

(i) the upadacitinib is to be administered twice daily at a dose of 3 mg each (3 mg BID), or

(ii) the upadacitinib is to be administered twice daily at a dose of 6 mg each (6 mg BID);

if the pediatric patient has a body weight in a range from about 20 kg to less than about 30 kg:

(i) the upadacitinib is to be administered twice daily at a dose of 4 mg each (4 mg BID), or

(ii) the upadacitinib is to be administered twice daily at a dose of 8 mg each (8 mg BID); and

if the pediatric patient has a body weight of about 30 kg or greater:

(i) the upadacitinib is to be administered twice daily at a dose of 6 mg each (6 mg BID),

(ii) the upadacitinib is to be administered twice daily at a dose of 8 mg each (8 mg BID), or

(iii) the upadacitinib is to be administered once daily at a dose of 15 mg (15 mg QD).

33. The use of claim 32, wherein the twice daily dose of upadacitinib is to be administered to the pediatric patient as a stable oral pharmaceutical solution.

34. The use of claim 32 or 33, wherein the stable oral pharmaceutical solution comprises upadacitinib, a buffer and/or pH adjusting agent, a preservative, a sweetener, and water.

35. The use of any one of claims 32-34, wherein the oral solution comprises upadacitinib at a concentration of about 0.5 mg/mL or about 1 mg/mL.

36. The use of any one of claims 32-35, wherein the once daily dose of upadacitinib is to be administered to the pediatric patient as a tablet.

37. The use of any one of claims 32-36, wherein the use results in an AA-IGA score of 0 or 1 at 40 weeks from the first daily administration.

38. The use of any one of claims 32-37, wherein the use results in a Severity of Alopecia Tool (SALT) 50 at 40 weeks from the first daily administration.

39. The use of any one of claims 32-37, wherein the use results in SALT 75 at 40 weeks from the first daily administration.

40. The use of any one of claims 32-37, wherein the use results in a SALT 90 at 40 weeks from the first daily administration.

41. The use of any one of claims 32-37, wherein the use results in a SALT 100 at 40 weeks from the first daily administration.

42. The use of any one of claims 32-36, wherein the use results in an AA-IGA score of 0 or 1 at 28 weeks from the first daily administration.

43. The use of any one of claims 32-36 or 42, wherein the use results in a Severity of Alopecia Tool (SALT) 50 at 28 weeks from the first daily administration.

44. The use of any one of claims 32-36 or 42, wherein the use results in SALT 75 at 28 weeks from the first daily administration.

45. The use of any one of claims 32-36 or 42, wherein the use results in a SALT 90 at 28 weeks from the first daily administration.

46. The use of any one of claims 32-36 or 42, wherein the use results in a SALT 100 at 28 weeks from the first daily administration.

47. The use of any one of claims 32-36, wherein the use results in an AA-IGA score of 0 or 1 at 16 weeks from the first daily administration.

48. The use of any one of claims 32-36, wherein the use results in a Severity of Alopecia Tool (SALT) score of ≤ 20 at 24 weeks from the first daily administration.

49. The use of any one of claims 32-36 or 47, wherein the use results in a Severity of Alopecia Tool (SALT) 50 at 16 weeks from the first daily administration.

50. The use of any one of claims 32-36 or 47, wherein the use results in a SALT 75 at 16 weeks from the first daily administration.

51. The use of any one of claims 32-36 or 47, wherein the use results in a SALT 90 at 16 weeks from the first daily administration.

52. The use of any one of claims 32-36 or 47, wherein the use results in a SALT 100 at 16 weeks from the first daily administration.

53. The use of any one of claims 32-36, wherein the use results in an AA-IGA score of 0 or 1 at 4 weeks from the first daily administration.

54. The use of any one of claims 32-36 or 53, wherein the use results in a SALT 50 at 4 weeks from the first daily administration.

55. The use of any one of claims 32-36 or 53, wherein the use results in SALT 75 at 4 weeks from the first daily administration.

56. The use of any one of claims 32-36 or 53, wherein the use results in a SALT 90 at 4 weeks from the first daily administration.

57. The use of any one of claims 32-36 or 53, wherein the use results in a SALT 100 at 4 weeks from the first daily administration.

58. The use of any one of claims 1-57, wherein the patient has moderate or severe alopecia areata.

59. The use of any one of claims 1-57, wherein the patient has severe alopecia areata.

60. The use of any one of claims 1-59, wherein the alopecia areata is localized on the fronto-parietal region of the scalp and the eyebrows.

61. The use of any one of claims 1-60, wherein the patient, prior to initiating treatment, has a serum IgE level >100 IU/ml.

62. The use of any one of claims 1-61, wherein the patient has previously received treatment with a systemic agent for alopecia areata.

63. The use of claim 62, wherein the systemic agent is cyclosporine or dupilumab.

64. The use of claim 62, wherein the systemic agent is baricitinib.