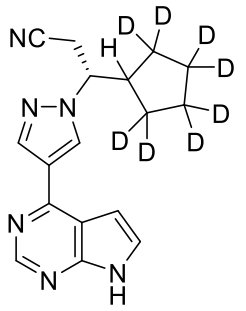
CLAIMS

1. Use of Compound (I) or a pharmaceutically acceptable salt thereof in the manufacture of a medicament for the treatment of alopecia areata, wherein the medicament is to be orally administered to a subject in need thereof at a dose of 16 mg/day or 24 mg/day of Compound (I), wherein Compound (I) is represented by the following structural formula:



Compound (I)

,

wherein each position designated specifically as deuterium has at least 95% incorporation of deuterium, and

wherein the subject has an estimated glomerular filtration rate (eGFR) of ≥30 mL/min, MDRD.

2. The use of claim 1, wherein the subject has mild to moderate renal impairment as evidenced by an eGFR of 30-89 mL/min.

3. The use of claim 1 or 2, wherein the subject has moderate renal impairment as evidenced by an eGFR of 30-59 mL/min, MDRD.

4. The use of claim 1 or 2, wherein the eGFR of the subject is between ≥60 mL/min and <90 mL/min, MDRD.

5. The use of any one of claims 1-4, wherein the subject has an absolute SALT score of ≥50 at the onset of treatment.

6. The use of any one of claims 1-4, wherein the subject has severe alopecia areata at the onset of treatment.

7. The use of any one of claims 1-6, wherein after 8 weeks of treatment the subject has an absolute SALT score of ≤20.

8. The use of any one of claims 1-6, wherein after 12 weeks of treatment the subject has an absolute SALT score of ≤20.

9. The use of any one of claims 1-6, wherein after 24 weeks of treatment the subject has an absolute SALT score of ≤20.

10. The use of claim 9, wherein after 24 weeks of treatment the subject has an absolute SALT score of ≤10.

11. The use of any one of claims 1-6, wherein after 52 weeks of treatment the subject has an absolute SALT score of ≤20.

12. The use of any one of Claims 1-6, wherein after 24 weeks of treatment the subject reports

(i) a response of "satisfied" or "very satisfied" on the Hair Satisfaction Patient Reported Outcome (SPRO) scale,

(ii) reports a response of "much improved" or "very much improved" using the Patient Global Impression of Improvement (PGI-I), or

(iii) reports a response of "much improved" or "very much improved" using the Clinical Global Impression of Improvement (CGI-I).

13. The use of any one of Claims 1-6, wherein after 12 weeks of treatment

(i) a reduction in score at least 1.5 points from baseline is reported by the subject on the Hair Satisfaction Patient Reported Outcome (SPRO) scale,

(ii) a reduction in score of at least 1.5 points from baseline is reported by the subject on the Patient Global Impression of Improvement (PGI-I),

(iii) a reduction in score of at least 1.0 point from baseline is reported by the subject on the Clinical Global Impression of Severity (CGI-S),

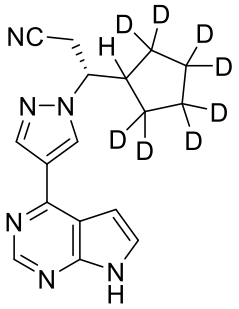
(iv) an increase in score of at least 0.5 points from baseline is achieved by the subject on the Brigham Eyelash Tool for Alopecia (BELA) or the Brigham Eyebrow Tool for Alopecia (BETA).

14. The use of any one of claims 1-13, wherein the subject is a human.

15. The use of any one of claims 1-14, wherein the medicament is to be administered at a dose of 16 mg/day of Compound (I) or a pharmaceutically acceptable salt thereof.

16. The use of claim 15, wherein the dose of 16 mg/day of Compound (I) or a pharmaceutically acceptable salt thereof is to be administered as 8 mg twice per day.

17. Use of Compound (I) or a pharmaceutically acceptable salt thereof in the manufacture of a medicament for the treatment of alopecia areata, wherein the medicament is to be orally administered to a sub-group of a population of subjects suffering from alopecia areata, at a dose of 16 mg/day or 24 mg/day of Compound (I), the sub-group of the population of subjects having an estimated glomerular filtration rate (eGFR) of ≥30 mL/min, MDRD, wherein Compound (I) is represented by the following structural formula:



Compound (I) ,

wherein each position designated specifically as deuterium has at least 95% incorporation of deuterium.

18. The use of claim 17, wherein the sub-group of the population of subjects has mild to moderate renal impairment as evidenced by an eGFR of 30-89 mL/min.

19. The use of claim 17 or 18, wherein the sub-group of the population of subjects has mild to moderate renal impairment as evidenced by an eGFR of 30-59 mL/min, MDRD.

20. The use of claim 17 or 18, wherein the eGFR of the sub-group of the population of subjects is between ≥30 mL/min, MDRD and <60 mL/min, MDRD.

21. The use of claim 17 or 18, wherein the eGFR of the sub-group of the population of subjects is between ≥60 mL/min, MDRD and <90 mL/min, MDRD.

22. The use of any one of claims 17-21, wherein the sub-group of the population of subjects has an absolute SALT score of ≥50 at the onset of treatment.

23. The use of any one of claims 17-21, wherein the sub-group of the population of subjects has moderate to severe alopecia areata at the onset of treatment.

24. The use of any one of claims 17-23, wherein after 12 weeks of treating at least 5% of the sub-group of the population of subjects has an absolute SALT score of ≤20.

25. The use of any one of claims 17-23, wherein after 24 weeks of treating at least 25% of the sub-group of the population of subjects has an absolute SALT score of ≤20.

26. The use of claim 17-23, wherein after 24 weeks of treating at least 15% of the sub-group of the population of subjects has an absolute SALT score of ≤10.