

CLAIMS

- ~~1. An antibody, antigen binding fragment thereof or a pharmaceutical formulation, which is an inhibitor of signalling through IL-13R α 1 by binding said receptor, for use in the treatment of atopic dermatitis (for example moderate to severe atopic dermatitis, in particular poorly controlled moderate to severe atopic dermatitis) by parenteral administration of a treatment cycle comprising a dose in the range 200mg to 600mg, (such as 400 to 600mg), wherein the disease is modified by a percentage reduction in EASI score in the range -20 to -100 % from the baseline.~~
- ~~1A. An antibody, antigen binding fragment thereof or a pharmaceutical formulation, which is an inhibitor of signalling through IL-13R α 1 by binding the said receptor, for use in the treatment to reduce EASI score in the range -20 to -100 % from the baseline in a patient with atopic dermatitis, for example moderate to severe atopic dermatitis (in particular poorly controlled moderate to severe atopic dermatitis) by parenteral administration of a treatment cycle comprising a dose in the range 200mg to 600mg, (such as 400 to 600mg) of an antibody or antigen binding fragment thereof, which is an inhibitor of signalling through of the IL-13R α 1 by binding the said receptor.~~
1. Use of an anti-IL-13R antibody, an antigen binding fragment or a pharmaceutical formulation thereof, which is an inhibitor of signalling through of the IL-13R α 1 by binding the said receptor, in the manufacture of a medicament to reduce EASI score in the range -20 to -100 % from the baseline in a patient with atopic dermatitis, for example moderate to severe atopic dermatitis (in particular poorly controlled moderate to severe atopic dermatitis), wherein the medicament is to be administered parentally in a treatment cycle comprising a dose in the range 200mg to 600mg; and wherein the anti-IL-13R antibody comprises a VH domain comprising an amino acid sequence shown in SEQ ID NO: 51 and a VL domain comprising an amino acid sequence shown in SEQ ID NO: 53.
- ~~2. An antibody, antigen binding fragment thereof or a pharmaceutical formulation~~Use according to claim 1,~~1A~~, wherein reduction in EASI is present after about two weeks from administration of the first dose (such as day 15).
- ~~3. An antibody, antigen binding fragment thereof or a pharmaceutical formulation~~Use according to claim 1,~~1A or 2~~, wherein reduction in EASI is present after about four weeks from administration of the first dose (day 29).
- ~~4. An antibody, antigen binding fragment thereof or a pharmaceutical formulation~~Use according to any one of claims 1,~~1A~~ to 3, wherein reduction in EASI is present after about six weeks from administration of the first dose (such as day 43).
- ~~5. An antibody or antigen binding fragment thereof~~Use according to ~~any one of~~ claims 1,~~1A~~ to 4, wherein reduction in EASI is present after about eight weeks from administration of the first dose (such as day 57).
- ~~6. An antibody, antigen binding fragment thereof or a pharmaceutical formulation~~Use according to any one of claims 1,~~1A~~ to ~~5~~5, wherein multiple doses are administered in a treatment cycle.

7. ~~An antibody or binding fragment thereof~~Use according to claim 6, wherein multiple treatment cycles are administered, for example 2, 3, 4 or more treatment cycles are administered.
8. ~~An antibody, binding fragment thereof or a pharmaceutical formulation~~Use according to claim 6 or 7, wherein following the treatment cycle or cycles and disease modification, maintenance therapy is administered, for example the same dose administered less frequently (for example monthly), or a lower dose (such as 200mg) administered the same frequency or less frequently (such as about 2 weekly, about 3 weekly, or about 4 weekly).
9. ~~An antibody, antigen binding fragment or a pharmaceutical formulation~~Use according to any one of claims 1, ~~1A~~ to 8, wherein said antibody or binding fragment thereof is administered approximately weekly, once approx. every 2 weeks, once approximately every 3 weeks, or once approximately every 4 weeks (for example monthly), (in particular a single treatment cycle, especially 8 weeks).

10. ~~An antibody, antigen binding fragment or a pharmaceutical formulation~~Use according to any one of claims 1, ~~1A~~ to 9, wherein a loading dose in the range 400 to 900mg, for example 400, 500, 600, 700, 800 or 900mg is employed before administration of the treatment cycle.
11. ~~An antibody, antigen binding fragment or a pharmaceutical formulation~~Use according to any one of claims 1, ~~1A~~ to ~~10~~9, wherein the treatment does not comprise a loading dose.
12. ~~An antibody, antigen binding fragment thereof or a pharmaceutical formulation according to any one of claims 1, 1A to 11, wherein the dose is 200mg.~~
13. ~~An antibody, antigen binding fragment thereof or a pharmaceutical formulation according to claim 12, wherein the reduction in EASI is in the range 15 to 60% (for example at about day 15).~~
14. ~~An antibody, antigen binding fragment thereof or a pharmaceutical formulation according to claim 12, or 13 wherein the reduction in EASI score is in the range 40 to 85% (eg at about day 29).~~
15. ~~An antibody, antigen binding fragment thereof or a pharmaceutical formulation according to claim 12 or 14, wherein the reduction in EASI score is in the range 25 to 85% (eg at about day 43 or 57)~~
12. Use according to any one of claims 1 to 11, wherein the dose is in the range 400 to 600 mg.
- 16.13. ~~An antibody, binding fragment thereof or a pharmaceutical formulation~~Use according to any one of claims 1 to ~~11~~12, wherein the dose is in the range 350 to 450mg, such as 400mg, for example wherein 80% of the patient population has an EASI 50 at about day 29 and/or day 57.
- 17.14. ~~An antibody, binding fragment thereof or a pharmaceutical formulation~~Use according to any one of claims 1, ~~1A~~ to ~~11~~13, wherein the dose is 600mg.
- 18.15. ~~An antibody, binding fragment thereof or a pharmaceutical formulation~~Use according to claims ~~18-13~~ or ~~17~~14, wherein the reduction in EASI score is in the range:
-25 to -60% (eg -39 to -59, such as -40 to -59, in particular -47, -48, -49, -50, -51, -52, -53, -54, -55, -56, -57, -58 or -59%) for example at about day 15;
50 to -100% (eg -55 to -97%) such as at about day 29;
range -60 to -100% (eg -70 to -97%) in particular at about day 43; or
-65 to -100% (for example -70 to -100, such as -90 to -100, in particular 91, 92, 93, 94, 95, 96, 97, 98, 99 or 100%) in particular at about day 57.
19. ~~An antibody, binding fragment thereof or a pharmaceutical formulation according to any one of claims 16 to 18, wherein the reduction in EASI is in the range 50 to 100% (eg 55 to 97%) such as at about day 29.~~
20. ~~An antibody, binding fragment thereof or a pharmaceutical formulation according to any one of claims 16 to 19, wherein the reduction in EASI is in the range 60 to 100% (eg 70 to 97%) in particular at about day 43.~~
21. ~~An antibody, binding fragment thereof or a pharmaceutical formulation according to any one of claims 16 to 20, wherein the reduction in EASI score is in the range 65 to 100% (for example 70 to 100, such as 90 to 100, in particular 91, 92, 93, 94, 95, 96, 97, 98, 99 or 100%) in particular at about day 57.~~

~~22.16. An antibody, binding fragment thereof or a pharmaceutical formulation~~Use according to any one of claims ~~16-13~~ to ~~21~~15, wherein 90% of the patient population has an EASI 50 at about day 57.

~~23.17. An antibody, binding fragment or a pharmaceutical formulation~~Use according to any one of claims 1, ~~1A~~ to ~~21~~16, wherein the treatment cycles comprises, a first dose at 600mg, followed by three weekly doses of 400mg, e.g. wherein the treatment cycle is repeated twice i.e. two treatment cycles lasting 8 weeks, in particular day 1 600mg, approx. day 8 400mg, approx. day 15

400mg, approx. day 22 400mg, approx. day 29 600mg, approx. day 36 400mg, approx. day 43 400mg, and approx. day 50 400mg are administered.

~~24.18. An antibody, binding fragment or a pharmaceutical formulation~~Use according to any one of claims 1, ~~1A~~ to ~~23~~17, wherein disease modification, occurs by day 4, wherein day 1 is the first administration of the antibody or binding fragment thereof, for example wherein the disease modification is a reduction in EASI score, such as wherein the reduction is a percentage from base line in the range -10 to 55%.

~~25.19. An antibody, binding fragment thereof or a pharmaceutical formulation~~Use according to any one of claims 1, ~~1A~~ to ~~24~~18, wherein the disease modification in the range -40 to -100% is achieved by about day 57 following first administration on day 1, e.g. maximum disease modification is achieved by about day 57.

20. Use according to any one of claims 1 to 19, wherein the incidence of side effects in the eyes are reduced in comparison to treatment with the therapeutic dose of dupilumab for treatment of the same.

~~26. A method of treating a patient to reduce EASI score in the range -20 to -100 % from the baseline in a patient with atopic dermatitis, for example moderate to severe atopic dermatitis (in particular poorly controlled moderate to severe atopic dermatitis) by parenteral administration of a treatment cycle comprising a dose in the range 200mg to 600mg of an antibody, antigen binding fragment thereof or a pharmaceutical formulation, which is an inhibitor of signalling through of the IL-13R α 1 by binding the said receptor, according to any one of claims 1 to 25.~~

~~27. Use of an antibody, antigen binding fragment or a pharmaceutical formulation, which is an inhibitor of signalling through of the IL-13R α 1 by binding the said receptor, according to any one of claims 1 to 25, for use in the manufacture of a medicament to reduce EASI score in the range -20 to -100 % from the baseline in a patient with atopic dermatitis, for example moderate to severe atopic dermatitis (in particular poorly controlled moderate to severe atopic dermatitis) by parenteral administration of a treatment cycle comprising a dose in the range 200mg to 600mg.~~