

CLAIMS

1. Use of a BTK inhibitor, e.g. a selective BTK inhibitor, e.g. LOU064 in the manufacture of a medicament for the treatment and/or prevention of Hidradenitis Suppurativa (HS).
2. The use according to claim 1 wherein LOU064 is to be administered at a dose of from about 50mg to about 200mg daily.
3. The use according to claim 2 wherein LOU064 is to be administered at a dose from about 25mg twice a day to about 100mg twice a day.
4. The use according to claim 2 wherein LOU064 is to be administered at a dose of about 100mg twice daily.
5. The use according to claim 2 wherein LOU064 is to be administered at a dose of about 25mg twice daily.
6. The use according to any one of claims 1 to 5 wherein LOU064 is to be administered for a short term, e.g. less than 6 months, preferably less than 3 months.
7. The use according to claim 6 wherein LOU064 is to be administered during up to 16 weeks, e.g. 4, 12 or 16 weeks.
8. The use according to any one of claims 1 to 5 wherein LOU064 is to be administered for a long term; e.g. more than 6 months, more than a year, chronic use.
9. The use according to any one of claims 1 to 8 wherein LOU064 is to be administered as a monotherapy.
10. The use according to any one of claims 1 to 9 wherein LOU064 is not to be administered concomitantly with a strong inhibitor of CYP3A.
11. The use according to any one of claims 1 to 10, wherein LOU064 is not to be administered concomitantly with a strong inhibitor of CYP3A4.
12. The use according to any one of claims 1 to 8, wherein LOU064 or a pharmaceutical composition comprising it, is to be administered in combination with one or more second therapeutic agents.

13. Use of a combination product comprising a therapeutically effective dose of LOU064 and one or more therapeutic agents, in the manufacture of a medicament for the treatment and/or prevention of HS in a patient in need of such treatment and/or prevention.

14. The use according to claim 13 wherein the patient is additionally to be treated with at least one topical medication and at least one antiseptic in combination with LOU064.

15. The use according to any one of claims 1 to 11 wherein, prior to treatment with the LOU064 the patient has not been previously treated with a systemic agent or a topical treatment for HS.

16 The use according to any one of claims 1 to 15 wherein the patient is selected according to at least one of the following criteria:

- a) the patient has moderate to severe HS;
- b) prior to treatment with the LOU064, the patient has at least 3 inflammatory lesions; or
- c) prior to treatment with the LOU064, the patient does not have extensive scarring no more than 15 fistulae) as a result of HS;
- d) the patient has a clinical diagnosis of HS for at least 12 months;
- e) the patient has at least two anatomical areas involved with HS lesions.

17. The use according to any one of claims 1 to 16, wherein said patient achieves by week 16 of treatment at least one of the following:

- a) a simplified HiSCR;
- b) a reduction in HS flares;
- c) a pain reduction as measured by pain NRS, e.g. a pain NRS30 ;
- d) a skin itch reduction as measured by itch NRS, e.g. a skin itch NRS30
- f) a reduction in total or different types of HS inflammatory lesion counts, e.g. AN50, AN75, AN90 or AN100;
- g) a reduction in IHS4 score;
- h) a reduction of ≤ 6 as measured by the DLQI; and/or
- i) an improvement in DLQI.

18. The use according to any of claims 1 to 17, wherein, when said use is for the treatment of a population of patients with moderate to severe HS, at least 40% of said patients achieve by

week 16 at least one of the following:

- a) a HiSCR50;
- b) a HiSCR75;
- c) a HiSCR90; or
- d) a simplified HiSCR.

19. The use according to any one of claims 1 to 17, wherein by week 16 of treatment, at least 25% of said patients achieve a NRS30 response (e.g. a pain NRS30 or a skin itch NRS30 response); or less than 15% of said patients experience an HS flare.

20. The use according to any one of claims 1 to 17, wherein the patient has at least one of the following as early as one or two weeks after the first dose of LOU064:

- a) a reduction in pain, as measured by pain NRS, e.g. patient achieving pain NRS30,
- b) a reduction in skin itch, as measured by itch NRS; e.g. patient achieving skin itch NRS30,
- c) a reduction in CRP, as measured using a standard CRP assay, at least 25% reduction.

21. The use according to any one of claims 1 to 20 wherein said patient achieves a sustained response 3 months after the end of the treatment, as measured by inflammatory lesion count e.g. AN50, Hidradenitis Suppurativa Clinical Response (HiSCR) (e.g. sHiSCR, HiSCR50, HiSCR75 or HiSCR90), itch or pain Numerical Rating Scale (NRS), Hidradenitis Suppurativa - Physician Global Assessment (HS-PGA), severity assessment of HS (SASH), international HS severity score system (IHS4) or Dermatology Life Quality Index (DLQI).

22. The use according claim 21, wherein said patient achieves a sustained response 3 months after the end of treatment, as measured by the simplified HiSCR (sHiSCR), HiSCR50, HiSCR75 or HiSCR90.

23. The use according to any one of claims 1 to 22 wherein LOU064 is disposed in a pharmaceutical composition, wherein said pharmaceutical composition comprises one or more

pharmaceutically acceptable carriers, each of which is independently selected from a filler, a lubricant, a binder, a disintegrant and a glidant.

24. The use according to claim 23, wherein the pharmaceutical composition is in tablet or capsule form.

25. The use according to claim 23 or 24, wherein the pharmaceutical composition comprises nanosized particles of LOU064.

26. The use according to claim 25, wherein the pharmaceutical composition comprises nanosized particles of LOU064 having a mean particle size as measured by PCS of between about 50 nm to about 750 nm.

27. The use according to any one of claims 23 to 26, wherein the pharmaceutical composition comprises LOU064 and binder at a weight ratio of about 2 : 1.

28. The use according to claim 27 wherein the pharmaceutical composition comprises LOU064, binder and surfactant at a weight ratio of about 2 : 1 : 0.08.

29. The use according to any one of claims 23 to 26, wherein the pharmaceutical composition comprises LOU064 and binder at a weight ratio of about 1 : 1.

30. The use according to claim 29, wherein the pharmaceutical composition comprises LOU064, binder and surfactant at a weight ratio of about 1 : 1 : 0.05.

31. The use according to any one of claims 23 to 30, wherein the pharmaceutical composition comprises LOU064, polyvinylpyrrolidone-vinyl acetate copolymer as a binder and sodium lauryl sulfate as a surfactant.

32. The use according to any one of previous claims wherein LOU064 is a crystalline form

of the anhydrous free base characterized by an x-ray powder diffraction pattern comprising one or more representative peaks in terms of 2θ selected from the group consisting of $7.8 \pm 0.2^\circ$, $9.2 \pm 0.2^\circ$, $12.0 \pm 0.2^\circ$, $13.6 \pm 0.2^\circ$, $15.6 \pm 0.2^\circ$, $16.0 \pm 0.2^\circ$, $17.8 \pm 0.2^\circ$, $18.3 \pm 0.2^\circ$, $18.7 \pm 0.2^\circ$, $19.2 \pm 0.2^\circ$, $19.9 \pm 0.2^\circ$, $22.1 \pm 0.2^\circ$, $23.4 \pm 0.2^\circ$, $23.9 \pm 0.2^\circ$, $24.8 \pm 0.2^\circ$, $25.2 \pm 0.2^\circ$, $25.5 \pm 0.2^\circ$, $27.2 \pm 0.2^\circ$, and $29.6 \pm 0.2^\circ$, when measured at a temperature of about 25°C and an x-ray wavelength, λ , of $1.5405 \text{ \AA}$.

33. A BTK inhibitor, e.g. a selective BTK inhibitor, e.g. LOU064 for use in the treatment and/or prevention of HS.

34. A combination product comprising a therapeutically effective dose of LOU064 and one or more therapeutic agents, for use in the treatment and/or prevention of HS in a patient in need of such treatment and/or prevention