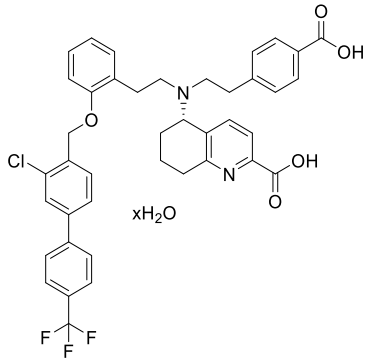
Patent claims:

1. Use of a crystalline monohydrate form of Compound 1:



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in the manufacture of a medicament for the treatment and/or prophylaxis of a cardiopulmonary disease or disorder in a subject, wherein:

about 240 µg to about 4000 µg of the crystalline monohydrate form is for administration to the subject; and

the X-ray powder diffractogram (measured at 25°C and with Cu-K alpha 1 as radiation source) of the crystalline monohydrate form comprises at least one reflection at 6.9 ± 0.2 °2θ, 7.2 ± 0.2 °2θ, 7.3 ± 0.2 °2θ, 12.8 ± 0.2 °2θ, 15.2 ± 0.2 °2θ, 16.0 ± 0.2 °2θ, 23.0 ± 0.2 °2θ, 25.8 ± 0.2 °2θ, or 29.2 ± 0.2 °2θ.

2. The use of claim 1, wherein the crystalline monohydrate form is for administration in an inhalative dosage form.

3. The use of claim 2, wherein the inhalative dosage form comprises the crystalline monohydrate form as a dry powder.

4. The use of claim 3, wherein the dry powder is within a capsule.

5. The use of any one of claims 2-4, wherein the inhalative dosage form further comprises lactose monohydrate.

6. The use of claim 5, wherein the lactose monohydrate comprises coarse and fine lactose.

7. The use of any one of claims 1-6, wherein the crystalline monohydrate form is for administration via a dry powder inhaler.

8. Use of a dry powder formulation in the manufacture of a medicament for the treatment and/or prophylaxis of a cardiopulmonary disease or disorder in a subject, wherein:

the dry powder formulation comprises from about 240 μg to about 4000 μg of the crystalline monohydrate form of claim 1, wherein the X-ray powder diffractogram (measured at 25°C and with Cu-K alpha 1 as radiation source) comprises at least one reflection at 6.9 ± 0.2 °2θ, 7.2 ± 0.2 °2θ, 7.3 ± 0.2 °2θ, 12.8 ± 0.2 °2θ, 15.2 ± 0.2 °2θ, 16.0 ± 0.2 °2θ, 23.0 ± 0.2 °2θ, 25.8 ± 0.2 °2θ, or 29.2 ± 0.2 °2θ; and

the dry powder formulation is for administration to the subject via a dry powder inhaler.

9. Use of a dry powder formulation in the manufacture of a medicament for the treatment and/or prophylaxis of a cardiopulmonary disease or disorder in a subject, wherein:

the dry powder formulation comprises from about 240 μg to about 4000 μg of the crystalline monohydrate form of claim 1, wherein the X-ray powder diffractogram (measured at 25°C and with Cu-K alpha 1 as radiation source) comprises at least one reflection at 6.9 ± 0.2 °2θ, 7.2 ± 0.2 °2θ, 7.3 ± 0.2 °2θ, 12.8 ± 0.2 °2θ, 15.2 ± 0.2 °2θ, 16.0 ± 0.2 °2θ, 23.0 ± 0.2 °2θ, 25.8 ± 0.2 °2θ, or 29.2 ± 0.2 °2θ;

the dry powder formulation is within a capsule; and

the dry powder formulation is for administration to the subject via a dry powder inhaler.

10. The use of any one of claims 1-9, wherein the crystalline monohydrate form has X-ray powder diffraction reflections at 12.8 ± 0.2 °2θ and 29.2 ± 0.2 °2θ, and at least one additional reflection at 6.9 ± 0.2 °2θ, 7.2 ± 0.2 °2θ, 7.3 ± 0.2 °2θ, 15.2 ± 0.2 °2θ, or 23.0 ± 0.2 °2θ.

11. The use of any one of claims 1-9, wherein the crystalline monohydrate form has X-ray powder diffraction reflections at 12.8 ± 0.2 °2θ, 16.0 ± 0.2 °2θ, and 25.8 ± 0.2 °2θ, and at least one additional reflection at 6.9 ± 0.2 °2θ, 7.2 ± 0.2 °2θ, 7.3 ± 0.2 °2θ, or 15.2 ± 0.2 °2θ.

12. The use of any one of claims 1-9, wherein the crystalline monohydrate form has X-ray powder diffraction reflections at 12.8 ± 0.2 °2θ, 20.5 ± 0.2 °2θ, and 25.8 ± 0.2 °2θ, and at least one additional reflection at 6.9 ± 0.2 °2θ, 7.2 ± 0.2 °2θ, 7.3 ± 0.2 °2θ, 15.2 ± 0.2 °2θ, or 25.1 ± 0.2 °2θ.

13. The use of any one of claims 1-12, wherein the crystalline monohydrate form is for administration at a dose of about 480 μg to about 4000 μg.

14. The use of claim 13, wherein the crystalline monohydrate form is for administration at a dose of about 480 μg to about 2000 μg.

15. The use of claim 13 or claim 14, wherein the crystalline monohydrate form is for administration at a dose of about 1000 μg.

16. The use of claim 13 or claim 14, wherein the crystalline monohydrate form is for administration at a dose of about 2000 μg.

17. The use of claim 13, wherein the crystalline monohydrate form is for administration at a dose of about 4000 μg.

18. The use of any one of claims 8-17, wherein the dry powder formulation further comprises lactose monohydrate.

19. The use of claim 18, wherein the lactose monohydrate comprises coarse and fine lactose.

20. The use of any one of claims 1-19, wherein the crystalline monohydrate form is for administration once or twice daily.

21. The use of claim 20, wherein the crystalline monohydrate form is for administration once daily.

22. The use of claim 20, wherein the crystalline monohydrate form is for administration twice daily.

23. The use of any one of claims 1-22, wherein the crystalline monohydrate form is for administration for at least two consecutive days.

24. The use of any one of claims 1-22, wherein the crystalline monohydrate form is for administration for from about two to about five consecutive days.

25. The use of any one of claims 1-22, wherein the crystalline monohydrate form is for administration for from about two to about seven consecutive days.

26. The use of any one of claims 1-22, wherein the crystalline monohydrate form is for administration for at least five consecutive days.

27. The use of any one of claims 1-22, wherein the crystalline monohydrate form is for administration for at least seven consecutive days.

28. The use of any one of claims 1-22, wherein the crystalline monohydrate form is for administration for a period of at least fourteen consecutive days.

29. The use of any one of claims 1-28, wherein the crystalline monohydrate form is for administration after onset of the cardiopulmonary disease or disorder.

30. The use of any one of claims 1-29, wherein the cardiopulmonary disease or disorder is selected from pulmonary arterial hypertension (PAH) and pulmonary hypertension (PH) associated with chronic lung disease (PH group 3).

31. The use of claim 30, wherein the pulmonary hypertension associated with chronic lung disease (PH group 3) is pulmonary hypertension in chronic obstructive pulmonary disease (PH-COPD) or pulmonary hypertension with idiopathic interstitial pneumonia (PH-IIP).