Claims

1. Use of Treprostinil or a pharmaceutically acceptable salt or derivative thereof in the manufacture of a medicament for the treatment of pulmonary hypertension in a subject being diagnosed with pulmonary hypertension or for the prevention of pulmonary hypertension in a subject being at risk of developing pulmonary hypertension, wherein the medicament is to be administered comprises the steps of

i) said subject is to be administered a first liquid composition comprising Treprostinil or a pharmaceutically acceptable salt or derivative thereof in a first concentration in aerosolized form for a first treatment period, and

ii) said subject is to be administered a second liquid composition comprising Treprostinil or a pharmaceutically acceptable salt or derivative thereof in a second concentration in aerosolized form for a second treatment period following the first treatment period;

wherein the second concentration of Treprostinil or a pharmaceutically acceptable salt or derivative thereof in the second liquid composition is higher than the first concentration of Treprostinil or a pharmaceutically acceptable salt or derivative thereof in the first liquid composition, and

wherein the first and the second liquid compositions are aerosolized and is to be administered to said subject using a soft mist inhaler.

2. The use according to claim 1, wherein the medicament is to be administered further comprises the step of

iii) said subject is to be administered a third liquid composition comprising Treprostinil or a pharmaceutically acceptable salt or derivative thereof in a third concentration in aerosolized form for a third treatment period following the second treatment period;

wherein the third concentration of Treprostinil or a pharmaceutically acceptable salt or derivative thereof in the third liquid composition is higher than the second concentration of Treprostinil or a pharmaceutically acceptable salt or derivative thereof in the second liquid composition, and

wherein the third liquid composition is aerosolized and is to be administered to said subject using a soft mist inhaler.

3. The use according to any one of the preceding claims, wherein the concentration of Treprostinil or a pharmaceutically acceptable salt or derivative thereof in the first liquid composition is selected within a range of from about 1 mg/mL to about 3 mg/mL.

4. The use according to any one of the preceding claims, wherein the concentration of Treprostinil or a pharmaceutically acceptable salt or derivative thereof in the second liquid composition is selected within a range of from about 2 mg/mL to about 4 mg/mL.

5. The use according to any one of claims 2-4, wherein the concentration of Treprostinil or a pharmaceutically acceptable salt or derivative thereof in the third liquid composition is selected within a range of from about 3 mg/mL to about 6 mg/mL.

6. The use according to any one of the preceding claims, wherein the first, the second and the optional third liquid composition each is an aqueous solution comprising an aqueous solvent or mixture of solvents.

7. The use according to any one of the preceding claims, wherein the first, the second and the optional third liquid composition further comprises one or more pharmaceutically acceptable excipients.

8. The use according to any one of the preceding claims, wherein the duration of the first treatment period is selected within the range of from about 1 day to about 15 days.

9. The use according to any one of the preceding claims, wherein the duration of the second treatment period is selected within the range of from about 1 day to about 15 days.

10. The use according to any one of the preceding claims, wherein the amount of Treprostinil or a pharmaceutically acceptable salt or derivative thereof is to be administered in a single event during the first treatment period is selected

with the range of from about 10 μg to about 25 μg, preferably of from about 15 μg to about 20 μg.

11. The use according to any one of the preceding claims, wherein the amount of Treprostinil or a pharmaceutically acceptable salt or derivative thereof is to be administered in a single event during the second treatment period is selected with the range of from about 25 μg to about 50 μg, preferably of from about 30 μg to about 40 μg.

12. The use according to any one of claims 2-11, wherein the amount of Treprostinil or a pharmaceutically acceptable salt or derivative thereof is to be administered in a single event during the third treatment period is selected with the range of from about 40 μg to about 70 μg, preferably of from about 45 μg to about 60 μg.

13. The use according to any one of the preceding claims, wherein the amount of Treprostinil or a pharmaceutically acceptable salt or derivative thereof is to be administered in a single event during the first, second and optional third treatment period is to be administered in one breath each upon a single activation of the soft mist inhaler upon which a single metered dose of Treprostinil or a pharmaceutically acceptable salt or derivative is dispensed.

14. The use according to any one of the preceding claims, wherein Treprostinil or a pharmaceutically acceptable salt or derivative thereof is to be administered to the subject during the first treatment period in a daily dose selected within a range of from about 40 μg to about 100 μg.

15. The use according to any one of the preceding claims, wherein Treprostinil or a pharmaceutically acceptable salt or derivative thereof is to be administered to the subject during the second treatment period in a daily dose selected within a range of from about 100 μg to about 200 μg.

16. The use according to any one of claims 2-15, wherein Treprostinil or a pharmaceutically acceptable salt or derivative thereof is to be administered to the subject during the third treatment period in a daily dose selected within a range of from about 160 μg to about 280 μg.

17. The use according to any one of the preceding claims, wherein Treprostinil or a pharmaceutically acceptable salt or derivative thereof in the first, the second and the optional third liquid composition is Treprostinil sodium.

18. The use according to any one of the preceding claims, wherein the soft mist inhaler is adapted to generate an aerosol or plume of aerosol of the first, second and optional third liquid composition having an average velocity of 1.0 to 2.5 m/s, preferably of 1.3 to 2.1 m/s.

19. The use according to any one of the preceding claims, wherein the soft mist inhaler is adapted to hold the first, second and the optional third liquid composition comprising Treprostinil or a pharmaceutically acceptable salt or derivative thereof at atmospheric pressure.

20. The use according to any one of the preceding claims, wherein the soft mist inhaler is adapted to aerosolize the first, second and optional third liquid composition comprising Treprostinil or a pharmaceutically acceptable salt or derivative thereof by an entirely mechanical mechanism, preferably by a mechanism that does not comprise electronic means.

21. The use according to any one of the preceding claims, wherein the soft mist inhaler comprises a nozzle for the aerosolization of the first, second and optional third liquid composition comprising Treprostinil or a pharmaceutically acceptable salt or derivative thereof.

22. The use according to any one of the preceding claims, wherein the soft mist inhaler comprises a pumping unit adapted to generate a working pressure of the first second and optional third liquid composition comprising Treprostinil or a pharmaceutically acceptable salt or derivative thereof within the range of from about 50 to about 350 bar.

23. The use according to any one of the preceding claims, wherein the soft mist inhaler is an impingement-type soft mist inhaler having at least one nozzle with at least two ejection channels adapted to generate at least two jets of the first, second and optional third liquid composition comprising Treprostinil or a pharmaceutically acceptable salt or derivative thereof that intersect to generate an aerosol.

24. The use according to any one of the preceding claims, wherein the soft mist inhaler is a hand-held inhalation device for delivering a nebulised medically active aerosol for inhalation therapy, comprising

(a) a housing having a user-facing side;

(b) an impingement-type nozzle for generating the nebulised aerosol by collision of at least two liquid jets, the nozzle being firmly affixed to the user-facing side of the housing such as to be immobile relative to the housing;

(c) a fluid reservoir arranged within the housing; and

(d) a pumping unit arranged within the housing, the pumping unit having

- an upstream end that is fluidically connected to the fluid reservoir;
- a downstream end that is fluidically connected to the nozzle;

wherein the pumping unit is adapted for pumping fluid from the fluid reservoir to the nozzle;

wherein the pumping unit further comprises

(i) a riser pipe having an upstream end, wherein the riser pipe is

- adapted to function as a piston in the pumping unit, and
- firmly affixed to the user-facing side of the housing such as to be immobile relative to the housing; and

(ii) a hollow cylinder located upstream of the riser pipe, wherein the upstream end of the riser pipe is inserted in the cylinder such that the cylinder is longitudinally movable on the riser pipe;

(iii) a lockable means for storing potential energy when locked and for releasing the stored energy when unlocked, the means being arranged outside of, and mechanically coupled to, the cylinder such that unlocking the means results in a propulsive longitudinal movement of the cylinder towards the downstream end of the pumping unit.

25. A kit comprising

a) a first liquid composition comprising Treprostinil or a pharmaceutically acceptable salt or derivative thereof in a first concentration; and

b) a second liquid composition comprising Treprostinil or a pharmaceutically acceptable salt or derivative thereof in a second concentration; and optionally

c) a third liquid composition comprising Treprostinil or a pharmaceutically acceptable salt or derivative thereof in a third concentration;

wherein the second concentration of Treprostinil or a pharmaceutically acceptable salt or derivative thereof in the second liquid composition is higher than the first concentration of Treprostinil or a pharmaceutically acceptable salt or derivative thereof in the first liquid composition and wherein the third concentration of Treprostinil or a pharmaceutically acceptable salt or derivative thereof in the optional third liquid composition is higher than the second concentration of Treprostinil or a pharmaceutically acceptable salt or derivative thereof in the second liquid composition.

26. The kit according to claim 25, wherein the first, the second and the optional third liquid composition comprising Treprostinil or a pharmaceutically acceptable salt or derivative thereof are provided separately in a first, a second and an optional third container.

27. The kit according to claim 25 or 26, further comprising a first, a second and optionally a third soft mist inhaler, wherein each soft mist inhaler comprises one of the first, second and optionally third liquid composition.

28. The kit according to claim 26, further comprising a single soft mist inhaler adapted to consecutively receive the first, second and optional third container.

29. The kit according to any one of claims 25 to 28, further comprising instructions for use of the first, second and optional third container.