

We claim:

1. An inhalable composition comprising: 2-{4-[(2S)-1,1-difluoro-2-hydroxypropyl]phenyl}-N-{4-[3-(2-ethylphenyl)pyrazine-2-yl] phenyl}acetamide (compound (I)) or a pharmaceutically acceptable salt thereof
2. An inhalable composition comprising: 2-{4-[(2S)-1,1-difluoro-2-hydroxypropyl]phenyl}-N-{4-[3-(2-ethylphenyl)pyrazine-2-yl] phenyl}acetamide (compound (I)) or a pharmaceutically acceptable salt thereof and one or more pharmaceutically acceptable excipient(s).
3. An inhalable composition comprising: a therapeutically effective dosage amount of 2-{4-[(2S)-1,1-difluoro-2-hydroxypropyl]phenyl}-N-{4-[3-(2-ethylphenyl)pyrazine-2-yl] phenyl}acetamide (compound (I)) or a pharmaceutically acceptable salt thereof and one or more pharmaceutically acceptable excipient(s).
4. An inhalable dry powder composition comprising: 2-{4-[(2S)-1,1-difluoro-2-hydroxypropyl]phenyl}-N-{4-[3-(2-ethylphenyl)pyrazine-2-yl] phenyl}acetamide (compound (I)) or a pharmaceutically acceptable salt thereof.
5. An inhalable dry powder composition comprising: a therapeutically effective dosage amount of 2-{4-[(2S)-1,1-difluoro-2-hydroxypropyl]phenyl}-N-{4-[3-(2-ethylphenyl)pyrazine-2-yl] phenyl}acetamide (compound (I)) or a pharmaceutically acceptable salt thereof.
6. An inhalable dry powder composition comprising: a therapeutically effective dosage amount of 2-{4-[(2S)-1,1-difluoro-2-hydroxypropyl]phenyl}-N-{4-[3-(2-ethylphenyl)pyrazine-2-yl] phenyl}acetamide (compound (I)) or a pharmaceutically acceptable salt thereof and one or more pharmaceutically acceptable excipient(s).
7. The composition of the claim 5 and the claim 6, wherein the therapeutically effective dosage amount of the compound (I) is in the range of from about 0.1 mg to about 20 mg.

8. The composition of the claim 6, wherein the pharmaceutically acceptable excipient(s) is selected from lactose, glucose, maltose, erythritol, sorbitol, raffinose, xylitol, maltitol, inositol, fructose, sucrose, dextrose, mannitol, trehalose, cyclodextrin and the mixtures thereof.
9. The composition of the claim 6, wherein the pharmaceutically acceptable excipient(s) is one or more inhalable grades of lactose.
10. The composition of the claims 4, 5 and 6, wherein the compound (I) is micronized.
11. The composition of the claims 4, 5 and 6, wherein d_{90} particle size of the compound (I) or a pharmaceutically acceptable salt thereof is less than about 10 microns.
12. The composition of the claims 4, 5 and 6, wherein d_{90} particle size of the compound (I) or a pharmaceutically acceptable salt thereof is less than about 5 microns.
13. The composition of the claim 9, wherein the weight ratio between compound (I) to lactose is from about 1:1 to about 1:100.
14. The composition of the claim 9, wherein the weight ratio between compound (I) to lactose is selected from 1:1, 1:2, 1:3, 1:4, 1:5, 1:6, 1:7, 1:8, 1:9, 1:10, 1:11, 1:12, 1:13, 1:14, 1:15, 1:16, 1:17, 1:18, 1:19, 1:20, 1:21, 1:22, 1:23, 1:24, 1:25, 1:26, 1:27, 1:28, 1:29, 1:30, 1:31, 1:32, 1:33, 1:34, 1:35, 1:36, 1:37, 1:38, 1:39, 1:40, 1:41, 1:42, 1:43, 1:44, 1:45, 1:46, 1:47, 1:48, 1:49, and 1:50.
15. The composition of the claim 9, wherein the weight ratio between compound (I) to lactose is selected from 1:1, 1:1.5, 1:3, 1:7, 1:19 and 1:39.
16. The composition of the claim 9, wherein the d_{90} particle size of inhalable grades of lactose is in the range of from about 1 micron to about 200 microns.

17. The composition of the claim 9, wherein the d_{90} particle size of an inhalable grade of lactose is less than about 60 microns.
18. The composition of the claim 9, wherein the d_{90} particle size of an inhalable grade of lactose is less than about 190 microns.
19. The composition of the claim 9, wherein the composition has particles with fine particle fraction in the range of from about 1% to about 99%.
20. The composition of the claim 9, wherein the composition has particles with fine particle fraction at least about 60%.
21. The composition of the claim 9, wherein the composition has particles with fine particle fraction in the range of from about 15% to about 60%.
22. The composition of the claim 9, wherein the composition has fine particle mass from about 5 mcg to about 6000 mcg.
23. The composition of the claim 6, wherein the composition has fine particle mass at least about 5 mcg.
24. The composition of the claim 9, wherein the composition has fine particle mass in the range of from about 50 mcg to about 6000 mcg.
25. The composition of the claim 9, wherein the composition comprises about 0.5 mg of compound (I) or a pharmaceutically acceptable salt thereof and one or more pharmaceutically acceptable excipient(s); wherein the composition has fine particle mass in the range of from about 50 mcg to about 200 mcg.
26. The composition of the claim 9, wherein the composition comprises about 1 mg of compound (I) or a pharmaceutically acceptable salt thereof and one or more pharmaceutically acceptable excipient(s); wherein the composition has fine particle mass in the range of from about 10 mcg to about 400 mcg.

27. The composition of the claim 9, wherein the composition comprises about 2.5 mg of compound (I) or a pharmaceutically acceptable salt thereof and one or more pharmaceutically acceptable excipient(s); wherein the composition has fine particle mass in the range of from about 500 mcg to about 1000 mcg.

28. The composition of the claim 9, wherein the composition comprises about 5 mg of compound (I) or a pharmaceutically acceptable salt thereof and one or more pharmaceutically acceptable excipient(s); wherein the composition has fine particle mass in the range of from about 1000 mcg to about 3000 mcg.

29. The composition of the claim 9, wherein the composition comprises about 10 mg of compound (I) or a pharmaceutically acceptable salt thereof and one or more pharmaceutically acceptable excipient(s); wherein the composition has fine particle mass in the range of from about 3000 mcg to about 6000 mcg.

30. The composition of the claim 9, wherein mass median aerodynamic diameter of the compound (I) in said composition is in the range of from about 1 micron to about 6 microns.

31. The composition of the claim 9, wherein the inhalable dry powder composition comprising i) a therapeutically effective dosage amount of compound (I) or a pharmaceutically acceptable salt thereof; ii) lactose particles having a d_{90} particle size less than about 50 microns; iii) lactose particles having a d_{90} particle size less than about 200 microns, wherein the average particle size of compound (I) or a pharmaceutically acceptable salt thereof is from about 0.1 microns to about 10 microns.

32. The composition of the claim 9, wherein the inhalable dry powder composition comprising a therapeutically effective dosage amount of compound (I) or a pharmaceutically acceptable salt thereof, in the range of from about 0.1 mg to about 20 mg and a lactose component.

33. The composition of the claim 9, wherein the inhalable dry powder composition comprising a therapeutically effective dosage amount of compound (I) or a pharmaceutically acceptable salt thereof, in the range of from about 0.1 mg to about 20 mg and a lactose component, wherein the lactose component is in the amount of from 0 mg to about 19.9 mg.

34. The composition of the claim 9, wherein the inhalable dry powder composition comprising a therapeutically effective dosage amount of compound (I) or a pharmaceutically acceptable salt thereof, in the range of from about 0.1 mg to about 20 mg and a lactose component, wherein the lactose component comprises lactose particles having d_{90} particle size less than about 60 microns and in the amount of from 0 mg to about 19.9 mg.

35. The composition of the claim 9, wherein the inhalable dry powder composition comprising 0.5 mg of compound (I) or a pharmaceutically acceptable salt thereof, and a lactose component, wherein the lactose component comprises lactose particles having a d_{90} particle size less than about 60 microns and in the amount of from about 1 mg to about 19.5 mg.

36. The composition of the claim 9, wherein the inhalable dry powder composition comprising 1 mg of compound (I) or a pharmaceutically acceptable salt thereof, and a lactose component, wherein the lactose component comprises lactose particles having a d_{90} particle size less than about 60 microns and in the amount of from about 1 mg to about 19 mg.

37. The composition of the claim 9, wherein the inhalable dry powder composition comprising 2.5 mg of compound (I) or a pharmaceutically acceptable salt thereof, and a lactose component, wherein the lactose component comprises lactose particles having a d_{90} particle size less than about 60 microns and in the amount of from about 1 mg to about 17.5 mg.

38. The composition of the claim 9, wherein the inhalable dry powder composition comprising 5 mg of compound (I) or a pharmaceutically acceptable salt thereof, and a lactose component, wherein the lactose component comprises lactose particles having a d_{90} particle size less than about 60 microns and in the amount of from about 1 mg to about 15mg.

39. The composition of the claim 9, wherein the inhalable dry powder composition comprising 10 mg of compound (I) or a pharmaceutically acceptable salt thereof, and a lactose component, wherein the lactose component comprises lactose particles having a d_{90} particle size less than about 60 microns and in the amount of from about 1 mg to about 10 mg.

40. The composition of the claim 9, wherein the inhalable dry powder composition comprising a therapeutically effective dosage amount of compound (I) or a pharmaceutically acceptable salt thereof, in the range of from about 0.1 mg to about 20 mg and a lactose component, wherein the lactose component comprises lactose particles having d_{90} particle size less than about 190 microns and in the amount of from about 1 mg to about 19.9 mg.

41. The composition of the claim 9, wherein the inhalable dry powder composition comprising 0.5 mg of compound (I) or a pharmaceutically acceptable salt thereof, and a lactose component, wherein the lactose component comprises lactose particles having a d_{90} particle size less than about 190 microns and in the amount of from about 1 mg to about 19.5 mg.

42. The composition of the claim 9, wherein the inhalable dry powder composition comprising 1 mg of compound (I) or a pharmaceutically acceptable salt thereof, and a lactose component, wherein the lactose component comprises lactose particles having a d_{90} particle size less than about 190 microns and in the amount of from about 1 mg to about 19 mg.

43. The composition of the claim 9, wherein the inhalable dry powder composition comprising 2.5 mg of compound (I) or a pharmaceutically acceptable salt thereof, and a lactose component, wherein the lactose component comprises lactose particles having a d_{90} particle size less than about 190 microns and in the amount of from about 1 mg to about 17.5 mg.

44. The composition of the claim 9, wherein the inhalable dry powder composition comprising 5 mg of compound (I) or a pharmaceutically acceptable salt thereof, and a lactose component, wherein the lactose component comprises lactose particles having a d_{90} particle size less than about 190 microns and in the amount of from about 1 mg to about 15 mg.

45. The composition of the claim 9, wherein the inhalable dry powder composition comprising 10 mg of compound (I) or a pharmaceutically acceptable salt thereof, and a lactose component, wherein the lactose component comprises lactose particles having a d_{90} particle size less than about 190 microns and in the amount of from about 1 mg to about 10 mg.

46. The composition of the claim 9, wherein the inhalable dry powder composition comprising a therapeutically effective dosage amount of compound (I) or a pharmaceutically acceptable salt thereof, in the range of from about 0.1 mg to about 20 mg and a lactose component, wherein the lactose component comprises i) lactose particles having a d_{90} particle size less than about 60 microns and ii) lactose particles having a d_{90} particle size less than about 200 microns.

47. The composition of the claim 9, wherein the inhalable dry powder composition comprising i) from about 0.5 mg to about 10 mg of compound (I) or a pharmaceutically acceptable salt thereof; ii) from about 3 mg to about 8 mg of lactose particles having a d_{90} particle size less than about 50 microns; iii) from about 5 to about 13 mg of lactose particles having a d_{90} particle size less than about 200 microns; wherein the weight ratio between the compound (I) to lactose is from about 1:1 to about 1:39.

48. A method of preventing, inhibiting, suppressing, and/or treating at least one pulmonary disease in a subject in need thereof comprising administering a therapeutically effective dosage amount of 2-{4-[(2S)-1,1-difluoro-2-hydroxypropyl]phenyl}-N-{4-[3-(2-ethylphenyl)pyrazine-2-yl] phenyl}acetamide (compound (I)) or a pharmaceutically acceptable salt thereof to the subject.

49. The method of the claim 48, wherein the therapeutically effective dosage amount of compound (I) is in the range of from about 0.1 mg to about 20 mg.

50. The method of the claim 48, wherein the method comprises administering the composition to the subject via inhalation.

51. The method of the claim 48, wherein the pulmonary disease is selected from asthma, emphysema, bronchitis, chronic obstructive pulmonary disease, sinusitis, respiratory depression, reactive airways dysfunction syndrome, acute respiratory distress syndrome, irritant induced asthma, occupational asthma, symptoms of pulmonary infection(s), sensory hyper-reactivity, airway inflammation, multiple chemical sensitivity, aid in smoking cessation therapy, pneumonia, bronchitis, influenza, SARS, SARS-CoV-2, tuberculosis, and whooping cough.

52. The method of the claim 48, wherein the pulmonary disease is chronic obstructive pulmonary disease.

53. The method of the claim 48, wherein the pulmonary disease is asthma.

54. A method of preventing, inhibiting, suppressing, and/or treating at least one pulmonary disease in a subject by inhibiting IL-17 in a subject, said method comprising administering to the subject a therapeutically effective amount of 2-{4-[(2S)-1,1-difluoro-2-hydroxypropyl]phenyl}-N-{4-[3-(2-ethylphenyl)pyrazine-2-yl] phenyl}acetamide (compound (I)) or a pharmaceutically acceptable salt.

55. The method of the claim 54, wherein the therapeutically effective amount of compound (I) of a pharmaceutically acceptable substance is from about 20 μM to about 0.1 nM.

56. A method of preventing, inhibiting, suppressing, and/or treating at least one pulmonary disease mediated by IL-17 blockade is a subject in need thereof, wherein the method comprising administering to the subject an therapeutically effective amount of compound (I) or a pharmaceutically acceptable salt thereof; wherein the therapeutically effective amount is from about 500 μM to about 50 nM, when ex-vivo evaluation of Compound (I) for IL-17 inhibition is conducted from Bronchoalveolar lavage (BAL) cells from COPD patients.

57. A method of preventing, inhibiting, suppressing, and/or treating at least one pulmonary disease mediated by IL-17 blockade is a subject in need thereof, wherein the method comprising administering to the subject an therapeutically effective amount of compound (I) or a pharmaceutically acceptable salt thereof; wherein the therapeutically effective amount is from about 500 μM to about 50 nM, when ex-vivo evaluation of Compound (I) for IL-17 inhibition is conducted from peripheral blood from COPD patients.

58. A process for preparing an inhalable dry powder composition comprising compound (I) or a pharmaceutically acceptable salt thereof, comprises steps of: i) blending compound (I) or a pharmaceutically acceptable salt thereof with a diluent selected from one or more lactose component; and ii) optionally preparing final blend comprising compound (I) or a pharmaceutically acceptable salt thereof and the lactose component; wherein the blending step is selected from i) simple blending, ii) co-milling of compound (I) with lactose component, iii) conditioning of compound (I) with or without lactose component; and v) metering of lactose component in blending process.

59. The process of claim 58, wherein the blending step is simple blending for at least for 10 minutes to 1 hour with the speed of about 20 to about 40 ± 10 RPM.

60. The process of the claim 58, wherein the blending process of the present invention is simple blending of compound (I) with lactose component having d_{90} particle size less than about 100 microns, and final blending is prepared with a lactose component having d_{90} particle size more than about 100 microns.

61. The process of the claim 58, wherein d_{90} particle size of the compound (I) or a pharmaceutically acceptable salt thereof is less than about 10 microns.

62. A process for preparing an inhalable dry powder composition comprising compound (I) or a pharmaceutically acceptable salt thereof comprising: i) mixing a therapeutically effective dosage amount of compound (I) or a pharmaceutically acceptable salt thereof with lactose particles having a d_{90} particle size less than about 60 microns to prepare a blend; and ii) mixing the blend of step i) with lactose particles having a d_{90} particle size more than about 100 microns to prepare a final inhalation powder comprising compound (I) or a pharmaceutically acceptable salt thereof.