WHAT IS CLAIMED IS:

1. An effective amount of roflumilast N-oxide or a pharmaceutically acceptable salt thereof for use in the treatment of an autoimmune, respiratory or inflammatory disease or condition in a subject in need thereof, which is to be administered via pulmonary administration.

2. The effective amount of roflumilast N-oxide or a pharmaceutically acceptable salt thereof of claim 1, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is to be administered by inhalation.

3. The effective amount of roflumilast N-oxide or a pharmaceutically acceptable salt thereof of claim 1, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is to be administered by inhalation as a dry powder, solution or suspension.

4. The effective amount of roflumilast N-oxide or a pharmaceutically acceptable salt thereof of claim 3, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is to be administered as a dry powder.

5. The effective amount of roflumilast N-oxide or a pharmaceutically acceptable salt thereof of claim 3, wherein roflumilast N-oxide or pharmaceutically acceptable salt thereof is to be administered as a solution or suspension.

6. The effective amount of roflumilast N-oxide or a pharmaceutically acceptable salt thereof of any one of the preceding claims, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is to be administered at a single dose of about 5 μg to about 2000 μg.

7. The effective amount of roflumilast N-oxide or a pharmaceutically acceptable salt thereof of claim 6, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is to be administered at a single dose of about 20 μg to about 1200 μg.

8. The effective amount of roflumilast N-oxide or a pharmaceutically acceptable salt thereof of claim 6, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is to be administered at a single dose of 50 μg to 1000 μg.

9. The effective amount of roflumilast N-oxide or a pharmaceutically acceptable salt thereof of claim 6, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is to be administered at a single dose of 100μg to 800 μg.

10. The effective amount of roflumilast N-oxide or a pharmaceutically acceptable salt thereof of claim 6, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is to be administered at a single dose of 100 μg, 200 μg, 400 μg, or 600 μg.

11. The effective amount of roflumilast N-oxide or a pharmaceutically acceptable salt thereof of any one of the preceding claims, wherein the disease or condition is selected from the group consisting of asthma, COPD, chronic obstructive bronchiolitis, acute bronchitis, chronic bronchitis, emphysema, allergic rhinitis and non-allergic rhinitis.

12. The effective amount of roflumilast N-oxide or a pharmaceutically acceptable salt thereof of any of the preceding claims, wherein the disease or condition is asthma.

13. The effective amount of roflumilast N-oxide or a pharmaceutically acceptable salt thereof of any of the preceding claims, wherein the disease or condition is COPD.

14. The effective amount of roflumilast N-oxide or a pharmaceutically acceptable salt thereof of any one of the preceding claims, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is administered in combination with a long-acting β2 agonist, an M3 antagonist, a corticosteroid, or any combination thereof.

15. The effective amount of roflumilast N-oxide or a pharmaceutically acceptable salt thereof of claim 12, wherein the long-acting β2 agonist is selected from carmoterol, GSK-642444, indacaterol, milveterol, arformoterol, formoterol, salbutamol, formoterol, levalbuterol, terbutaline, AZD-3199, BI-1744-CL, LAS-100977, bambuterol, isoproterenol, procaterol, clenbuterol, reproterol, fenoterol, ASF-1020, and any combination thereof.

16. The effective amount of roflumilast N-oxide or a pharmaceutically acceptable salt thereof of claim 14, wherein the M3 antagonist is selected from aclidinium, tiotropium, ipratropium and oxitropium, and any combination thereof.

17. The effective amount of roflumilast N-oxide or a pharmaceutically acceptable salt thereof of claim 14, wherein the corticosteroid is selected from the group consisting of dexamethasone, flutiasone, fluticasone furoate, prednisolone, betamethasone, budesonide, mometasone, mometasone furoate, triamcinolone acetonide, ciclesonide, TPI- 1020, beclomethasone, beclomethasone dipropionate, prednisone, deflazacort, hydrocortisone, QAE-397, flunisolide, and any combination thereof.

18. The effective amount of roflumilast N-oxide or a pharmaceutically acceptable salt thereof of any one of the preceding claims, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is anhydrous, a solvate, or a hydrate.

19. Roflumilast N-oxide having a d_{50} or d_{90} of less than about 10 microns (e.g., from about 0.1 to about 10 microns, such as about 0.5 to about 5 microns).

20. The roflumilast N-oxide of claim 19, wherein the d_{50} or d_{90} is (i) equal to or less than about 10 microns, (ii) less than about 6 microns, or (iii) between about 1 and about 6 microns.

21. Roflumilast N-oxide having a d_{50} or d_{90} equal to or less than 10 microns suitable for inhalation.

22. The roflumilast N-oxide of claim 21, having a d_{50} or d_{90} of (i) less than about 6 microns or (ii) between about 1 and about 6 microns.

23. A pharmaceutical composition comprising roflumilast N-oxide and, optionally, one or more pharmaceutically acceptable carriers and/or excipients, wherein the composition is to be administrated by inhalation.

24. The pharmaceutical composition of claim 23, in the form of a metered dose inhaler (MDI) or a dry powder inhaler (DPI).

25. The pharmaceutical composition of claim 23, wherein the pharmaceutical composition is in the form of an inhalable dry powder comprising micronized particles of roflumilast N-oxide or a pharmaceutically acceptable salt thereof as an active ingredient and particles of a physiologically acceptable pharmacologically-inert solid carrier.

26. The pharmaceutical composition of claim 23, wherein the pharmaceutical composition is in the form of an aerosol comprising roflumilast N-oxide or a pharmaceutically acceptable salt thereof as an active ingredient, a propellant and, optionally, one or more co-solvents, pharmaceutically acceptable carriers and/or excipients.

27. The pharmaceutical composition of claim 26, wherein the roflumilast N-oxide is in the form of a suspension of particles of micronized roflumilast N-oxide in the propellant.

28. The pharmaceutical composition of any one of claims 23-27, wherein the d_{50} or d_{90} of the roflumilast N-oxide is (i) about 10 microns or less, (ii) less than about 6 microns or (iii) between about 1 and about 6 microns.

29. The pharmaceutical composition of any one of claims 23-28, further comprising a long-acting β2 agonist, an M3 agonist, a corticosteroid, or any combination thereof.

30. The pharmaceutical composition of claim 29, wherein the long-acting β2 agonist is selected from carmoterol, GSK-642444, indacaterol, milveterol, arformoterol, formoterol, salbutamol, formoterol, levalbuterol, terbutaline, AZD-3199, BI-1744-CL, LAS-100977, bambuterol, isoproterenol, procaterol, clenbuterol, reproterol, fenoterol, ASF-1020, and any combination thereof.

31. The pharmaceutical composition of claim 29, wherein the M3 antagonist is selected from aclidinium, tiotropium, ipratropium and oxitropium, and any combination thereof.

32. The pharmaceutical composition of claim 29, wherein the corticosteroid is selected from the group consisting of dexamethasone, fluticasone, fluticasone furoate, prednisolone, betamethasone, budesonide, mometasone, mometasone furoate, triamcinolone acetonide, ciclesonide, TPI- 1020, beclomethasone, beclomethasone dipropionate, prednisone, deflazacort, hydrocortisone, QAE-397, flunisolide, and any combination thereof.

33. The pharmaceutical composition of any one of claims 23-32, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is anhydrous, a solvate, or a hydrate.

34. The use of an effective amount of roflumilast N-oxide or a pharmaceutically acceptable salt thereof in the manufacture of a medicament for the treatment of an autoimmune, respiratory or inflammatory disease or condition in a subject in need thereof, which is to be administered via pulmonary administration.

35. The use of claim 34, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is to be administered by inhalation.

36. The use of claim 34, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is to be administered by inhalation as a dry powder, solution or suspension.

37. The use of claim 36, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is to be administered as a dry powder.

38. The use of claim 36, wherein roflumilast N-oxide or pharmaceutically acceptable salt thereof is to be administered as a solution or suspension.

39. The use of any of the claims 34 to 38, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is to be administered at a single dose of about 5 μg to about 2000 μg.

40. The use of claim 39, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is to be administered at a single dose of about 20 μg to about 1200 μg.

41. The use of claim 39, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is to be administered at a single dose of 50 μg to 1000 μg.

42. The use of claim 39, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is to be administered at a single dose of 100μg to 800 μg.

43. The use of claim 39, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is to be administered at a single dose of 100 μg, 200 μg, 400 μg, or 600 μg.

44. The use of any of the claims 34 to 43, wherein the disease or condition is selected from the group consisting of asthma, COPD, chronic obstructive bronchiolitis, acute bronchitis, chronic bronchitis, emphysema, allergic rhinitis and non-allergic rhinitis.

45. The use of any of the claims 34 to 44, wherein the disease or condition is asthma.

46. The use of any of the claims 34 to 45, wherein the disease or condition is COPD.

47. The use of any of the claims 34 to 46, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is administered in combination with a long-acting $\beta 2$ agonist, an M3 antagonist, a corticosteroid, or any combination thereof.

48. The use of claim 45, wherein the long-acting $\beta 2$ agonist is selected from carmoterol, GSK-642444, indacaterol, milveterol, arformoterol, formoterol, salbutamol, formoterol, levalbuterol, terbutaline, AZD-3199, BI-1744-CL, LAS-100977, bambuterol, isoproterenol, procaterol, clenbuterol, reproterol, fenoterol, ASF-1020, and any combination thereof.

49. The use of claim 47, wherein the M3 antagonist is selected from aclidinium, tiotropium, ipratropium and oxitropium, and any combination thereof.

50. The use of claim 47, wherein the corticosteroid is selected from the group consisting of dexamethasone, fluticasone, fluticasone furoate, prednisolone, betamethasone, budesonide, mometasone, mometasone furoate, triamcinolone acetonide, ciclesonide, TPI- 1020, beclomethasone, beclomethasone dipropionate, prednisone, deflazacort, hydrocortisone, QAE-397, flunisolide, and any combination thereof.

51. The use of any of the claims 34 to 50, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is anhydrous, a solvate, or a hydrate.

CLAIMS

1. Roflumilast N-oxide or a pharmaceutically acceptable salt thereof for use in the treatment of an autoimmune, respiratory or inflammatory disease or condition in a subject in need thereof, which is to be administered via pulmonary administration at a single dose of 600 μg to 1200 μg, wherein the roflumilast N-oxide or a pharmaceutically acceptable salt thereof has a d_{50} of less than 6 microns.

2. The roflumilast N-oxide or a pharmaceutically acceptable salt thereof of claim 1, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is to be administered by inhalation.

3. The roflumilast N-oxide or a pharmaceutically acceptable salt thereof of claim 1, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is to be administered by inhalation as a dry powder, solution or suspension.

4. The roflumilast N-oxide or a pharmaceutically acceptable salt thereof of claim 3, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is to be administered as a dry powder.

5. The roflumilast N-oxide or a pharmaceutically acceptable salt thereof of claim 3, wherein roflumilast N-oxide or pharmaceutically acceptable salt thereof is to be administered as a solution or suspension.

6. The roflumilast N-oxide or a pharmaceutically acceptable salt thereof of any one of claims 1 to 5, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is to be administered at a single dose of 1200 μg.

7. The roflumilast N-oxide or a pharmaceutically acceptable salt thereof of any one of claims 1 to 5, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is to be administered at a single dose of 1000 μg.

8. The roflumilast N-oxide or a pharmaceutically acceptable salt thereof of any one of claims 1 to 5, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is to be administered at a single dose of 800 μg.

9. The roflumilast N-oxide or a pharmaceutically acceptable salt thereof of any one of claims 1 to 5, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is to be administered at a single dose of 600 μg.

10. The roflumilast N-oxide or a pharmaceutically acceptable salt thereof of any one of the preceding claims, wherein the disease or condition is selected from the group consisting of asthma, COPD, chronic obstructive bronchiolitis, acute bronchitis, chronic bronchitis, emphysema, allergic rhinitis and non-allergic rhinitis.

11. The roflumilast N-oxide or a pharmaceutically acceptable salt thereof of any of the preceding claims, wherein the disease or condition is asthma.

12. The roflumilast N-oxide or a pharmaceutically acceptable salt thereof of any of the preceding claims, wherein the disease or condition is COPD.

13. The roflumilast N-oxide or a pharmaceutically acceptable salt thereof of any one of the preceding claims, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is administered in combination with a long-acting $\beta 2$ agonist, an M3 antagonist, a corticosteroid, or any combination thereof.

14. The roflumilast N-oxide or a pharmaceutically acceptable salt thereof of claim 13, wherein the long-acting $\beta 2$ agonist is selected from carmoterol, GSK-642444, indacaterol, milveterol, arformoterol, formoterol, salbutamol, formoterol, levalbuterol, terbutaline, AZD-3199, BI-1744-CL, LAS-100977, bambuterol, isoproterenol, procaterol, clenbuterol, reproterol, fenoterol, ASF-1020, and any combination thereof.

15. The roflumilast N-oxide or a pharmaceutically acceptable salt thereof of claim 13, wherein the M3 antagonist is selected from aclidinium, tiotropium, ipratropium and oxitropium, and any combination thereof.

16. The roflumilast N-oxide or a pharmaceutically acceptable salt thereof of claim 13, wherein the corticosteroid is selected from the group consisting of dexamethasone, fluticasone, fluticasone furoate, prednisolone, betamethasone, budesonide, mometasone, mometasone furoate, triamcinolone acetonide, ciclesonide, TPI- 1020, beclomethasone, beclomethasone dipropionate, prednisone, deflazacort, hydrocortisone, QAE-397, flunisolide, and any combination thereof.

17. The roflumilast N-oxide or a pharmaceutically acceptable salt thereof of any one of the preceding claims, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is anhydrous, a solvate, or a hydrate.

18. A pharmaceutical composition comprising 600 μg to 1200 μg roflumilast N-oxide and, optionally, one or more pharmaceutically acceptable carriers and/or excipients, wherein the composition is to be administrated by inhalation, and wherein the roflumilast N-oxide or a pharmaceutically acceptable salt thereof has a d_{50} of less than 6 microns.

19. The pharmaceutical composition of claim 18, in the form of a metered dose inhaler (MDI) or a dry powder inhaler (DPI).

20. The pharmaceutical composition of claim 18, wherein the pharmaceutical composition is in the form of an inhalable dry powder comprising micronized particles of roflumilast N-oxide or a pharmaceutically acceptable salt thereof as an active ingredient and particles of a physiologically acceptable pharmacologically-inert solid carrier.

21. The pharmaceutical composition of claim 18, wherein the pharmaceutical composition is in the form of an aerosol comprising roflumilast N-oxide or a pharmaceutically acceptable salt thereof as an active ingredient, a propellant and, optionally, one or more co-solvents, pharmaceutically acceptable carriers and/or excipients.

22. The pharmaceutical composition of claim 21, wherein the roflumilast N-oxide is in the form of a suspension of particles of micronized roflumilast N-oxide in the propellant.

23. The pharmaceutical composition of any one of claims 18-22, wherein the d_{50} of the roflumilast N-oxide is between 1 and 6 microns.

24. The pharmaceutical composition of any one of claims 18-23, further comprising a long-acting $\beta 2$ agonist, an M3 agonist, a corticosteroid, or any combination thereof.

25. The pharmaceutical composition of claim 24, wherein the long-acting $\beta 2$ agonist is selected from carmoterol, GSK-642444, indacaterol, milveterol, arformoterol, formoterol, salbutamol, formoterol, levalbuterol, terbutaline, AZD-3199, BI-1744-CL, LAS-100977, bambuterol, isoproterenol, procaterol, clenbuterol, reproterol, fenoterol, ASF-1020, and any combination thereof.

26. The pharmaceutical composition of claim 24, wherein the M3 antagonist is selected from aclidinium, tiotropium, ipratropium and oxitropium, and any combination thereof.

27. The pharmaceutical composition of claim 24, wherein the corticosteroid is selected from the group consisting of dexamethasone, fluticasone, fluticasone furoate, prednisolone, betamethasone, budesonide, mometasone, mometasone furoate, triamcinolone acetonide, ciclesonide, TPI- 1020, beclomethasone, beclomethasone dipropionate, prednisone, deflazacort, hydrocortisone, QAE-397, flunisolide, and any combination thereof.

28. The pharmaceutical composition of any one of claims 18-27, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is anhydrous, a solvate, or a hydrate.

29. The use of roflumilast N-oxide or a pharmaceutically acceptable salt thereof in the manufacture of a medicament for the treatment of an autoimmune, respiratory or inflammatory disease or condition in a subject in need thereof, which is to be administered via pulmonary administration at a single dose of 600 μg to 1200 μg, wherein the roflumilast N-oxide or a pharmaceutically acceptable salt thereof has a d_{50} of less than 6 microns.

30. The use of claim 29, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is to be administered by inhalation.

31. The use of claim 29, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is to be administered by inhalation as a dry powder, solution or suspension.

32. The use of claim 31, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is to be administered as a dry powder.

33. The use of claim 31, wherein roflumilast N-oxide or pharmaceutically acceptable salt thereof is to be administered as a solution or suspension.

34. The use of any one of claims 29 to 33, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is to be administered at a single dose of 1200 μg.

35. The use of any one of claims 29 to 33, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is to be administered at a single dose of 1000 μg.

36. The use of any one of claims 29 to 33, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is to be administered at a single dose of 800 μg.

37. The use of any one of claims 29 to 33, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is to be administered at a single dose of 600 μg.

38. The use of any of the claims 29 to 37, wherein the disease or condition is selected from the group consisting of asthma, COPD, chronic obstructive bronchiolitis, acute bronchitis, chronic bronchitis, emphysema, allergic rhinitis and non-allergic rhinitis.

39. The use of any of the claims 29 to 38, wherein the disease or condition is asthma.

40. The use of any of the claims 29 to 39, wherein the disease or condition is COPD.

41. The use of any of the claims 29 to 40, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is administered in combination with a long-acting $\beta 2$ agonist, an M3 antagonist, a corticosteroid, or any combination thereof.

42. The use of claim 39, wherein the long-acting $\beta 2$ agonist is selected from carmoterol, GSK-642444, indacaterol, milveterol, arformoterol, formoterol, salbutamol, formoterol, levalbuterol, terbutaline, AZD-3199, BI-1744-CL, LAS-100977, bambuterol, isoproterenol, procaterol, clenbuterol, reproterol, fenoterol, ASF-1020, and any combination thereof.

43. The use of claim 41, wherein the M3 antagonist is selected from aclidinium, tiotropium, ipratropium and oxitropium, and any combination thereof.

44. The use of claim 41, wherein the corticosteroid is selected from the group consisting of dexamethasone, fluticasone, fluticasone furoate, prednisolone, betamethasone, budesonide, mometasone, mometasone furoate, triamcinolone acetonide, ciclesonide, TPI-1020, beclomethasone, beclomethasone dipropionate, prednisone, deflazacort, hydrocortisone, QAE-397, flunisolide, and any combination thereof.

45. The use of any of the claims 29 to 44, wherein the roflumilast N-oxide or pharmaceutically acceptable salt thereof is anhydrous, a solvate, or a hydrate.