CLAIMS

What is claimed is:

1. ~~A method of~~Use of levodopa in the manufacture of a medicament for providing rapid relief of motor fluctuations in a Parkinson's disease patient, ~~comprising:~~

~~administering~~ wherein at least one dose of levodopa is to be administered by inhalation to ~~a~~the Parkinson's disease patient~~;~~,

wherein within about 10 minutes of administration of levodopa by inhalation, the patient's plasma levodopa concentration increases by at least about 200 ng/ml as compared to the patient's plasma levodopa concentration prior to administration~~;~~, and

wherein said patient's plasma levodopa concentration maintains said increase of at least about 200 ng/ml for a time period of at least about 15 minutes after administration.

2. Use of levodopa in the manufacture of a medicament for providing rapid relief of motor fluctuations in a Parkinson's disease patient,

wherein at least one dose of levodopa is to be administered by inhalation to the Parkinson's disease patient,

wherein within about 10 minutes of administration, the patient's plasma levodopa concentration increases by at least about 200 ng/ml for every 10 mg of levodopa delivered as compared to the patient's plasma levodopa concentration prior to administration of levodopa by inhalation, and

wherein said patient's plasma levodopa concentration maintains said increase of at least about 200 ng/ml for a time period of at least about 15 minutes after administration.

3. Use of levodopa in the manufacture of a medicament for providing rapid relief of motor fluctuations in a Parkinson's disease patient population,

wherein at least one dose of levodopa is to be administered by inhalation to a first Parkinson's disease patient who takes a first average daily dose of oral levodopa,

at least one dose of levodopa is to be administered by inhalation to a second Parkinson's disease patient who takes a second average daily dose of oral levodopa, and

wherein both patients have a reduction in motor symptoms within 20 minutes of administration of said levodopa by inhalation upon administration of the same dose of pulmonary levodopa.

4. The use of claim 3, wherein said first average daily dose of oral levodopa is higher than the second average daily dose of oral levodopa.

5. The use of claim 3, wherein said first average daily dose of oral levodopa is higher than the second average daily dose of oral levodopa and both average daily doses range from 200mg to 2500mg of levodopa.

6. The use of claim 3, wherein said first average daily dose of levodopa is between 400-700mg.

7. The use of claim 3, wherein said second average daily dose of levodopa is between 700-2000mg.

8. The use of claim 3, wherein said first average daily dose of levodopa is between 400-700mg.

9. The use of claim 3, wherein said second average daily dose of levodopa is between 1000-2000mg.

10. The use of claim 3, wherein said pulmonary levodopa is to be administered to more than two patients wherein said patients take multiple different average daily oral doses of levodopa ranging from 200mg to 3000 per day.

11. The use of claim 3, wherein within about 10 minutes of administration of levodopa by inhalation, the patient's plasma levodopa concentration increases by at least about 200 ng/ml as compared to the patient's plasma levodopa concentration prior to administration; and wherein said patient's plasma levodopa concentration maintains said increase of at least about 200 ng/ml for a time period of at least about 15 minutes after administration.

12. The use of claim 3, wherein said pulmonary levodopa dose comprises about 10 mg to about 75 mg of levodopa.

13. The use of claim 3, wherein said pulmonary levodopa dose contains a salt.

14. The use of claim 3, wherein said pulmonary levodopa dose contains a phospholipid.

15. The use of claim 3, wherein said pulmonary levodopa dose comprises about 12 mg to about 35 mg of levodopa.

~~2.~~16. The ~~method~~ use of any one of claims 1 or 2, wherein the dose comprises about 10 mg to about 75 mg of levodopa.

~~3.~~17. The ~~method~~ use of any one of claims 1 or 2, wherein the dose contains a salt.

~~4.~~18. The ~~method~~ use of any one of claims 1 or 2, wherein the dose contains a phospholipid.

~~5.~~19. The ~~method~~ use of any one of claims 1, 2 or 11, wherein the AUC of levodopa in the patient's plasma at about 10 minutes after administration of ~~a~~ the dose of levodopa by inhalation, is increased by at least about 1000 ng-min/ml for every 4 mg of levodopa administered as compared to the patient's plasma levodopa concentration prior to administration of levodopa by inhalation.

~~6.~~20. The ~~method~~ use of any one of claims 1, 2 or 11, wherein the AUC of said levodopa in the plasma at about 10 minutes after administration of ~~a~~the dose of levodopa by inhalation is increased by at least about 1000-1500 ng-min/ml for every 4 mg of levodopa administered as compared to the patient's plasma levodopa concentration prior to administration of levodopa by inhalation.

~~7.~~21. The ~~method~~ use of any one of claims 1 or 2, wherein the dose comprises about 12 mg to about 35 mg of levodopa.

~~8.~~22. The ~~method~~ use of any one of claims 1, 2 or 3, ~~further comprising co-administering~~wherein a dopa decarboxylase inhibitor is to be co-administered to the patient.

~~9.~~23. The ~~method~~ use of any one of claims 1, 2 or 3, wherein the patient's plasma levodopa concentration maintains said increase of at least about 200 ng/ml for a time period of at least about 20 minutes after administration.

~~10.~~24. The ~~method~~ use of any one of claims 1, 2 or 3, wherein the patient's plasma levodopa concentration maintains said increase of at least about 200 ng/ml for a time period of at least about 30 minutes after administration.

~~11.~~25. The ~~method~~ use of any one of claims 1, 2 or 3, wherein the patient's plasma levodopa concentration maintains said increase of at least about 200 ng/ml for a time period of at least about 60 minutes after administration.

~~12.~~26. The ~~method~~ use of any one of claims 1, 2 or 3, wherein the dose of levodopa comprises at least about 10 mg of levodopa.

~~13.~~27. The ~~method~~ use of any one of claims 1, 2 or 3, wherein said patient's plasma levodopa concentration does not increase by more than about 1000 ng/ml within 10 minutes.

~~14. A method of providing rapid relief of motor fluctuations in a Parkinson's disease patient comprising:~~

~~administering at least one dose of levodopa by inhalation to a Parkinson's disease patient,~~

~~wherein within about 10 minutes of administration, the patient's plasma levodopa concentration increases by at least about 200 ng/ml for every 10 mg of levodopa delivered as compared to the patient's plasma levodopa concentration prior to administration of levodopa by inhalation, wherein said patient's plasma~~

levodopa concentration maintains said increase of at least about 200 ng/ml for a time period of at least about 15 minutes after administration.

15. The method of claim 14, wherein said dose comprises about10 mg to about 75 mg of levodopa.

16. The method of claim 14, wherein said dosage contains a salt.

17. The method of claim 14, wherein said dosage contains a phospholipid.

18. The method of claim 14, wherein the AUC of levodopa in the patient's plasma at about 10 minutes after administration of a dose of levodopa by inhalation, is increased by at least about 1000 ng-min/ml for every 4 mg of levodopa administered as compared to the patient's plasma levodopa concentration prior to administration of levodopa by inhalation.

19. The method of claim 14, wherein the AUC of said levodopa in the plasma at about 10 minutes after administration of a dose of levodopa by inhalation is increased by at least about 1000-1500 ng-min/ml for every 4 mg of levodopa administered as compared to the patient's plasma levodopa concentration prior to administration of levodopa by inhalation.

20. The method of claim 14, wherein the dose comprises about 12 mg to about 35mg of levodopa.

21. The method of claim 14, further comprising co-administering a dopa decarboxylase inhibitor to the patient.

22. The method of claim 14, wherein the patient's plasma levodopa concentration maintains said increase of at least about 200 ng/ml for a time period of at least about 20 minutes after administration.

~~23. The method of claim 14, wherein the patient's plasma levodopa concentration maintains said increase of at least about 200 ng/ml for a time period of at least about 30 minutes after administration.~~

~~24. The method of claim 14, wherein the patient's plasma levodopa concentration maintains said increase of at least about 200 ng/ml for a time period of at least about 60 minutes after administration.~~

~~25. The method of claim 14, wherein the dose of levodopa comprises at least about 10 mg of levodopa.~~

~~26. The method of claim 14, wherein said patient's plasma levodopa concentration does not increase more than about 1000 ng/ml within 10 minutes.~~

~~27.~~28. ~~A method of~~Use of levodopa in the manufacture of a medicament for providing rapid relief of motor fluctuations in a Parkinson's disease patient, ~~comprising:~~

~~administering~~ wherein about 20 mg to about 75 mg of levodopa is to be administered to ~~a~~the patient by inhalation~~;~~,

wherein said patient receives immediate relief of motor fluctuations within 10 minutes of said inhalation~~;~~, and

wherein said patient maintains said relief for a period of at least 30 minutes.

~~28.~~29. The ~~method~~ use of claim ~~27~~28, ~~further comprising administering~~wherein an oral dosage of levodopa is to be administered to said patient.

~~29.~~30. The ~~method~~ use of claim ~~27~~28, wherein said relief of motor fluctuations is maintained for a period of at least 4 hours.

~~30.~~31. The ~~method~~ use of claim 1, wherein said Parkinson's disease patient is a stage 2, 3 or stage 4 Parkinson's disease patient.

~~31.~~32. The ~~method~~ use of claims 1, wherein said dosages of levodopa are not affected by a central nervous system food effect.

~~32.~~33. ~~A method of~~Use of levodopa in the manufacture of a medicament for providing rapid relief of motor fluctuations in a Parkinson's disease patient, ~~comprising:~~

~~administering~~ wherein about 20mg to about 75mg of levodopa is to be administered to a~~t~~he patient by inhalation wherein the $Cmax^{Pul}/AUC^{Pul}$ divided by $Cmax^{Oral}/AUC^{Oral}$ is greater than 1 on a comparative dose of levodopa.

~~33.~~34. ~~A method of~~Use of levodopa in the manufacture of a medicament for providing rapid relief of motor fluctuations in a Parkinson's disease patient, ~~comprising:~~

~~administering~~ wherein one or more dosages of levodopa is to be administered by inhalation~~;~~,

wherein the ratio of $T^{1/2} / T^{max}$ is less than 1/2.

~~34.~~35. The ~~method~~ use of claim ~~33~~34, wherein said ratio is less than 1/5.

~~35.~~36. The ~~method~~ use of claim ~~8~~22, wherein the dopa decarboxylase inhibitor is to be administered to the patient before, simultaneously with or after, administration of levodopa by inhalation.

~~36.~~37. The ~~method~~ use of claim 1, wherein the dose of levodopa comprises 90% by dry weight levodopa, 8% by dry weight dipalmitoylphosphatidylcholine (DPPC) and 2% sodium chloride.

~~37.~~38. ~~A method of~~Use of levodopa in the manufacture of a medicament for providing rapid relief of motor fluctuations in a Parkinson's disease patient, ~~comprising:~~

~~administering~~ wherein about 20 mg to about 75 mg of levodopa is to be administered to a patient, and

wherein the $Cmax^{Pul}/AUC^{Pul}$ divided by $Cmax^{Oral}/AUC^{Oral}$ is greater than 1 on a comparative dose of levodopa.

~~38.~~39. ~~A method of~~Use of levodopa in the manufacture of a medicament for providing rapid relief of motor fluctuations in a Parkinson's disease patient, ~~comprising:~~

~~administering~~ wherein levodopa is to be administered to said patient such that the patient's plasma levodopa levels is increased by about 200-500 ng/ml.

~~39.~~40. The ~~method~~ use of claim ~~38~~39, wherein said levodopa is to be administered by the oral route, pulmonary route or parenteral route.

~~40~~41.. The ~~method~~ use of claim ~~38~~39, wherein said plasma levodopa levels are increased by 200-400 ng/ml, 300-400 ng/ml, 350-450 ng/ml or about 400 ng/ml.

~~41.~~42. The ~~method~~ use of claim ~~38~~39, wherein said levodopa is to be administered by the pulmonary route and is at a dose of about 25-40 mg of levodopa to the pulmonary system.

~~42.~~43. The ~~method~~ use of claim ~~38~~39, wherein said patient has at least a 100% improvement in UPDRS score within 20 minutes of administering said levodopa.

~~43. A method of providing rapid relief of motor fluctuations in a Parkinson's disease patient population comprising:~~

~~administering at least one dose of levodopa by inhalation to a first Parkinson's disease patient who takes a first average daily dose of oral levodopa;~~

~~administering at least one dose of levodopa by inhalation to a second Parkinson's disease patient who takes a second average daily dose of oral levodopa;~~

~~wherein both patients have a reduction in motor symptoms within 20 minutes of administration of said levodopa by inhalation upon administration of the same dose of pulmonary levodopa.~~

~~44. The method of claim 43, wherein said first average daily dose of oral levodopa is higher than the second average daily dose of oral levodopa.~~

~~45. The method of claim 43, wherein said first average daily dose of oral levodopa is higher than the second average daily dose of oral levodopa and both average daily doses range from 200mg to 2500mg of levodopa.~~

~~46. The method of claim 43, wherein said first average daily dose of levodopa between 400-700mg.~~

47. The method of claim 43, wherein said second average daily dose of levodopa is between 700-2000mg.

48. The method of claim 43, wherein said first average daily dose of levodopa between 400-700mg.

49. The method of claim 43, wherein said second average daily dose of levodopa is between 1000-2000mg.

50. The method of claim 43, wherein said method further comprises administering said pulmonary levodopa to more than two patients wherein said patients take multiple different average daily oral doses of levodopa ranging from 200mg to 3000 per day.

51. The method of claim 43, wherein within about 10 minutes of administration of levodopa by inhalation, the patient's plasma levodopa concentration increases by at least about 200 ng/ml as compared to the patient's plasma levodopa concentration prior to administration; and wherein said patient's plasma levodopa concentration maintains said increase of at least about 200 ng/ml for a time period of at least about 15 minutes after administration.

52. The method of claim 43, wherein said pulmonary levodopa dose comprises about 10 mg to about 75 mg of levodopa.

53. The method of claim 43, wherein said pulmonary levodopa dose contains a salt.

54. The method of claim 43, wherein said pulmonary levodopa dose contains a phospholipid.

55. The method of claim 51, wherein the AUC of levodopa in the patient's plasma at about 10 minutes after administration of a dose of levodopa by inhalation, is increased by at least about 1000 ng-min/ml for every 4 mg of levodopa

administered as compared to the patient's plasma levodopa concentration prior to administration of levodopa by inhalation.

56. The method of claim 51, wherein the AUC of said levodopa in the plasma at about 10 minutes after administration of a dose of levodopa by inhalation is increased by at least about 1000-1500 ng-min/ml for every 4 mg of levodopa administered as compared to the patient's plasma levodopa concentration prior to administration of levodopa by inhalation.

57. The method of claim 43, wherein said pulmonary levodopa dose comprises about 12 mg to about 35 mg of levodopa.

58. The method of claim 43, further comprising co-administering a dopa decarboxylase inhibitor to the patient.

59. The method of claim 43, wherein the patient's plasma levodopa concentration maintains said increase of at least about 200 ng/ml for a time period of at least about 20 minutes after administration.

60. The method of claim 43, wherein the patient's plasma levodopa concentration maintains said increase of at least about 200 ng/ml for a time period of at least about 30 minutes after administration.

61. The method of claim 43, wherein the patient's plasma levodopa concentration maintains said increase of at least about 200 ng/ml for a time period of at least about 60 minutes after administration.

62. The method of claim 43, wherein the dose of levodopa comprises at least about 10 mg of levodopa.

63. The method of claim 43, wherein said patient's plasma levodopa concentration does not increase more than about 1000 ng/ml within 10 minutes.