Claims:

1. A method of administering botulinum toxin to achieve an extended duration therapeutic effect in an individual with cervical dystonia, the method comprising:

administering by injection a first treatment dose of a sterile injectable composition into one or more of the muscles causing the cervical dystonia in the individual in need of treatment to achieve the therapeutic effect following a first treatment with the composition;

wherein the composition comprises a pharmaceutically acceptable diluent suitable for injection; and

a botulinum toxin component selected from the group consisting of a botulinum toxin, a botulinum toxin complex, or a reduced botulinum toxin complex; and

a positively charged carrier component comprising a positively charged polylysine backbone having covalently attached thereto one or more positively charged efficiency groups having an amino acid sequence of $(gly)_p$-RGRDDRRQRRR-$(gly)_q$ (SEQ ID NO: 1), $(gly)_p$-YGRKKRRQRRR-$(gly)_q$ (SEQ ID NO: 2) or $(gly)_p$-RKKRRQRRR-$(gly)_q$ (SEQ ID NO: 3), wherein the subscripts p and q are each independently an integer of from 0 to 20;

wherein the total treatment dose of botulinum toxin component administered to the individual is 100 U to 450 U;

wherein the positively charged carrier is non-covalently associated with the botulinum toxin component; and

wherein the first treatment dose of the composition administered by injection to the individual achieves the extended duration therapeutic or cosmetic effect having at least about a 24 week duration of effect, optionally, before a second or subsequent treatment dose is administered.

2. A method of treating cervical dystonia in an individual in need thereof, the method comprising:

administering to the individual by injection to one or more muscles causing the cervical dystonia in the individual a composition comprising:

a pharmaceutically acceptable diluent for injection;

a botulinum toxin componenst selected from the group consisting of a botulinum toxin, a botulinum toxin complex, or a reduced botulinum toxin complex; and

a positively charged carrier component comprising a positively charged polylysine backbone having covalently attached thereto one or more positively charged efficiency groups having an amino acid sequence of $(gly)_p$-RGRDDRRQRRR-$(gly)_q$ (SEQ ID NO: 1), $(gly)_p$-YGRKKRRQRRR-$(gly)_q$ (SEQ ID NO: 2) or $(gly)_p$-RKKRRQRRR-$(gly)_q$ (SEQ ID NO: 3), wherein the subscripts p and q are each independently an integer of from 0 to 20;

wherein the botulinum toxin is administered to the individual in a total treatment dose amount of 100 U to 450 U;

wherein the positively charged carrier is non-covalently associated with the botulinum component; and

wherein the injection of the composition provides a single treatment dose having at least about a 24 week duration of effect in reducing the symptoms of cervical dystonia in the individual, thereby extending treatment interval duration for the individual.

3. A pharmaceutical composition in a sterile injectable formulation for use in administering botulinum toxin to achieve an extended duration therapeutic effect in an individual with cervical dystonia,

said composition comprising a pharmaceutically acceptable diluent suitable for injection;

a botulinum toxin component in a treatment dose of 100 U to 450 U, wherein said botulinum toxin component is selected from the group consisting of a botulinum toxin complex, a reduced botulinum toxin complex, or a botulinum toxin; and

a positively charged carrier component comprising a positively charged polylysine backbone having covalently attached thereto one or more positively charged efficiency groups having an amino acid sequence of $(gly)_p$-RGRDDRRQRRR-$(gly)_q$ (SEQ ID NO: 1), $(gly)_p$-YGRKKRRQRRR-$(gly)_q$ (SEQ ID NO: 2) or $(gly)_p$-RKKRRQRRR-$(gly)_q$ (SEQ ID NO: 3), wherein the subscripts p and q are each independently an integer of from 0 to 20;

wherein the positively charged carrier is non-covalently associated with the botulinum toxin component; and

wherein said treatment dose of the composition achieves the extended duration therapeutic effect having at least about a 24 week duration of effect in the individual administered said formulation by injection.

4. A pharmaceutical composition in a sterile injectable formulation for use in reducing the symptoms of cervical dystonia in an individual in need thereof, said composition comprising:

a botulinum toxin component in a dose of 100 U to 450 U, said botulinum toxin component selected from the group consisting of a botulinum toxin complex, a reduced botulinum toxin complex, or a botulinum toxin,

a positively charged carrier component comprising a positively charged polylysine backbone having covalently attached thereto one or more positively charged efficiency groups having an amino acid sequence of $(gly)_p$-RGRDDRRQRRR-$(gly)_q$ (SEQ ID NO: 1), $(gly)_p$-YGRKKRRQRRR-$(gly)_q$ (SEQ ID NO: 2) or $(gly)_p$-RKKRRQRRR-$(gly)_q$ (SEQ ID NO: 3), wherein the subscripts p and q are each independently an integer of from 0 to 20; and

a pharmaceutically acceptable diluent for injection;

wherein the positively charged carrier is non-covalently associated with the botulinum toxin component; and

wherein said dose of the composition provides a single treatment having at least about a 24 week duration of effect in reducing the symptoms of cervical dystonia in the individual, thereby extending treatment interval duration for the individual.

5. The method according to claim 1 or claim 2, or the pharmaceutical composition for use according to claim 3 or claim 4, wherein the composition achieves the extended duration therapeutic effect for at least about a 8 months.

6. The method or pharmaceutical composition for use according to claim 5, wherein the composition comprises botulinum toxin of serotype A.

7. The method or pharmaceutical composition for use according to claim 6, wherein the composition comprises botulinum toxin of serotype A having a molecular weight of 150 kDa.

8. The method or pharmaceutical composition for use according to any one of claims 1 to 7, wherein the positively charged polylysine backbone has covalently attached thereto one or more positively charged efficiency groups having the amino acid sequence $(gly)_p$-RGRDDRRQRRR-$(gly)_q$ (SEQ ID NO: 1), wherein the subscripts p and q are each independently an integer of from 0 to 20.

9. The method or pharmaceutical composition for use according to any one of claims 1 to 7, wherein the positively charged polylysine backbone has covalently attached thereto one or more positively charged efficiency groups having the amino acid sequence $(gly)_p$-YGRKKRRQRRR-$(gly)_q$ (SEQ ID NO: 2), wherein the subscripts p and q are each independently an integer of from 0 to 20.

10. The method or pharmaceutical composition for use according to any one of claims 1 to 7, wherein the positively charged polylysine backbone has covalently attached thereto one or more positively charged efficiency groups having the amino acid sequence $(gly)_p$-RKKRRQRRR-$(gly)_q$ (SEQ ID NO: 3), wherein the subscripts p and q are each independently an integer of from 0 to 20.

11. The method or pharmaceutical composition for use according to any one of claims 1 to 10, wherein (i) the subscripts p and q are each independently an integer of from 0 to 8; or (ii) are each independently an integer of from 2 to 5.

12. The method or pharmaceutical composition for use according to any one of claims 1 to 11, wherein the one or more positively charged efficiency groups are attached to either end, or both ends, of the positively charged polylysine backbone of the positively charged carrier.

13. The method or pharmaceutical composition for use according to claim 12, wherein the positively charged carrier has the amino acid sequence RKKRRQRRRG-$(K)_{15}$-GRKKRRQRRR (SEQ ID NO: 4).

14. The method or pharmaceutical composition for use according to any one of claims 1 to 13, wherein the composition does not locally diffuse from the site of injection following injection.

15. The method or pharmaceutical composition for use according to any one of claims 1 to 14, wherein the treatment dose of botulinum toxin is administered to the individual in an amount of about 100 U to 200U.

16. The method or pharmaceutical composition for use according to any one of claims 1 to 14, wherein the treatment dose of botulinum toxin is administered to the individual in an amount of about 200 U to 300 U.

17. The method or pharmaceutical composition for use according to any one of claims 1 to 14, wherein the treatment dose of botulinum toxin is administered to the individual in an amount of 300 U to 450 U.

18. The method or pharmaceutical composition for use according to any one of claims 1 to 17, wherein the duration of treatment effect comprises greater than 3 months.

19. The method or pharmaceutical composition for use according to any one of claims 1 to 17, wherein the duration of treatment effect comprises greater than 4 months.

20. The method or pharmaceutical composition for use according to any one of claims 1 to 17, wherein the duration of treatment effect comprises greater than 5 months.

21. The method or pharmaceutical composition for use according to any one of claims 1 to 17, wherein the duration of treatment effect comprises greater than 6 months.

22. The method or pharmaceutical composition for use according to any one of claims 1 to 17, wherein the duration of treatment effect comprises greater than 7 months.

23. The method or pharmaceutical composition for use according to any one of claims 1 to 17, wherein the duration of treatment effect comprises greater than 8 months.

24. The method or pharmaceutical composition for use according to any one of claims 1 to 17, wherein the duration of treatment effect comprises greater than 9 months.

25. The method or pharmaceutical composition for use according to any one of claims 1 to 17, wherein the duration of treatment effect comprises at least 6 months through 10 months.

26. A sterile injectable composition comprising:

a botulinum toxin component selected from the group consisting of a botulinum toxin, a botulinum toxin complex, or a reduced botulinum toxin complex, in a dosage amount selected from 100 U, 200 U, 300 U or 450 U; and

a positively charged carrier component comprising a positively charged polylysine backbone having covalently attached thereto one or more positively charged efficiency groups having an amino acid sequence of $(gly)_p$-RGRDDRRQRRR-$(gly)_q$ (SEQ ID NO: 1), $(gly)_p$-YGRKKRRQRRR-$(gly)_q$ (SEQ ID NO: 2) or $(gly)_p$-RKKRRQRRR-$(gly)_q$ (SEQ ID NO: 3), wherein the subscripts p and q are each independently an integer of from 0 to 20; and

a pharmaceutically acceptable diluent for injection;

wherein the positively charged carrier is non-covalently associated with the botulinum toxin component; and

wherein the composition provides a cosmetic or therapeutic effect which endures for at least 24 weeks following a single treatment of an individual with the injectable composition.

27. The composition according to claim 26, wherein the positively charged carrier has the amino acid sequence RKKRRQRRRG-$(K)_{15}$-GRKKRRQRRR (SEQ ID NO: 4).

28. The composition according to claim 26 or claim 27, wherein the composition comprises botulinum toxin of serotype A.

29. The composition according to claim 28, wherein the composition comprises botulinum toxin of serotype A having a molecular weight of 150 kDa.

30. The composition according to any one of claims 26 to 29, wherein the treatment dose of botulinum toxin is administered to the individual in the amount of 100 U.

31. The composition according to any one of claims 26 to 29, wherein the treatment dose of botulinum toxin is administered to the individual in the amount of 200 U.

32. The composition according to any one of claims 28 to 31, wherein the treatment dose of botulinum toxin is administered to the individual in the amount of 450 U.

33. A method of treating an individual with cervical dystonia in need of treatment with injectable botulinum toxin, wherein the method of treatment comprises a treatment course having multiple treatment intervals with prolonged duration of effect and duration time between each treatment interval, the treatment course comprising:

administering by injection an initial treatment dose of a sterile injectable composition into one or more muscles causing cervical dystonia in the individual in need of treatment to achieve a therapeutic effect of reducing the symptoms of cervical dystonia following the initial treatment with the composition;

wherein the composition comprises a pharmaceutically acceptable diluent suitable for injection;

a botulinum toxin component selected from the group consisting of a botulinum toxin, a botulinum toxin complex, or a reduced botulinum toxin complex; and

a positively charged carrier component comprising a positively charged polylysine backbone having covalently attached thereto one or more positively charged efficiency groups having an amino acid sequence of $(gly)_p$-RGRDDRRQRRR-$(gly)_q$ (SEQ ID NO: 1), $(gly)_p$-YGRKKRRQRRR-$(gly)_q$ (SEQ ID NO: 2) or $(gly)_p$-RKKRRQRRR-$(gly)_q$ (SEQ ID NO: 3), wherein the subscripts p and q are each independently an integer of from 0 to 20; and

wherein the botulinum toxin component is administered to the individual in a treatment dose of about 100 U to about 450 U;

wherein the positively charged carrier is non-covalently associated with the botulinum toxin component;

wherein the initial treatment dose of the composition administered by injection to the individual provides a therapeutic duration of effect lasting through at least about 10 months; and

administering subsequent treatment doses of the composition by injection to the individual at treatment intervals comprising a duration of greater than or equal to 6 months to at least about 10 months following the initial treatment dose and between each subsequent treatment dose.

34. The method according to any one of claims 33 to claim 35, wherein the composition comprises botulinum toxin of serotype A.

35. The method according to claim 34, wherein the composition comprises botulinum toxin of serotype A having a molecular weight of 150 kDa.

36. The method according to any one of claims 33 to 35, wherein the positively charged polylysine backbone has covalently attached thereto one or more positively charged efficiency groups having the amino acid sequence $(gly)_p$-RGRDDRRQRRR-$(gly)_q$ (SEQ ID NO: 1), wherein the subscripts p and q are each independently an integer of from 0 to 20.

37. The method according to any one of claims 33 to 35, wherein the positively charged polylysine backbone has covalently attached thereto one or more positively charged efficiency groups having the amino acid sequence $(gly)_p$-YGRKKRRQRRR-$(gly)_q$ (SEQ ID NO: 2), wherein the subscripts p and q are each independently an integer of from 0 to 20.

38. The method according to any one of claims 33 to 35, wherein the positively charged polylysine backbone has covalently attached thereto one or more positively charged efficiency groups having the amino acid sequence $(gly)_p$-RKKRRQRRR-$(gly)_q$ (SEQ ID NO: 3), wherein the subscripts p and q are each independently an integer of from 0 to 20.

39. The method according to any one of claims 33 to 38, wherein (i) the subscripts p and q are each independently an integer of from 0 to 8; or (ii) are each independently an integer of from 2 to 5.

40. The method according to any one of claims 33 to 39, wherein the one or more positively charged efficiency groups are attached to either end, or both ends, of the positively charged polylysine backbone of the positively charged carrier.

41. The method according to any one of claims 33 to 35, wherein the positively charged carrier has the amino acid sequence RKKRRQRRRG-$(K)_{15}$-GRKKRRQRRR (SEQ ID NO: 4).

42. The method according to any one of claims 33 to 41, wherein the composition does not locally diffuse from the site of injection following injection.

43. The method according to any one of claims 33 to 42, wherein the botulinum toxin is administered to the individual in an amount of about 100 U to 200 U.

44. The method according to any one of claims 33 to 42, wherein the botulinum toxin is administered to the individual in an amount of 200 U to 300 U.

45. The method according to any one of claims 33 to 42, wherein the botulinum toxin is administered to the individual in an amount of 300 U to 450 U.

46. The method according to any one of claims 33 to 45, wherein the duration of the treatment interval comprises greater than 3 months.

47. The method according to any one of claims 33 to 45, wherein the duration of the treatment interval comprises greater than 4 months.

48. The method according to any one of claims 33 to 45, wherein the duration of the treatment interval comprises greater than 5 months.

49. The method according to any one of claims 33 to 45, wherein the duration of the treatment interval comprises greater than 6 months.

50. The method according to any one of claims 33 to 45, wherein the duration of the treatment interval comprises greater than 7 months.

51. The method according to any one of claims 33 to 45, wherein the duration of the treatment interval comprises greater than 8 months.

52. The method according to any one of claims 33 to 45, wherein the duration of the treatment interval comprises greater than 9 months.

53. The method according to any one of claims 33 to 45, wherein the duration of the treatment interval comprises at least 6 months through 10 months.