CLAIMS

1. ~~A composition comprising~~Use of the fusion protein of SEQ ID NO: 1 (Lip-S1D1-S2D1), the fusion protein of SEQ ID NO: 2 (Lip-S4D1-S3hybD1) and the fusion protein of SEQ ID NO: 3 (Lip-S5D1-S6D1) in the preparation of a composition as ~~for use in~~ a vaccine, wherein the ~~vaccine~~ composition is to be administered

- to a human adult or human child at least three times or at least two times at a total protein content of said 3 fusion proteins in the range of from 120 to 200 µg per dose; or
- to a human child at least three times or at least two times at a total protein content of said 3 fusion proteins in the range of from 60 to 100 µg per dose.

2. Use of ~~A composition comprising~~ the fusion protein of SEQ ID NO: 1 (Lip-S1D1-S2D1), the fusion protein of SEQ ID NO: 2 (Lip-S4D1-S3hybD1) and the fusion protein of SEQ ID NO: 3 (Lip-S5D1-S6D1) in the preparation of a composition for ~~use in a method for~~ eliciting an immune response in a human against Lyme disease, wherein the ~~method comprising administering the~~ composition is to be administered~~.~~

- to a human adult or human child at least three times or at least two times at a total protein content of said 3 fusion proteins is in the range of from 120 to 200 µg per dose; or
- to a human child at least three times or at least two times at a total protein content of said 3 fusion proteins in the range of from 60 to 100 µg per dose.

3. The ~~composition for~~ use according to claim 1 or 2, wherein the composition is to be administered at least three times, wherein the second administration is in the period of at least 6 weeks to at most 3 months after the first administration and/or the third administration is in the period of at least 5 months to at most 7 months after the first administration; or wherein the second administration is in the period of at least 50 days to at most 70 days, particularly in the period of at least 55 days to at most 60 days, especially 56 day, after the first administration and/or wherein the third administration is in the period of at least 170 days to at most 190 days, in the period of at least 175 days to at most 185 days, especially 180 day, after the first administration.

~~4. The composition for use according to claims 1 to 3, wherein the second administration is in the period of at least 50 days to at most 70 days, particularly in the period of at least 55 days to at most 60 days, especially 56 day, after the first administration; and/or wherein the third administration is in the period of at least 170 days to at most 190 days, in the period of at least 175 days to at most 185 days, especially 180 day, after the first administration.~~

~~5~~4. The ~~composition for~~ use according to any of claims 1 to ~~4~~3, wherein the composition is to be administered at least three times, wherein a fourth administration of the composition is in the period of at least 15 months to at most 21 months, particularly in the period of at least 17 months to at most 19 months, especially 18 months, after the first administration.

5. The use according to any of claims 1 to 4, wherein the composition is to be administered at least two times, wherein the second administration is in the period of at least 5 months to at most 7 months after the first administration; or wherein the second administration is in the period of at least 170 days to at most 190 days, in the period of at least 175 days to at most 185 days, especially 180 days, after the first administration.

6. The use according to any of claims 1 to 5, wherein the composition is to be administered at least two times, wherein, wherein a third administration of the composition is in the period of at least 15 months to at most 21 months, particularly in the period of at least 17 months to at most 19 months, especially 18 months, after the first administration.

~~6~~7. The ~~composition for~~ use according to any of claims 1 to ~~5~~6, wherein the total protein content of said 3 fusion proteins is in the range of from 135 µg to 180 µg per dose, particularly 135 µg or 180 µg per dose for a human adult or child, or wherein the total protein content of said 3 fusion proteins is in the range of from 67.5 µg to 90 µg per dose, particularly 67.5 µg or 90 µg per dose for a young child.

~~7~~8. The ~~composition for~~ use according to any of claims 1 to ~~6~~7, wherein the 3 fusion proteins comprise at least 60%, preferably at least 70%, more preferably 80% of all proteins in the composition.

~~8~~9. The ~~composition for~~ use according to any of claims 1 to ~~7~~8, wherein the composition comprises the fusion proteins in a weight ratio of 1:1:1 (Lip-S1D1-S2D1 : Lip-S4D1-S3hybD1 : Lip-S5D1-S6D1).

~~9~~10. The ~~composition for~~ use according to any of claims 1 to ~~8~~9, wherein the composition comprises an adjuvant.

~~10~~11. The ~~composition for~~ use according to any of claims 1 to ~~9~~10, wherein the composition comprises an aluminum adjuvant, preferably an aluminium adjuvant with low copper content, preferably less than 1.25 ppb copper.

~~11~~12. The ~~composition for~~ use according to any of claims 1 to ~~10~~11, wherein the composition is to be administered at least three times, wherein the total protein content of said 3 fusion proteins is 135 µg or 180 µg per dose for a human adult or child, wherein the second administration is 56 day after the first administration, wherein the third administration is 180 day after the first administration, and wherein the optional fourth administration is 18 months after the first administration; or wherein the total protein content of said 3 fusion proteins is 67.5 µg or 90 µg per dose for a young child, wherein the second administration is 56 day after the first administration, wherein the third administration is 180 day after the first administration, and wherein the optional fourth administration is 18 months after the first administration.

~~12. The composition for use according to any of claims 1 to 10, wherein the total protein content of said 3 fusion proteins is 67.5 µg per dose for a young child, wherein the second administration is 56 day after the first administration, wherein the third administration is 180 day after the first administration, and wherein the optional fourth administration is 18 months after the first administration.~~

~~13. The composition for use according to any of claims 1 to 10, wherein the total protein content of said 3 fusion proteins is 180 µg per dose for a human adult or child, wherein the second administration is 56 day after the first administration, wherein the third administration~~

~~is 180 day after the first administration, and wherein the optional fourth administration is 18 months after the first administration.~~

~~14. The composition for use according to any of claims 1 to 10, wherein the total protein content of said 3 fusion proteins is 90 μg per dose for a young child, wherein the second administration is 56 day after the first administration, wherein the third administration is 180 day after the first administration, and wherein the optional fourth administration is 18 months after the first administration.~~

~~15~~13. The ~~composition for~~ use according to any of claims 1 to ~~10~~12, wherein the composition is to be administered at least three times, wherein the total protein content of said 3 fusion proteins is 135 μg or 180 μg per dose for a human adult or child, wherein the second administration is 2 months day after the first administration, wherein the third administration is 6 months after the first administration, and wherein the optional fourth administration is 18 months after the first administration; or wherein the total protein content of said 3 fusion proteins is 67.5 μg or 90 μg per dose for a young child, wherein the second administration is 2 months after the first administration, wherein the third administration is 6 months after the first administration, and wherein the optional fourth administration is 18 months after the first administration.

~~16. The composition for use according to any of claims 1 to 10, wherein the total protein content of said 3 fusion proteins is 67.5 μg per dose for a young child, wherein the second administration is 2 months after the first administration, wherein the third administration is 6 months after the first administration, and wherein the optional fourth administration is 18 months after the first administration.~~

~~17. The composition for use according to any of claims 1 to 10, wherein the total protein content of said 3 fusion proteins is 180 μg per dose for a human adult or child, wherein the second administration is 2 months after the first administration, wherein the third administration is 6 months the first administration, and wherein the optional fourth administration is 18 months after the first administration.~~

~~18. The composition for use according to any of claims 1 to 10, wherein the total protein content of said 3 fusion proteins is 90 µg per dose for a young child, wherein the second administration is 2 months day after the first administration, wherein the third administration is 6 months after the first administration, and wherein the optional fourth administration is 18 months after the first administration.~~

14. The use according to any of claims 1 to 13, wherein the composition is to be administered at least two times, wherein the total protein content of said 3 fusion proteins is 135 µg or 180 µg per dose for a human adult or child, wherein the second administration is 180 days after the first administration, and wherein the optional third administration is 18 months after the first administration and optionally thereafter every 12 months; or wherein the total protein content of said 3 fusion proteins is 67.5 µg or 90 µg per dose for a young child, wherein the second administration is 180 days after the first administration, and wherein the optional third administration is 18 months after the first administration and optionally thereafter every 12 months.

15. The use according to any of claims 1 to 14, wherein the composition is to be administered at least two times, wherein the total protein content of said 3 fusion proteins is 135 µg or 180 µg per dose for a human adult or child, wherein the second administration is 6 months after the first administration, and wherein the optional third administration is 18 months after the first administration and optionally thereafter every 12 months; or wherein the total protein content of said 3 fusion proteins is 67.5 µg or 90 µg per dose for a young child, wherein the second administration is 6 months after the first administration, and wherein the optional third administration is 18 months after the first administration and optionally thereafter every 12 months.

~~19~~16. The ~~composition for~~ use according to any of claims 1 to ~~18~~15, wherein further administrations are every year after the ~~third administration~~last primary immunization or at the beginning of each tick season, particularly after 1 year, after 2 years and after 3 years and so on.

~~20~~17. The ~~composition for~~ use according to any of claims 1 to ~~19~~16, wherein the immune response elicited comprises an anti-OspA serotype 1, an anti-OspA serotype 2, an anti-OspA

serotype 3, an anti-OspA serotype 4, anti-OspA serotype 5 and/or an anti-OspA serotype 6 antibody response with bactericidal activity.

~~21~~18. The ~~composition for~~ use according to any of claims 1 to ~~20~~17, wherein the immune response elicited comprises antibodies against ~~borrelia~~ OspA serotypes 1, 2, 3, 4, 5 and 6.

~~22~~19. The ~~composition for~~ use according to any of claims 1 to ~~21~~18, wherein the immune response against ~~borrelia~~ OspA serotypes 1, 2, 3, 4, 5 and 6 is sustained for at least about 60 days, for at least about 180 days, for at least about 365 days or for at least about 540 days.

~~23~~20. The ~~composition for~~ use of any of claims 1 to ~~22~~19, wherein the composition comprises less than 1.25 ppb copper and/or a sufficient amount of L-methionine.

~~24~~21. The ~~composition for~~ use of any of claims 1 to ~~23~~20, wherein copper is in form of an ion, particularly as Cu^{+} or Cu^{2+}, wherein L-methionine is present in a concentration of at least 10 mmol/l and/or wherein the concentration of L-methionine in mol/l is at least equivalent with the concentration of copper in the composition.

~~25. The composition for use of any of claims 1 to 24, wherein L-methionine is present in a concentration of at least 10 mmol/l.~~

~~26. The composition for use of any of claims 23 to 25, wherein the concentration of L-methionine in mol/l is at least equivalent with the concentration of copper in the composition.~~

~~27~~22. The ~~composition for~~ use of any of claims 1 to ~~26~~ 21, further comprising a reactive compound, wherein the reactive compound is selected from the group consisting of a redox active compound, a radical building compound, a stabilizing compound and a combination of any thereof, especially wherein the reactive compound is selected from the group consisting of formaldehyde, ethanol, chloroform, trichloroethylene, acetone, triton-X-100, deoxycholate, diethylpyrocarbonate, sulphite, $Na_2S_2O_5$, beta-proprio-lacton, polysorbate such as Tween 20®, Tween 80®, O_2, phenol, pluronic type copolymers, and a combination of any thereof.

~~28~~23. The ~~composition for~~ use according to any of claims 1 to ~~27~~22, wherein said human adult is a subject who is 18 years or older, such as 18-65 years old.

~~29~~24. The ~~composition for~~ use according to any of claims 1 to ~~27~~22, wherein said human adult is an elderly subject who is 50 years or older.

~~30~~25. The ~~composition for~~ use according to any of claims 1 to ~~27~~22, wherein said human child is a subject who is 5-17 years old, such as 12-17 years old or 5-11 years old.

~~31~~26. The ~~composition for~~ use according to any of claims 1 to ~~27~~22, wherein said human child is a subject who is 0-4 years old, such as 1-4 years old, or 2-4 years old.

~~32~~27. The ~~composition for~~ use according to any of claims 1 to ~~31~~26, wherein said composition is to be administered to a human adult or child in a volume of 0.25 milliliter (ml) to 1.0 ml, such as 0.25 ml, 0.3 ml, 0.4 ml, 0.5 ml, 0.6 ml, 0.7 ml, 0.8 ml, 0.9 ml, or 1.0 ml.

~~33~~28. The ~~composition for~~ use according to any of claims 1 to ~~32~~27, wherein said composition is to be administered to a human adult or child in a volume of 0.25 ml, 0.5 ml, or 1.0 ml.

~~34. A composition for use for vaccinating a human, the method comprising administering a composition comprising the fusion protein of SEQ ID NO: 1 (Lip-S1D1-S2D1), the fusion protein of SEQ ID NO: 2 (Lip-S4D1-S3hybD1) and the fusion protein of SEQ ID NO: 3 (Lip-S5D1-S6D1)~~

~~- to a human adult or human child at least two times at a total protein content of said 3 fusion proteins in the range of from 120 to 200 µg per dose; or~~

~~- to a human child at least two times at a total protein content of said 3 fusion proteins in the range of from 60 to 100 µg per dose.~~

~~35. A composition for use for eliciting an immune response in a human against Lyme disease, the method comprising administering a composition comprising the fusion protein of~~

~~SEQ ID NO: 1 (Lip-S1D1-S2D1), the fusion protein of SEQ ID NO: 2 (Lip-S4D1-S3hybD1) and the fusion protein of SEQ ID NO: 3 (Lip-S5D1-S6D1)~~

~~- to a human adult or human child at least two times at a total protein content of said 3 fusion proteins in the range of from 120 to 200 µg per dose; or~~

~~- to a human child at least two times at a total protein content of said 3 fusion proteins in the range of from 60 to 100 µg per dose.~~

~~36. The composition for use according to claim 34 or claim 35, wherein the second administration is in the period of at least 5 months to at most 7 months after the first administration.~~

~~37. The composition for use according to any of claims 34 to 36, wherein the second administration is in the period of at least 170 days to at most 190 days, in the period of at least 175 days to at most 185 days, especially 180 days, after the first administration.~~

~~38. The composition for use according to any of claims 34 to 37, wherein a third administration of the composition is in the period of at least 15 months to at most 21 months, particularly in the period of at least 17 months to at most 19 months, especially 18 months, after the first administration.~~

~~39. The composition for use according to any of claims 34 to 38, wherein the total protein content of said 3 fusion proteins is in the range of from 135 µg to 180 µg per dose, particularly 135 µg or 180 µg per dose for a human adult or child, or wherein the total protein content of said 3 fusion proteins is in the range of from 67.5 µg to 90 µg per dose, particularly 67.5 µg or 90 µg per dose for a young child.~~

~~40. The composition for use according to any of claims 34 to 39, wherein the 3 fusion proteins comprise at least 60%, preferably at least 70%, more preferably at least 80% of all proteins in the composition.~~

41. The composition for use according to any of claims 34 to 40, wherein the composition comprises the fusion proteins in a weight ratio of 1:1:1 (Lip-S1D1-S2D1 : Lip-S4D1-S3hybD1 : Lip-S5D1-S6D1).

42. The composition for use according to any of claims 34 to 41, wherein the composition comprises an adjuvant.

43. The composition for use according to any of claims 34 to 42, wherein the composition comprises an aluminum adjuvant.

44. The composition for use according to any of claims 34 to 43, wherein the total protein content of said 3 fusion proteins is 135 µg per dose for a human adult or child, wherein the second administration is 180 days after the first administration, and wherein the optional third administration is 18 months after the first administration and optionally thereafter every 12 months.

45. The composition for use according to any of claims 34 to 43, wherein the total protein content of said 3 fusion proteins is 67.5 µg per dose for a young child, wherein the second administration is 180 days after the first administration, and wherein the optional third administration is 18 months after the first administration and optionally thereafter every 12 months.

46. The composition for use according to any of claims 34 to 43, wherein the total protein content of said 3 fusion proteins is 180 µg per dose for a human adult or child, wherein the second administration is 180 days after the first administration, and wherein the optional third administration is 18 months after the first administration and optionally thereafter every 12 months.

47. The composition for use according to any of claims 34 to 43, wherein the total protein content of said 3 fusion proteins is 90 µg per dose for a young child, wherein the second administration is 180 days after the first administration, and wherein the optional third

~~administration is 18 months after the first administration and optionally thereafter every 12 months.~~

~~48. The composition for use according to any of claims 34 to 43, wherein the total protein content of said 3 fusion proteins is 135 µg per dose for a human adult or child, wherein the second administration is 6 months after the first administration, and wherein the optional third administration is 18 months after the first administration and optionally thereafter every 12 months.~~

~~49. The composition for use according to any of claims 34 to 43, wherein the total protein content of said 3 fusion proteins is 67.5 µg per dose for a young child, wherein the second administration is 6 months after the first administration, and wherein the optional third administration is 18 months after the first administration and optionally thereafter every 12 months.~~

~~50. The composition for use according to any of claims 34 to 43, wherein the total protein content of said 3 fusion proteins is 180 µg per dose for a human adult or child, wherein the second administration is 6 months the first administration, and wherein the optional third administration is 18 months after the first administration and optionally thereafter every 12 months.~~

~~51. The composition for use according to any of claims 34 to 43, wherein the total protein content of said 3 fusion proteins is 90 µg per dose for a young child, wherein the second administration is 6 months after the first administration, and wherein the optional third administration is 18 months after the first administration and optionally thereafter every 12 months.~~

~~52. The composition for use according to any of claims 34 to 51, wherein further administrations are every year after the last primary immunization or at the beginning of each tick season, particularly after 1 year, after 2 years and after 3 years and so on.~~

53. The composition for use according to any of claims 34 to 52, wherein the immune response elicited comprises an anti-OspA serotype 1, an anti-OspA serotype 2, an anti-OspA serotype 3, an anti-OspA serotype 4, anti-OspA serotype 5 and/or an anti-OspA serotype 6 antibody response with bactericidal activity.

54. The composition for use according to any of claims 34 to 53, wherein the immune response elicited comprises antibodies with bactericidal activity against OspA serotypes 1, 2, 3, 4, 5 and 6 expressing spirochetes.

55. The composition for use according to any of claims 34 to 54, wherein the immune response against OspA serotypes 1, 2, 3, 4, 5 and 6 is sustained for at least about 60 days, for at least about 180 days, for at least about 365 days or for at least about 540 days.

56. The composition for use of any of claims 34 to 55, wherein the composition comprises less than 1.25 ppb copper or a sufficient amount of L-methionine.

57. The composition for use of any of claims 34 to 56, wherein copper is in form of an ion, particularly as Cu+ or Cu2+.

58. The composition for use of any of claims 34 to 57, wherein L-methionine is present in a concentration of at least 10 mmol/l.

59. The composition for use of any of claims 56 to 58, wherein the concentration of L-methionine in mol/l is at least equivalent with the concentration of copper in the composition.

60. The composition for use of any of claims 34 to 59, wherein the composition further comprises a reactive compound, wherein the reactive compound is selected from the group consisting of a redox active compound, a radical building compound, a stabilizing compound and a combination of any thereof, especially wherein the reactive compound is selected from the group consisting of formaldehyde, ethanol, chloroform, trichloroethylene, acetone, triton-X-100, deoxycholate, diethylpyrocarbonate, sulphite, Na2S2O5, beta-proprio-lacton,

polysorbate such as Tween 20®, Tween 80®, O2, phenol, pluronic type copolymers, and a combination of any thereof.

61. The composition for use according to any of claims 34 to 60, wherein said human adult is a subject who is 18 years or older, such as 18-65 years.

62. The composition for use according to any of claims 34 to 60, wherein said human adult is an elderly subject who is 50 years or older.

63. The composition for use according to any of claims 34 to 60, wherein said human child is a subject who is 5-17 years old, such as 12-17 years old or 5-11 years old.

64. The composition for use according to any of claims 34 to 60, wherein said human child is a subject who is 0-4 years old, such as 1-4 years old, or 2-4 years old.

65. The composition for use according to any of claims 34 to 64, wherein said composition is administered to a human adult or child in a volume of 0.25 milliliter (ml) to 1.0 ml, such as 0.25 ml, 0.3 ml, 0.4 ml, 0.5 ml, 0.6 ml, 0.7 ml, 0.8 ml, 0.9 ml, or 1.0 ml.

66. The composition for use according to any of claims 34 to 65, wherein said composition is administered to a human adult or child in a volume of 0.25 ml, 0.5 ml, or 1.0 ml.