CLAIMS

1. Use of a tetravalent dengue vaccine composition including four live attenuated dengue virus strains representing serotype 1, serotype 2, serotype 3 and serotype 4 in the manufacture of a medicament for preventing dengue disease in a subject or subject population, wherein preventing dengue disease comprises that one dose of the dengue vaccine composition is to be administered to the subject or subject population, wherein the administration of the one dose results in a reduction of risk of dengue disease after said one dose represented by a combined vaccine efficacy against all four dengue virus serotypes of at least 60%, and wherein each of the four live, attenuated dengue virus strains is selected from the following:
(i) a non-chimeric dengue virus comprising all components from the same dengue serotype, and
(ii) a chimeric dengue virus having parts from two dengue serotypes.

2. The use according to claim 1,
wherein the one dose results in a reduction of risk of dengue disease after said one dose represented by a combined vaccine efficacy against all four dengue virus serotypes of at least 70%.

3. The use according to claim 1,
wherein the one dose results in a reduction of risk of dengue disease after said one dose represented by a combined vaccine efficacy against all four dengue virus serotypes of at least 80%.

4. The use according to claim 1,
wherein the one dose results in a reduction of risk of dengue disease after said one dose represented by a combined vaccine efficacy against all four dengue virus serotypes of at least 80%, wherein the lower bound of the two-sided 95% confidence interval is more than 60%.

5. The use of any one of claims 1 to 4,
wherein the vaccine efficacy is measured from day 1 after the one dose to day 90 after the one dose or is measured over three months after the one dose.

6. The use of any one of claims 1 to 5, wherein the dengue disease is due to dengue serotype 1 and/or dengue serotype 2.

7. Use of a tetravalent dengue vaccine composition including four live attenuated dengue virus strains representing serotype 1, serotype 2, serotype 3 and serotype 4 in the manufacture of a medicament for preventing dengue disease in a subject or subject population traveling to a dengue endemic region, wherein preventing dengue disease comprises that one dose of the dengue vaccine composition is to be administered to the subject or subject population, wherein the administration of the one dose results in a reduction of risk of dengue disease after said one dose represented by a combined vaccine efficacy against all four dengue virus serotypes of at least 60%, and
wherein each of the four live, attenuated dengue virus strains is selected from the following:
(i) a non-chimeric dengue virus comprising all components from the same dengue serotype, and
(ii) a chimeric dengue virus having parts from two dengue serotypes.

8. The use of claim 7, wherein the dengue disease is due to dengue serotype 1 and/or dengue serotype 2.

9. The use of claim 7 or 8, wherein the dengue endemic region is characterized by a seroprevalence rate with respect to dengue serotype 1 and/or dengue serotype 2 of at least about 80% or at least about 90%.

10. The use of any one of claims 7 to 9, wherein the dengue endemic region is in Latin America, Southeast Asia and/or the Pacific Islands.

11. The use of any one of claims 7 to 10, the subject or subject population travelling to Australia, Brazil, Bangladesh, Colombia, China, the Dominican Republic, Indonesia, India, Mexico, Malaysia, Nicaragua, Nigeria, Pakistan, Panama, Philippines, Puerto Rico, Singapore, Sri Lanka, Thailand and/or Vietnam.

12. The use of any one of claims 7 to 11, wherein the subject or subject population is from a dengue non-endemic region.

13. Use of a tetravalent dengue vaccine composition including four live attenuated dengue virus strains representing serotype 1, serotype 2, serotype 3 and serotype 4 in the manufacture of a medicament for preventing dengue disease in a subject or subject population exposed to a dengue outbreak, wherein preventing dengue disease comprises that one dose of the dengue vaccine composition is to be administered to the subject or subject population, wherein the administration of the one dose results in a reduction of risk of dengue disease after said one dose represented by a combined vaccine efficacy against all four dengue virus serotypes of at least 60%, and wherein each of the four live, attenuated dengue virus strains is selected from the following:

(i) a non-chimeric dengue virus comprising all components from the same dengue serotype, and

(ii) a chimeric dengue virus having parts from two dengue serotypes.

14. The use of claim 13, wherein the composition is for controlling a dengue outbreak.

15. The use of claim 13 or 14, wherein the dengue outbreak occurs in a dengue endemic region.

16. The use of claim 15, wherein the dengue endemic region is in Latin America, Southeast Asia and/or the Pacific Islands.

17. The use of any one of claims 13 to 16, wherein the dengue outbreak occurs in Australia, Brazil, Bangladesh, Colombia, China, the Dominican Republic, Indonesia, India, Mexico, Malaysia, Nicaragua, Nigeria, Pakistan, Panama, Philippines, Puerto Rico, Singapore, Sri Lanka, Thailand and/or Vietnam.

18. The use of any one of claims 13 to 17, wherein the dengue outbreak and the dengue disease are due to a dengue serotype 2 and/or dengue serotype 1.

19. Use of a tetravalent dengue vaccine composition including four live attenuated dengue virus strains representing serotype 1, serotype 2, serotype 3 and serotype 4 in the manufacture of a medicament for

preventing dengue disease in a subject or subject population, wherein preventing dengue disease comprises that one dose of the dengue vaccine composition is to be administered to the subject or subject population, wherein the administration of the one dose results in a reduction of risk of dengue disease within three months after said one dose, wherein the administration of the one dose results in a reduction of risk of dengue disease after said one dose represented by a combined vaccine efficacy against all four dengue virus serotypes of at least 60%, and

wherein each of the four live, attenuated dengue virus strains is selected from the following:

(i) a non-chimeric dengue virus comprising all components from the same dengue serotype, and

(ii) a chimeric dengue virus having parts from two dengue serotypes.

20. The use of claim 19, wherein the one dose results in a reduction of risk of dengue disease within 90 days, within two months, within one month, or within two weeks after said one dose.

21. The use of claim 19 or 20, wherein the dengue disease is due to dengue serotype 1 and/or dengue serotype 2.

22. The use of any one of claims 7 to 21, wherein the one dose results in a reduction of risk of dengue disease after said one dose represented by a combined vaccine efficacy against all four dengue virus serotypes of at least 70%.

23. The use of any one of claims 7 to 21, wherein the one dose results in a reduction of risk of dengue disease after said one dose represented by a combined vaccine efficacy against all four dengue virus serotypes of at least 80%.

24. The use of any one of claims 7 to 21, wherein the one dose results in a reduction of risk of dengue disease after said one dose represented by a combined vaccine efficacy against all four dengue virus serotypes of at least 80%, wherein the lower bound of the two-sided 95% confidence interval is more than 60%.

25. The use of any one of claims 7 to 24, wherein the vaccine efficacy is measured from day 1 after the one dose to day 90 after the one dose, or is measured over three months after the one dose.

26. The use of any one of claims 1 to 25, wherein the dengue vaccine composition includes at least one chimeric dengue virus and at least one non-chimeric dengue virus.

27. The use of any one of claims 1 to 26, wherein each of the four live, attenuated dengue virus strains comprises dengue structural proteins including capsid protein (C), pre-membrane protein (prM), and envelope protein (E), and dengue non-structural proteins including NS1, NS2A, NS2B, NS3, NS4A, NS4B, and NS5.

28. The use of any one of claims 1 to 27, wherein the subject or subject population is seronegative at baseline.

29. The use of any one of claims 1 to 27, wherein the subject or subject population is seropositive with respect to at least one dengue serotype at baseline.

30. The use of any one of claims 1 to 29, wherein the one dose of the dengue vaccine composition results in reduction of risk of dengue disease in the subject or subject population regardless of the baseline serostatus of the subject or subject population.

31. The use of any one of claims 1 to 29, wherein the one dose of the dengue vaccine composition results in reduction of risk of dengue disease in the subject or subject population regardless of whether said subject or subject population is seronegative at baseline or seropositive with respect to at least one dengue serotype at baseline.

32. The use of any one of claims 1 to 31, wherein the subject or subject population has been subject to prior vaccination against Yellow Fever, wherein prior vaccination against Yellow Fever refers to a vaccination prior to the administration of said one dose.

33. The use of any one of claims 1 to 32, wherein the subject or subject population has been subject to prior vaccination against Japanese Encephalitis, wherein prior vaccination against Japanese Encephalitis refers to a vaccination prior to the administration of said one dose.

34. The use of any one of claims 1 to 33, wherein the subject or subject population is under 9 years of age, or 4 to 5 years of age, or 6 to 11 years of age, or 12 to 16 years of age, or 6 to 16 years of age, or 4 to 16 years of age, or 2 to 17 years of age, or 9 years of age, or over 9 years of age, or 9 to 19 years of age, or 18 to 60 years of age, or 18 to 45 years of age, or 46 to 60 years of age.

35. The use of any one of claims 1 to 34, wherein the subject or subject population is over 60 years of age, such as 61 years to 100 years of age, or 61 years to 90 years of age, or 61 years to 80 years of age, or 61 years to 75 years of age, or 61 years to 70 years of age.

36. The use of claim 35, wherein the subject or subject population has at least one chronic disease or condition, optionally wherein the at least one chronic condition or disease is selected from diabetes, hypertension, allergies, previous strokes, ischemic heart disease, chronic renal impairment and chronic obstructive pulmonary disease.

37. The use of any one of claims 1 to 36, further comprising that a second dose of the dengue vaccine composition is to be administered to the subject or subject population, wherein the second dose is to be administered within 12 months, or within six months, or within three months of the administration of the first dose, preferably wherein the second dose is to be administered at least 4 weeks after the administration of the first dose.

38. The use of any one of claims 1 to 37, further comprising that a booster dose of the dengue vaccine composition is to be administered to the subject or subject population after the primary vaccination, optionally wherein the booster dose is the third dose of the dengue vaccine composition that is to be administered to the subject or subject population.

39. The use of claim 38, wherein the booster dose is to be administered at least 12 months or at least 5 years after the administration of said one dose, optionally wherein the booster dose is to be administered 12 months after the administration of said one dose.

40. The use of any one of claims 1 to 39, wherein the dengue vaccine composition is to be administered by subcutaneous injection, preferably to the deltoid region of the arm.

41. The use of any one of claims 1 to 40, further comprising that the subject or subject population is to be co-vaccinated with another dengue vaccine composition.

42. The use of claim 41, wherein the other dengue vaccine composition is a tetravalent dengue vaccine composition based on a yellow fever backbone.

43. The use of claim 42, wherein the other dengue vaccine composition is to be administered within 4.5 years after administration of the one dose.

44. The use of any one of claims 1 to 43, wherein the dengue vaccine composition is to be co-administered with a cholera vaccine, hepatitis E vaccine, Japanese encephalitis vaccine, meningococcal disease vaccine, rabies vaccine, tick-borne encephalitis vaccine, typhoid fever vaccine, or a combination thereof.

45. The use of any one of claims 1 to 43, wherein the dengue vaccine composition is to be administered concomitantly, simultaneously, or sequentially with another vaccine, optionally wherein the dengue vaccine composition and the other vaccine are to be administered on the same day.

46. The use of claim 45, wherein the other vaccine is to be administered by subcutaneous injection or intramuscular injection.

47. The use of claim 45 or 46, wherein the dengue vaccine composition and the other vaccine are to be administered to different anatomical sites, such as to opposite arms or to arm and thigh.

48. The use of any one of claims 45 to 47, wherein the dengue vaccine composition is to be administered concomitantly, simultaneously, or sequentially with a yellow fever vaccine, such as YF-17D, for preventing yellow fever; and/or a hepatitis A vaccine, such as HAVRIX® or VAQTA®, for preventing hepatitis A; and/or an HPV vaccine for preventing HPV-associated cancers or genital warts, preferably wherein the HPV vaccine is a 9vHPV vaccine, such as GARDASIL® 9; and/or an MMR vaccine, such as M-M-R® II, for preventing measles, mumps and rubella; and/or a tetanus, diphtheria, and pertussis (Tdap) vaccine for preventing tetanus, diphtheria, and pertussis, preferably wherein the Tdap vaccine is a combined tetanus toxoid, reduced diphtheria toxoid and acellular pertussis (adsorbed) vaccine, such as BOOSTRIX®; and/or a DTaP/IPV/Hib vaccine, such as Pentacel®, for preventing diphtheria, tetanus, pertussis, poliomyelitis and diseases caused by *Haemophilus influenzae* type b.

49. The use of any one of claims 45 to 48, wherein the dengue vaccine composition is to be administered simultaneously with a yellow fever vaccine and a hepatitis A vaccine, optionally wherein the dengue vaccine composition, the yellow fever vaccine, and the hepatitis A vaccine are to be administered on the same day.

50. The use of any one of claims 45 to 48, wherein the dengue vaccine composition is to be administered concomitantly, simultaneously, or sequentially with a yellow fever vaccine, such as YF-17D, for preventing yellow fever.

51. The use of any one of claims 45 to 48, wherein the dengue vaccine composition is to be administered simultaneously with a yellow fever vaccine, such as YF-17D, for preventing yellow fever, optionally wherein the dengue vaccine composition and the yellow fever vaccine are to be administered on the same day.

52. The use of any one of claims 45 to 48, wherein the dengue vaccine composition is to be administered concomitantly, simultaneously, or sequentially with a yellow fever vaccine, such as YF-17D, for preventing yellow fever, wherein:

-the yellow fever vaccine is to be administered on day 0,

-the first dose of the dengue vaccine composition is to be administered after said administration of the yellow fever vaccine, such as 3 months later and preferably on day 90, and

-a second dose of the dengue vaccine composition is to be administered after said administration of the first dose of the dengue vaccine composition, such as 3 months later and preferably on day 180,

or

-the first dose of the dengue vaccine composition is to be administered on day 0,

-a second dose of the dengue vaccine composition is to be administered after said administration of the first dose of the dengue vaccine composition, such as 3 months later and preferably on day 90, and

-the yellow fever vaccine is to be administered after said administration of the second dose of dengue vaccine composition, such as 3 months later and preferably on day 180,

or

-the first dose of the dengue vaccine composition and the yellow fever vaccine are to be simultaneously administered on day 0,

-a second dose of the dengue vaccine composition is to be administered after said simultaneous administration of the first dose of the dengue vaccine composition and the yellow fever vaccine, such as 3 months later and preferably on day 90.

53. The use of any one of claims 45 to 48, wherein the dengue vaccine composition is to be administered concomitantly, simultaneously, or sequentially with a hepatitis A vaccine, such as HAVRIX® or VAQTA®, for preventing hepatitis A.

54. The use of any one of claims 45 to 48, wherein the dengue vaccine composition is to be administered simultaneously with a hepatitis A vaccine, such as HAVRIX® or VAQTA®, for preventing hepatitis A, optionally wherein the dengue vaccine composition and the hepatitis A vaccine are to be administered on the same day.

55. The use of any one of claims 45 to 48, wherein the dengue vaccine composition is to be administered concomitantly, simultaneously, or sequentially with a hepatitis A vaccine, such as HAVRIX® or VAQTA®, for preventing hepatitis A, wherein:

-the first dose of the dengue vaccine composition and the hepatitis A vaccine are to be simultaneously administered on day 0,

-a second dose of the dengue vaccine composition is to be administered after said simultaneous administration of the first dengue vaccine composition and the hepatitis A vaccine, such as 3 months later and preferably on day 90.

56. The use of any one of claims 45 to 48, wherein the dengue vaccine composition is to be administered concomitantly, simultaneously, or sequentially with an HPV vaccine for preventing HPV-associated cancers or genital warts, preferably wherein the HPV vaccine is a 9vHPV vaccine, such as GARDASIL® 9.

57. The use of any one of claims 45 to 48, wherein the dengue vaccine composition is to be administered simultaneously with an HPV vaccine for preventing HPV-associated cancers or genital warts, preferably wherein the HPV vaccine is a 9vHPV vaccine, such as GARDASIL® 9, optionally wherein the dengue vaccine composition and the HPV vaccine are to be administered on the same day.

58. The use of any one of claims 45 to 48, wherein the dengue vaccine composition is to be administered concomitantly, simultaneously, or sequentially with an HPV vaccine for preventing HPV-associated cancers or genital warts, preferably wherein the HPV vaccine is a 9vHPV vaccine, such as GARDASIL® 9, wherein:

-the first dose of the dengue vaccine composition and a first dose of HPV vaccine are to be simultaneously administered on day 0,

-a second dose of dengue vaccine composition is to be administered after said simultaneous administration of the first dose of the dengue vaccine composition and the first dose of the HPV vaccine such as 3 months later and preferably on day 90,

-a second dose of the HPV vaccine is to be administered after said administration of the second dose of the dengue vaccine composition, such as 3 months later and preferably on day 180.

59. The use of any one of claims 45 to 48, wherein the dengue vaccine composition is to be administered concomitantly, simultaneously, or sequentially, with an MMR vaccine, such as M-M-R® II, for preventing measles, mumps and rubella.

60. The use of any one of claims 45 to 48, wherein the dengue vaccine composition is to be administered simultaneously with an MMR vaccine, such as M-M-R® II, for preventing measles, mumps and rubella, optionally wherein the dengue vaccine composition and the MMR vaccine are to be administered on the same day.

61. The use of any one of claims 45 to 48, wherein the dengue vaccine composition is to be administered concomitantly, simultaneously, or sequentially, with an MMR vaccine, such as M-M-R® II, for preventing measles, mumps and rubella, wherein:

-the first dose of the dengue vaccine composition and a first dose of the MMR vaccine are to be simultaneously administered on day 0,

-a second dose of the dengue vaccine composition is to be administered after said simultaneous administration of the first dose of the dengue vaccine composition and the first dose of the MMR vaccine such as 3 months later and preferably on day 90,

-a second dose of the MMR vaccine is to be administered after said administration of the second dose of the dengue vaccine composition, such as 3 to 6 years after said simultaneous administration of the first dose of the dengue vaccine composition and the first dose of the MMR vaccine.

62. The use of any one of claims 45 to 48, wherein the dengue vaccine composition is to be administered concomitantly, simultaneously, or sequentially, with a tetanus, diphtheria, and pertussis (Tdap) vaccine for preventing tetanus, diphtheria, and pertussis, preferably wherein the Tdap vaccine is a combined tetanus toxoid, reduced diphtheria toxoid and acellular pertussis (adsorbed) vaccine, such as BOOSTRIX®.

63. The use of any one of claims 45 to 48, wherein the dengue vaccine composition is to be administered simultaneously with a tetanus, diphtheria, and pertussis (Tdap) vaccine for preventing tetanus, diphtheria, and pertussis, preferably wherein the Tdap vaccine is a combined tetanus toxoid, reduced diphtheria toxoid and acellular pertussis (adsorbed) vaccine, such as BOOSTRIX®, optionally wherein the dengue vaccine composition and the tetanus, diphtheria, and pertussis (Tdap) vaccine are to be administered on the same day.

64. The use of any one of claims 45 to 48, wherein the dengue vaccine composition is to be administered concomitantly, simultaneously, or sequentially, with a tetanus, diphtheria, and pertussis (Tdap) vaccine for preventing tetanus, diphtheria, and pertussis, preferably wherein the Tdap vaccine is a combined tetanus toxoid, reduced diphtheria toxoid and acellular pertussis (adsorbed) vaccine, such as BOOSTRIX®, wherein:

-the first dose of the dengue vaccine composition and the Tdap vaccine are to be simultaneously administered on day 0, and

-a second dose of the dengue vaccine composition is to be administered after said simultaneous administration of the first dose of the dengue vaccine composition and the first dose of the Tdap vaccine, such as 3 months later and preferably on day 90.

65. The use of any one of claims 45 to 48, wherein the dengue vaccine composition is to be administered concomitantly, simultaneously, or sequentially, with a DTaP/IPV/Hib vaccine, such as Pentacel®, for preventing diphtheria, tetanus, pertussis, poliomyelitis and diseases caused by *Haemophilus influenzae* type b.

66. The use of any one of claims 45 to 48, wherein the dengue vaccine composition is to be administered simultaneously with a DTaP/IPV/Hib vaccine, such as Pentacel®, for preventing diphtheria, tetanus, pertussis, poliomyelitis and diseases caused by *Haemophilus influenzae* type b, optionally wherein the dengue vaccine composition and the DTaP/IPV/Hib vaccine are to be administered on the same day.

67. The use of any one of claims 45 to 48, wherein the dengue vaccine composition is to be administered concomitantly, simultaneously, or sequentially, with a DTaP/IPV/Hib vaccine, such as Pentacel®, for preventing diphtheria, tetanus, pertussis, poliomyelitis and diseases caused by *Haemophilus influenzae* type b, wherein:

-the first dose of the dengue vaccine composition and a first dose of the DTaP/IPV/Hib vaccine are to be simultaneously administered on day 0,

-a second dose of the DTaP/IPV/Hib vaccine is to be administered after said simultaneous administration of the first dose of the dengue vaccine composition and the first dose of the DTaP/IPV/Hib vaccine such as 2 months later and preferably on day 60,

-a second dose of the dengue vaccine composition is to be administered after said second dose of the DTaP/IPV/Hib vaccine such as 3 months after the simultaneous administration of the first dose of the dengue vaccine composition and the first dose of the DTaP/IPV/Hib vaccine, and preferably on day 90,

-a third dose of the DTaP/IPV/Hib vaccine is to be administered after said administration of the second dose of the dengue vaccine composition, such as 4 months after the simultaneous administration of the first dose of the dengue vaccine composition and the first dose of the DTaP/IPV/Hib vaccine, and preferably on day 120,

-a fourth dose of the DTaP/IPV/Hib vaccine is to be administered after said administration of the third dose of the DTaP/IPV/Hib vaccine, such as 9 to 12 months later, and preferably on day 390,

or

-a first dose of the DTaP/IPV/Hib vaccine is to be administered on day 0,

-a second dose of the DTaP/IPV/Hib vaccine is to be administered after said administration of the first dose of the DTaP/IPV/Hib vaccine, such as 2 months later and preferably on day 60,

-a third dose of the DTaP/IPV/Hib vaccine is to be administered after said administration of the second dose of the DTaP/IPV/Hib vaccine, such as 4 months later and preferably on day 120,

-the first dose of the dengue vaccine composition and a fourth dose of the DTaP/IPV/Hib vaccine are to be simultaneously administered after said administration of the third dose of the DTaP/IPV/Hib vaccine, such as 9 to 12 months later and preferably on day 390,

-a second dose of the dengue vaccine composition is to be administered after said simultaneous administration of the first dose of the dengue vaccine composition and the fourth dose of the DTaP/IPV/Hib vaccine, such as 3 months later and preferably on day 480.

68. The use of any one of claims 1 to 67, wherein the use does not include a step of determination whether there was a previous dengue infection in the subject or subject population before administration of the dengue vaccine composition, wherein the step of determination of the previous dengue infection is characterized by a laboratory confirmed history of dengue or a validated serological test, or
wherein the serostatus of the subject or subject population is unknown before administration of the dengue vaccine composition.

69. The use of any one of claims 1 to 67, wherein the use does not include a step of determination whether there was a previous dengue infection in the subject or subject population at any time before, during or after administering the dengue vaccine composition, wherein the step of determination of the previous dengue infection is characterized by a laboratory confirmed history of dengue or a validated serological test, or
wherein the serostatus of the subject or subject population is unknown at any time before, during or after administering the dengue vaccine composition.