CLAIMS:

1. A liposomal vaccine composition comprising:
    a. A β-amyloid (Aβ)-derived peptide antigen displayed on the surface of the liposome that comprises, consists essentially of or consists of amino acids 1-15 of Aβ; and
    b. An adjuvant comprising monophosphoryl lipid A (MPLA)

    for use in inducing an anti-Aβ immune response in a human subject without inducing a serious adverse event, wherein the β-amyloid (Aβ)-derived peptide antigen is administered in an amount of 300-2000 µg.
2. The liposomal vaccine composition for use of claim 1 wherein the β-amyloid (Aβ)-derived peptide antigen is administered in an amount of 500-2000 µg, preferably 1000-1500 µg, more preferably in an amount of 1000 µg.
3. The liposomal vaccine composition for use of claim 1 or 2 wherein the MPLA is administered in an amount of 15-600 µg, such as 50-600 µg, preferably 150-450 µg and more preferably 175 or 225 µg.
4. The liposomal vaccine composition for use of any one of claims 1 to 3 wherein the β-amyloid (Aβ)-derived peptide antigen is administered in an amount between 850 and 1150 µg, preferably 1000 µg and the MPLA adjuvant is administered in an amount of between 50 and 300 µg, preferably 175 or 225 µg.
5. The liposomal vaccine composition for use of any one of claims 1 to 3 wherein the β-amyloid (Aβ)-derived peptide antigen is administered in an amount between 255 and 345 µg, preferably 300 µg and the MPLA adjuvant is administered in an amount of between 15 and 90 µg, preferably 52.5 or 67.5 µg.
6. The liposomal vaccine composition for use of any one of claims 1 to 5 wherein the β-amyloid (Aβ)-derived peptide antigen is lipidated.
7. The liposomal vaccine composition for use of any one of claims 1 to 6 wherein the β-amyloid (Aβ)-derived peptide antigen is tetrapalmitoylated.
8. The liposomal vaccine composition for use of any one of claims 1 to 7 wherein the adjuvant forms part of the outer layer of the liposome, optionally wherein the adjuvant is, at least in part, displayed on the surface of the liposome.
9. The liposomal vaccine composition for use of any one of claims 1 to 8 wherein the monophosphoryl lipid A (MPLA) comprises synthetic monophosphoryl lipid A (MPLA).

10. The liposomal vaccine composition for use of claim 9 wherein the monophosphoryl lipid A (MPLA) comprises monophosphoryl Hexa-acyl Lipid A, 3-Deacyl (Synthetic) (3D-(6-acyl) PHAD®) and/or Phosphorylated HexaAcyl Disaccharide (PHAD®).
11. The liposomal vaccine composition for use of any one of claims 1 to 10 wherein the liposome comprises phospholipids.
12. The liposomal vaccine composition for use of any one of claims 1 to 11 wherein the phospholipids comprise dimyrsitoylphosphatidyl-choline (DMPC) and dimyrsitoylphosphatidyl-glycerol (DMPG).
13. The liposomal vaccine composition for use of any one of claims 1 to 12 wherein the liposome comprises cholesterol.
14. The liposomal vaccine composition for use of claim 13 wherein the molar ratio of dimyrsitoylphosphatidyl-choline (DMPC): dimyrsitoylphosphatidyl-glycerol (DMPG): cholesterol is 9:1:7.
15. The liposomal vaccine composition for use of claim 14 wherein the molar ratio of dimyrsitoylphosphatidyl-choline (DMPC): dimyrsitoylphosphatidyl-glycerol (DMPG): cholesterol: MPLA is 9:1:7:0.05.
16. The liposomal vaccine composition for use of any one of claims 1 to 15 wherein the liposomal vaccine composition is administered by injection.
17. The liposomal vaccine composition for use of any one of claims 1 to 16 wherein the liposomal vaccine composition is administered intramuscularly or subcutaneously.
18. The liposomal vaccine composition for use of claim 17 wherein the liposomal vaccine composition is administered intramuscularly.
19. The liposomal vaccine composition for use of claim 17 wherein the liposomal vaccine composition is administered subcutaneously.
20. The liposomal vaccine composition for use of any one of claims 1 to 19 wherein the liposomal vaccine composition is administered at a first time and is administered at a second time 1 to 4 weeks later.
21. The liposomal vaccine composition for use of any one of claims 1 to 20 wherein the liposomal vaccine composition is administered every 4-12 weeks for a period of at least 48 weeks, preferably wherein the liposomal vaccine composition is administered every 4 weeks for a period of 12 weeks and every 12 weeks for a further period of at least 36 weeks.
22. The liposomal vaccine composition for use of any one of claims 1 to 21 further comprising a booster administration at a subsequent time point.

23. The liposomal vaccine composition for use of any one of claims 1 to 22 wherein the induced anti-Aβ immune response is for treatment, prevention, induction of a protective immune response against or alleviating the symptoms associated with an amyloid-beta associated disease or condition in the human subject.
24. The liposomal vaccine composition for use of claim 23 wherein the amyloid-beta associated disease or condition is selected from Alzheimer's Disease, mild cognitive impairment (MCI), Down syndrome (DS), including Down syndrome-related Alzheimer's disease, cardiac amyloidosis, cerebral amyloid angiopathy (CAA), multiple sclerosis, Parkinson's disease, Lewy body dementia, ALS (amyotrophic lateral sclerosis), Adult Onset Diabetes, inclusion body myositis (IBM), ocular amyloidosis, glaucoma, macular degeneration, lattice dystrophy and optic neuritis.
25. The liposomal vaccine composition for use of claim 24 wherein the amyloid-beta associated disease or condition is Alzheimer's Disease.
26. The liposomal vaccine composition for use of claim 25 wherein the Alzheimer's Disease is early Alzheimer's Disease.
27. The liposomal vaccine composition for use of claim 26 wherein the early Alzheimer's Disease includes mild cognitive impairment due to Alzheimer's Disease and mild Alzheimer's Disease.
28. The liposomal vaccine composition for use of claim 25 wherein the Alzheimer's Disease is mild Alzheimer's Disease.
29. The liposomal vaccine composition for use of claim 25 wherein the Alzheimer's Disease is mild-to-moderate Alzheimer's Disease.
30. The liposomal vaccine composition for use of claim 25 wherein the Alzheimer's Disease is moderate Alzheimer's Disease.
31. The liposomal vaccine composition for use of claim 25 wherein the Alzheimer's Disease is not severe Alzheimer's Disease.
32. The liposomal vaccine composition for use of claim 24 wherein the amyloid-beta associated disease or condition is Down Syndrome.
33. The liposomal vaccine composition for use of claim 24 or 32 wherein the amyloid-beta associated disease or condition is Down syndrome-related Alzheimer's disease.
34. The liposomal vaccine composition for use of any one of claims 1 to 33 wherein the human subject, prior to treatment, displays cognitive function consistent with a Mini Mental State Examination (MMSE) score of at least 18, such as 18-28, or at least 20, such as 20-28.

35. The liposomal vaccine composition for use of any one of claims 1 to 34 wherein the β-amyloid (Aβ)-derived peptide antigen is tetrapalmitoylated Abeta 1-15 as set forth in SEQ ID NO: 1.

36. The liposomal vaccine composition for use of any one of claims 1 to 35 wherein the administered amount of Abeta 1-15 as set forth in SEQ ID NO: 2 is 152-1016 µg.

CLAIMS

1. Use of a liposomal vaccine composition comprising:

(a) a β-amyloid (Aβ)-derived peptide antigen displayed on the surface of the liposome that comprises, consists essentially of or consists of amino acids 1-15 of human Aβ as set forth in SEQ ID NO: 2; and

(b) an adjuvant comprising monophosphoryl lipid A (MPLA)

in the preparation of a medicament for inducing an anti-Aβ immune response in a human subject without inducing a serious adverse event, wherein the β-amyloid (Aβ)-derived peptide antigen is to be administered in an amount of 300-2000 μg.

2. Use according to Claim 1, in which the β-amyloid (Aβ)-derived peptide antigen is to be administered in an amount of 500-2000 μg, preferably 1000-1500 μg, more preferably in an amount of 1000 μg.

3. Use according to Claim 1 or 2, in which the MPLA is to be administered in an amount of 15-600 μg, such as 50-600 μg, preferably 150-450 μg and more preferably 175 or 225 μg.

4. Use according to Claim 1, 2 or 3, in which the β-amyloid (Aβ)-derived peptide antigen is to be administered in an amount between 850 and 1150 μg, preferably 1000 μg and the MPLA adjuvant is to be administered in an amount of between 50 and 300 μg, preferably 175 or 225 μg.

5. Use according to Claim 1, 2 or 3, in which the β-amyloid (Aβ)-derived peptide antigen is to be administered in an amount between 255 and 345 μg, preferably 300 μg and the MPLA adjuvant is to be administered in an amount of between 15 and 90 μg, preferably 52.5 or 67.5 μg.

6. Use according to any preceding claim, in which the β-amyloid (Aβ)-derived peptide antigen is lipidated.

7. Use according to any preceding claim, in which the β-amyloid (Aβ)-derived peptide antigen is tetrapalmitoylated.

8. Use according to any preceding claim, in which the adjuvant forms part of the outer layer of the liposome, optionally wherein the adjuvant is, at least in part, displayed on the surface of the liposome.

9. Use according to any preceding claim, in which the monophosphoryl lipid A (MPLA) comprises synthetic monophosphoryl lipid A (MPLA).

10. Use according to Claim 9, in which the monophosphoryl lipid A (MPLA) comprises monophosphoryl Hexa-acyl Lipid A, 3-Deacyl (Synthetic) (3D-(6-acyl) PHAD®) and/or Phosphorylated HexaAcyl Disaccharide (PHAD®).

11. Use according to any preceding claim, in which the liposome comprises phospholipids.

12. Use according to any preceding claim, in which the phospholipids comprise dimyrsitoylphosphatidyl-choline (DMPC) and dimyrsitoylphosphatidyl-glycerol (DMPG).

13. Use according to any preceding claim, in which the liposome comprises cholesterol.

14. Use according to Claim 13, in which the molar ratio of dimyrsitoylphosphatidyl-choline (DMPC): dimyrsitoylphosphatidyl-glycerol (DMPG): cholesterol is 9:1:7.

15. Use according to Claim 14, in which the molar ratio of dimyrsitoylphosphatidyl-choline (DMPC): dimyrsitoylphosphatidyl-glycerol (DMPG): cholesterol: MPLA is 9:1:7:0.05.

16. Use according to any preceding claim, in which the liposomal vaccine composition is to be administered by injection.

17. Use according to any preceding claim, in which the liposomal vaccine composition is to be administered intramuscularly or subcutaneously.

18. Use according to Claim 17, in which the liposomal vaccine composition is to be administered intramuscularly.

19. Use according to Claim 17, in which the liposomal vaccine composition is to be administered subcutaneously.

20. Use according to any preceding claim, in which the liposomal vaccine composition is to be administered at a first time and is to be administered at a second time 1 to 4 weeks later.

21. Use according to any preceding claim, in which the liposomal vaccine composition is to be administered every 4-12 weeks for a period of at least 48 weeks, preferably wherein the liposomal vaccine composition is to be administered every 4 weeks for a period of 12 weeks and every 12 weeks for a further period of at least 36 weeks.

22. Use according to any preceding claim, further comprising a booster to be administered at a subsequent time point.

23. Use according to any preceding claim, in which the induced anti-Aβ immune response is for treatment, prevention, induction of a protective immune response against or alleviating the symptoms associated with an amyloid-beta associated disease or condition in the human subject.

24. Use according to Claim 23, in which the amyloid-beta associated disease or condition is selected from Alzheimer's Disease, mild cognitive impairment (MCI), Down syndrome (DS), including Down syndrome-related Alzheimer's disease, cardiac amyloidosis, cerebral amyloid angiopathy (CAA), multiple sclerosis, Parkinson's disease, Lewy body dementia, ALS (amyotrophic lateral sclerosis), Adult Onset Diabetes, inclusion body myositis (IBM), ocular amyloidosis, glaucoma, macular degeneration, lattice dystrophy and optic neuritis.

25. Use according to Claim 24, in which the amyloid-beta associated disease or condition is Alzheimer's Disease.

26. Use according to Claim 25, in which the Alzheimer's Disease is early Alzheimer's Disease.

27. Use according to Claim 26, in which the early Alzheimer's Disease includes mild cognitive impairment due to Alzheimer's Disease and mild Alzheimer's Disease.

28. Use according to Claim 25, in which the Alzheimer's Disease is mild Alzheimer's Disease.

29. Use according to Claim 25, in which the Alzheimer's Disease is mild-to-moderate Alzheimer's Disease.

30. Use according to Claim 25, in which the Alzheimer's Disease is moderate Alzheimer's Disease.

31. Use according to Claim 25, in which the Alzheimer's Disease is not severe Alzheimer's Disease.

32. Use according to Claim 24, in which the amyloid-beta associated disease or condition is Down Syndrome.

33. Use according to Claim 24 or 32, in which the amyloid-beta associated disease or condition is Down syndrome-related Alzheimer's disease.

34. Use according to any preceding claim, in which the human subject, prior to treatment, displays cognitive function consistent with a Mini Mental State Examination (MMSE) score of at least 18, such as 18-28, or at least 20, such as 20-28.

35. Use according to any preceding claim, in which the β-amyloid (Aβ)-derived peptide antigen is tetrapalmitoylated Abeta 1-15 as set forth in SEQ ID NO: 1.

36. Use according to any preceding claim, in which the to be administered amount of Abeta 1-15 as set forth in SEQ ID NO: 2 is 152-1016 µg.