merely illustrative of specific ways to make and use the invention and do not delimit the scope of the invention.

To facilitate the understanding of this invention, a number of terms are defined below. Terms defined herein have meanings as commonly understood by a person of ordinary skill in the areas relevant to the present invention. Terms such as “a”, “an” and “the” are not intended to refer to only a singular entity, but include the general class of which a specific example may be used for illustration. The terminology herein is used to describe specific embodiments of the invention, but their usage does not delimit the invention, except as outlined in the claims.

The term “Amyloid ABeta-42” taught herein refers to the nucleotides encoding the Amyloid ABeta-42 peptide variant taught herein that is a portion of the entire vector set forth (SEQ ID NO: 1), and that has amino acid sequence SEQ ID NO: 3.

The terms “a sequence essentially as set forth in SEQ ID NO: (#)”, “a sequence similar to”, “nucleotide sequence” and similar terms, with respect to nucleotides, refers to sequences that substantially correspond to any portion of the sequence identified herein as SEQ ID NO: 1. These terms refer to synthetic as well as naturally derived molecules and includes sequences that possess biologically, immunologically, experimentally, or otherwise functionally equivalent activity, for instance with respect to hybridization by nucleic acid segments, or the ability to encode all or portions of Amyloid ABeta-42 or Amyloid ABeta-42 activities. Naturally, these terms are meant to include information in such a sequence as specified by its linear order.

The terms “a sequence essentially as set forth in SEQ ID NO: 2", “a sequence similar to”, “amino acid sequence” and similar terms, with respect to amino acids, refers to peptides, polypeptides, proteins, fragments, fusions, derivatives and alterations thereof that substantially correspond to the sequences of SEQ ID NO: 2. These terms refer to synthetic as well as naturally derived molecules and includes sequences that possess biologically, immunologically, experimentally, or otherwise functionally equivalent activities, for instance, segments of amino acids which possess immunological activity as an antigenic determinant. Naturally, these terms are meant to include information in such a sequence as specified by its linear order.

The term “gene” is used to refer to a functional protein, polypeptide or peptide-encoding unit. As will be understood by those in the art, this functional term includes genomic sequences, cDNA sequences, or fragments or combinations thereof, as well as gene products, including those that may have been altered by the hand of man. Purified genes, nucleic acids, protein and the like are used to refer to these entities when identified and separated from at least one contaminating nucleic acid or protein with which it is ordinarily associated.

As used herein, the term “vector” is used in reference to nucleic acid molecules that transfer DNA segment(s) from one cell to another. The vector may be further defined as one designed to propagate the

WHAT IS CLAIMED IS:

1. The use of a composition comprising a single vector that expresses an Aβ42 trimer peptide in the manufacture of a medicament for the diagnosis, treatment or prevention of Alzheimer's Disease, wherein

a biological sample is to be obtained from a subject suspected of having Alzheimer's Disease;

the level of expression of HSP 27 is to be determined, wherein a statistically significant increase in HSP27 protein expression in the sample as compared to a sample from a non-Alzheimer's patient is indicative that the subject has Alzheimer's Disease; and

a treatment of the subject is to be modified as a result of the detection of Alzheimer's Disease by providing the subject with said medicament, wherein the medicament triggers an immune response to the Aβ42 trimer peptide.

2. The use of claim 1, wherein the composition further comprises an Aβ42 peptide and the medicament is injected intramuscularly, without the need for a gene gun or gold particles, to trigger an immune response to the Aβ42 peptide.

3. The use of claim 1, wherein the subject is a human.

4. The use of claim 2, wherein the treatment comprises vector of SEQ ID NO: 1 and the peptide of SEQ ID NO: 3.

5. The use of claim 1, wherein the level of HSP 27 is to be determined by measuring protein expression, and the method is selected from fluorescence detection, chemiluminescence detection, electrochemiluminescence detection and patterned arrays, antibody binding, fluorescence activated sorting, detectable bead sorting, antibody arrays, microarrays, enzymatic arrays, receptor binding arrays, solid-phase binding arrays, liquid phase binding arrays, fluorescent resonance transfer, or radioactive labeling.

6. The use of claim 1, wherein the level of expression of HSP27 is to be determined at the nucleic acid level, and the method is selected from fluorescence detection, chemiluminescence detection, electrochemiluminescence detection and patterned arrays, reverse transcriptase-polymerase chain reaction, detectable bead sorting, microarrays, enzymatic arrays, allele specific primer extension, target specific primer extension, solid-phase binding arrays, liquid phase binding arrays, fluorescent resonance transfer, or radioactive labeling.

7. The use of claim 1, wherein the level of expression of HSP27 is higher than 85, 90, 95, 100, 110, 115, 120, 125, 130, 145, 150, 275, 300, or 315 ng/ml HSP27 in a blood sample.

8. The use of claim 1, wherein the level of expression of HSP27 is higher than 105, 130, 145, 150, 275, 300, or 315 ng/ml HSP27 in a blood sample.

9. The use of claim 1, wherein the expressed Aβ42 trimer peptide triggers a non-inflammatory IgGl response.

10. The use of claim 2, wherein the Aβ42 peptide and the expressed Aβ42 trimer peptide are effective to trigger an immune response to the Aβ42 peptide without an adjuvant.

11. A method to evaluate a candidate drug believed to be useful in treating Alzheimer's Disease, wherein

(a) the level of expression of HSP27 from a sample obtained from an Alzheimer's Disease patient is to be measured;

(b) the candidate drug is to be administered to a first subset of the patients, and a placebo to a second subset of the patients, wherein the candidate drug comprises a single DNA vector encoding an Aβ42 trimer peptide; and

(c) the level of expression of HSP27 or the symptoms of Alzheimer's Disease in the first set of patient is to be compared to the second subset of patients, wherein a statistically significant decrease is indicative that the candidate drug is useful for treating Alzheimer's Disease.

12. The method of claim 11, wherein the drug candidate further comprises the addition of an Aβ42 peptide, wherein the DNA vector expressing the Aβ42 trimer peptide and the Aβ42 peptide are to be injected intramuscularly, without the need for a gene gun or gold particles, to trigger an immune response to the Aβ42 peptide.

13. The method of claim 11, wherein the subject is a human.

14. The method of claim 11, wherein the DNA vector encoding the Aβ42 trimer peptide is SEQ ID NO: 1, and the Aβ42 peptide is SEQ ID NO: 3.

15. The method of claim 11, wherein the level of HSP 27 is to be determined by measuring protein expression, and the method is selected from fluorescence detection, chemiluminescence detection, electrochemiluminescence detection and patterned arrays, antibody binding, fluorescence activated sorting, detectable bead sorting, antibody arrays, microarrays, enzymatic arrays, receptor binding arrays, solid-phase binding arrays, liquid phase binding arrays, fluorescent resonance transfer, or radioactive labeling.

16. The method of claim 11, wherein the level of expression of HSP27 is to be determined at the nucleic acid level, and the method is selected from fluorescence detection, chemiluminescence detection, electrochemiluminescence detection and patterned arrays, reverse transcriptase-polymerase chain reaction, detectable bead sorting, microarrays, enzymatic arrays, allele specific primer extension, target specific primer extension, solid-phase binding arrays, liquid phase binding arrays, fluorescent resonance transfer, or radioactive labeling.

17. The method of claim 11, wherein the level of expression of HSP27 is higher than 85, 90, 95, 100, 110, 115, 120, 125, 130, 145, 150, 275, 300, or 315 ng/ml HSP27 in a blood sample.

18. The method of claim 11, wherein the level of expression of HSP27 is higher than 105, 130, 145, 150, 275, 300, or 315 ng/ml HSP27 in a blood sample.

19. A vector comprising:

a single nucleic acid that comprises in the following order, a viral gene leader sequence, a Aβ42 trimer sequence, and an endosomal targeting sequence.

20. The vector of claim 19, wherein the viral gene leader sequence is an adenovirus E3 gene leader sequence.

21. The vector of claim 19, further comprises a CMV promoter upstream from the nucleic acid.

22. The vector of claim 19, wherein the vector comprises SEQ ID NO: 1.

23. The vector of claim 19, wherein the endosomal targeting sequence is DXXLL (SEQ ID NO: 2).

24. The vector of claim 19, wherein the vector is PV1-H3 and is adapted for is used to treat or prevent Alzheimer's Disease.

25. A composition for ameliorating the symptoms of Alzheimer's Disease with a composition comprising an Aβ42 peptide and a DNA vector that expresses an Aβ42 trimer peptide in an amount sufficient to ameliorate the symptoms of Alzheimer's Disease, wherein the composition triggers an immune response to the Aβ42 peptide.

26. The composition of claim 25, wherein the DNA vector and the A|342 peptide and the DNA vector are injected intramuscularly without the need for a gene gun or gold particles.

27. The composition of claim 25, wherein the Aβ42 peptide is provided at a subtoxic dose.

28. The composition of claim 25, wherein the composition is provided without an adjuvant.

29. The composition of claim 25, wherein the composition leads to a predominantly Th2 response.

30. The composition of claim 25, wherein the peptide comprises SEQ ID NO: 3.

31. The composition of claim 25, wherein the vector comprises SEQ ID NO: 1.

32. The composition of claim 25, wherein the composition consists essentially of the vector of SEQ ID NO: 1 and the peptide of SEQ ID NO: 3.

33. The composition of claim 25, wherein the DNA vector is a single DNA vector.

34. A composition for ameliorating the symptoms of Alzheimer's Disease comprising both an Aβ42 peptide and a DNA vector that expresses an Aβ42 trimer peptide in an amount sufficient to

ameliorate the symptoms of Alzheimer's Disease, wherein the Aβ42 peptide and the DNA vector are injected intramuscularly without the need for a gene gun or gold particles, and wherein the composition triggers an immune response to the Aβ42 peptide.

35. The composition of claim 34, wherein the Aβ42 peptide and the DNA vector that expresses the Aβ42 trimer peptide are both provided without an adjuvant.

36. The composition of claim 34, wherein the DNA vector is a single DNA vector.

37. The composition of claim 34, wherein the composition leads to a predominantly Th2 response.

38. The composition of claim 34, wherein the peptide comprises SEQ ID NO: 3.

39. The composition of claim 34, wherein the vector comprises SEQ ID NO: 1.

40. The composition of claim 34, wherein the composition consists essentially of the vector of SEQ ID NO: 1 and the peptide of SEQ ID NO: 3.

41. The use of an Aβ42 peptide and a DNA vector that expresses an Aβ42 trimer peptide in the preparation of a medicament for the treatment or prevention of Alzheimer's Disease, wherein said medicament is adapted for injection intramuscularly without the need for a gene gun or gold particles, and the medicament triggers an immune response to the Aβ42 peptide.

42. The use of claim 41, wherein the injection triggers a non-inflammatory IgGl response.

43. The use of claim 41, wherein the Aβ42 peptide and the DNA vector that expresses the Aβ42trimer peptide are both provided without an adjuvant.

44. The use of claim 41, wherein the DNA vector is a single DNA vector.

45. The use of claim 41, wherein the medicament leads to a predominantly Th2 response.

46. The use of claim 41, wherein the Aβ42 peptide comprises SEQ ID NO: 3.

47. The use of claim 41, wherein the vector comprises SEQ ID NO: 1.

48. The use of claim 41, wherein the composition consists essentially of the vector of SEQ ID NO: 1 and the peptide of SEQ ID NO: 3.