antigen-specific immunological response. In this context, the adjuvants may not only elicit an immunological response against the antigen but also direct the immune response that the antigen elicited in the host. If the immune response goes in the appropriate direction, the nature of the adjuvant will substantially influence the value of the antigen as a therapeutic product. In addition to helping the induction of an immunological (humoral or cell-mediated) response against antigens, the objective of the adjuvant is to elicit immune effectors that result in the production of specific cytokines. Moreover, since the specificity and magnitude of immune responses induced by the antigen-adjuvant construct may largely depend on the nature of the host immune cells, the potency of the adjuvants cannot be analyzed without reference to the host. Thus, the immune responses induced by an antigen may vary depending on the nature of the adjuvant and of the nature of the host immune system.

There is always a need for new adjuvants since new vaccines are being developed and adjuvants are almost always needed in order to get an efficient induction of an immune response. New adjuvants may also confer new attractive properties to vaccines. For example, they can influence the type and direction of the immune response induced.

Summary of the Disclosure

In one embodiment, there is provided a nucleic acid molecule comprising a nucleotide sequence selected from the group consisting of:

i. nucleotide sequences encoding a polypeptide comprising an amino acid sequence that has at least 70% sequence identity with the amino acid sequence of SEQ ID NO:1 over its entire length,

ii. nucleotide sequences comprising a nucleotide sequence that has at least 70% sequence identity with the nucleotide sequence of SEQ ID NO:2 over its entire length,

iii. nucleotide sequences the complementary strand of which hybridizes to a nucleic acid molecule of sequence of (i) or (ii) and

iv. nucleotide sequences which differ from the nucleotide sequences of (iii) due to the degeneracy of the genetic code,

for use as an adjuvant in the treatment or prevention of a disease or a condition, wherein said nucleotide sequence is operably linked to a nucleotide sequence encoding an antigen, wherein said antigen is associated or linked with said disease or condition,

wherein the nucleic acid molecule encodes a polypeptide which is able to elicit an immune response in a subject, said immune response being specific for said antigen.

In one embodiment, there is provided a polypeptide encoded by a nucleic acid molecule as identified above.

In one embodiment, there is provided a nucleic acid construct comprising a nucleic acid molecule as identified above.

In one embodiment, there is provided a composition comprising a nucleic acid molecule as identified above and/or a polypeptide as identified above and/or a nucleic construct as identified above.

In one embodiment, there is provided a nucleic acid molecule as defined above, a polypeptide as defined above a nucleic acid construct as defined above and/or a composition as defined above for use as a medicament, preferably wherein the medicament is a vaccine.

In one embodiment, there is provided the use of a nucleic acid molecule as identified above, a polypeptide as identified above, a nucleic acid construct as identified above and/or a composition as defined above for the manufacture of a medicament for treating a disease associated with an antigen or a condition associated with an antigen, said disease associated with an antigen or condition associated with an antigen being identified above, wherein said antigen:

i) is specific for said disease or condition, or

ii) originates from an organism that causes said disease or condition in the subject, or

iii) comprises an allergen causing an allergy if said disease or condition is said allergy, or

iv) comprises a cancer antigen associated with a cancer if said disease or condition is said cancer.

Description of the invention

We surprisingly show that the genetic fusion of particular protein fragments originating from a *Leishmania* species to a defined antigen is able to significantly increase the immunogenic potentiality of the fused antigen when the resulting chimeric protein is administered *in vivo* to mice. We also show that the protein resulting from the *in vivo* expression of the chimeric gene present in a DNA plasmid also induces a high

humoral response against the genetically fused antigen while the administration of the plasmid containing the gene coding for the antigen alone does not.

Nucleic acid molecule

In a first aspect there is provided a nucleic acid molecule represented by a nucleotide sequence selected from the group consisting of:

i. nucleotide sequences encoding a polypeptide or a peptide comprising an amino acid sequence that has at least 50% sequence identity or similarity with the amino acid sequence of SEQ ID NO:1,

Claims

1. A nucleic acid molecule comprising ~~represented by~~ a nucleotide sequence selected from the group consisting of:

i. nucleotide sequences encoding a polypeptide comprising an amino acid sequence that has at least 70% ~~50%~~ sequence identity with the amino acid sequence of SEQ ID NO:1 over its entire length,

ii. nucleotide sequences comprising a nucleotide sequence that has at least 70% ~~50%~~ sequence identity with the nucleotide sequence of SEQ ID NO:2 over its entire length,

iii. nucleotide sequences the complementary strand of which hybridizes to a nucleic acid molecule of sequence of (i) or (ii) and

iv. nucleotide sequences which differ from the nucleotide sequences ~~of a nucleic acid molecule~~ of (iii) due to the degeneracy of the genetic code,

for use as an adjuvant in the treatment or prevention of a disease or a condition, wherein said nucleotide sequence ~~nucleic acid molecule~~ is operably linked to a nucleotide sequence encoding an antigen, wherein said antigen is associated or linked with said disease or condition, wherein the nucleic acid molecule encodes a polypeptide which is able to elicit an ~~antigen-specific~~ immune response in a subject, said immune response being specific for said antigen.

2. A nucleic acid molecule according to claim 1 for use as an adjuvant according to claim 1, wherein said nucleic acid molecule is free of a sequence encoding for a polypeptide which is identical to SEQ ID NO: 3 over its entire length.

3. A nucleic acid molecule according to any of the claims 1 – 2 for use as an adjuvant according to claim 1, wherein said antigen originates from any organism known to be associated with a disease or a condition in a subject.

4. A nucleic acid molecule according to any of the claims 1 - 3 for use as an adjuvant according to claim 1, wherein said antigen is a self or auto antigen or originates from virus or a microorganism such as a bacterium, a yeast, a fungus or a parasite.

5. A polypeptide encoded by a nucleic acid molecule as identified in claim 1.

6. A polypeptide encoded by a nucleic acid molecule as identified in any of the claims 2 to 4.

7. A nucleic acid construct comprising a nucleic acid molecule as identified in claim 1.

8. A nucleic acid construct comprising a nucleic acid molecule as identified in any of the claims 2 to 4.

9. A composition comprising a nucleic acid molecule as identified claim 1 and/or a polypeptide as identified in claim 5 and/or a nucleic construct as identified in claim 7.

10. A composition comprising a nucleic acid molecule as identified in any of the claims 2 to 4 and/or a polypeptide as identified in claim 6 and/or a nucleic construct as identified in claim 8.

11. A nucleic acid molecule according to any of the claims 2 to 4, a polypeptide according to claim 6, a nucleic acid construct according to claim 8 and/or a composition according to claim 10 for use as a medicament, preferably wherein the medicament is a vaccine.

12. Use of a nucleic acid molecule as identified in claim 1, a polypeptide as identified in claim 5, a nucleic acid construct as identified in claim 7 and/or a composition according to claim 9 for the manufacture of a medicament for treating a disease associated with an antigen or a condition associated with an antigen, said disease associated with an antigen or condition associated with an antigen being ~~as~~ identified in claim 1, wherein said antigen:

i) is specific for said disease or condition, or

ii) originates from an organism that causes said disease or condition in the subject, or

iii) comprises an allergen causing an allergy if said disease or condition is said allergy, or

iv) comprises a cancer antigen associated with a cancer if said disease or condition is said cancer.

13. Use of a nucleic acid molecule as identified in claims 2 to 4, a polypeptide as identified in claim 6, a nucleic acid construct as identified in claim 8 and/or

a composition according to claim 10 for the manufacture of a medicament being a vaccine for treating a disease associated with an antigen or a condition associated with ~~the~~ an antigen, said disease associated with an antigen or condition associated with an antigen being ~~as~~ identified in claim 1, wherein said antigen:

i) is specific for said disease or condition, or

ii) originates from an organism that causes said disease or condition in the subject, or

iii) comprises an allergen causing an allergy if said disease or condition is said allergy, or

iv) comprises a cancer antigen associated with a cancer if said disease or condition is said cancer.