

CLAIMS

We claim:

1. An immunogenic composition for stimulating an immune response against a varicella zoster virus (VZV), comprising a VZV glycoprotein E (gE) antigen and a toll-like receptor 9 (TLR9) agonist, wherein the TLR9 agonist is an oligonucleotide of from 10 to 35 nucleotides in length comprising an unmethylated cytidine-phospho-guanosine (CpG) motif, and the gE antigen and the oligonucleotide are present in the immunogenic composition in amounts effective to stimulate an immune response against the gE antigen in a mammalian subject.
2. The immunogenic composition of claim 1, wherein the oligonucleotide comprises the sequence 5'-AACGTTTCGAG-3' (SEQ ID NO:3).
3. The immunogenic composition of claim 1, wherein the oligonucleotide comprises the sequence of 5'-TGACTGTGAA CGTTCGAGAT GA-3' (SEQ ID NO:1).
4. The immunogenic composition of claim 1, wherein the oligonucleotide comprises a modified nucleoside, optionally wherein the modified nucleoside is selected from the group consisting of 2'-deoxy-7-deazaguanosine, 2'-deoxy-6-thioguanosine, arabinoguanosine, 2'-deoxy-2'-substituted-arabinoguanosine, and 2'-O-substituted-arabinoguanosine.
5. The immunogenic composition of claim 4, wherein the oligonucleotide comprises the sequence 5'-TCG₁AACG₁TTCG₁-3' (SEQ ID NO:2) in which G₁ is 2'-deoxy-7-deazaguanosine, optionally wherein the oligonucleotide comprises the sequence 5'-TCG₁AACG₁TTCG₁-X-G₁CTTG₁CAAG₁CT-5', and in which G₁ is 2'-deoxy-7-deazaguanosine and X is glycerol (5'-SEQ ID NO:2-3'-X-3'-SEQ ID NO:2-5').
6. The immunogenic composition of claim 3, wherein the oligonucleotide comprises at least one phosphorothioate linkage, or wherein all nucleotide linkages are phosphorothioate linkages.
7. The immunogenic composition of claim 6, wherein the oligonucleotide is a single-stranded oligodeoxynucleotide.

8. The immunogenic composition of claim 6, wherein a 0.5 ml dose of the immunogenic composition comprises from about 375 µg to about 6000 µg of the oligonucleotide or from about 750 µg to about 3000 µg of the oligonucleotide, or wherein a 0.5 ml dose of the immunogenic composition comprises about 375 µg, about 750 µg, about 1500 µg, about 3000 µg, or 6000 µg about of the oligonucleotide.

9. The immunogenic composition of claim 8, wherein the VZV gE antigen is a truncated, recombinant protein devoid of signal peptide, transmembrane and cytoplasmic domains of a full-length VZV gE antigen.

10. The immunogenic composition of claim 9, wherein a 0.5 ml dose of the immunogenic composition comprises from about 25 to about 75 µg of the gE antigen, or wherein the immunogenic composition comprises from about 40 to about 60 µg of the gE antigen, or about 50 µg of the gE antigen.

11. The immunogenic composition of claim 10, further comprising an aluminum salt adjuvant.

12. The immunogenic composition of claim 11, wherein the aluminum salt adjuvant comprises one or more of the group consisting of amorphous aluminum hydroxyphosphate sulfate, aluminum hydroxide, aluminum phosphate, and potassium aluminum sulfate.

13. The immunogenic composition of claim 11, wherein the aluminum salt adjuvant comprises aluminum hydroxide.

14. The immunogenic composition of claim 11, wherein a 0.5 ml dose of the immunogenic composition comprises from about 0.25 to about 0.50 mg Al³⁺, or wherein a 0.5 ml dose of the immunogenic composition comprises from about 0.30 to about 0.40 mg Al³⁺.

15. The immunogenic composition of any one of claims 1-14, wherein the mammalian subject is a human subject.

16. A kit comprising:
- i) the immunogenic composition of claim 15, and
 - ii) instructions for administration of the immunogenic composition to stimulate an immune response against the gE antigen in the mammalian subject.
17. A kit comprising:
- i) a first composition comprising glycoprotein E (gE) antigen of a varicella zoster virus;
 - ii) a second composition comprising a TLR9 agonist; and
 - iii) instructions for mixing the first composition with the second composition to prepare an immunogenic composition.
18. The kit of claim 17, further comprising:
- iv) a further set of instructions for administration of the immunogenic composition to stimulate an immune response against the gE antigen in a mammalian subject.
19. The kit of claim 18, further comprising a syringe and needle for intramuscular injection of the immunogenic composition.
20. A method for stimulating an immune response against varicella zoster virus (VZV) in a mammalian subject, comprising administering the immunogenic composition of any one of claims 1-15 to a mammalian subject so as to stimulate an immune response against the gE antigen in the mammalian subject.
21. The method of claim 20, wherein the immunogenic composition is administered by intramuscular injection.