

Claims:

1. A composition comprising at least one Norovirus antigen and at least one adjuvant, wherein said adjuvant is not a bacterially-derived exotoxin, and wherein the composition is formulated as a dry powder.
2. The composition of claim 1, wherein the adjuvant is selected from the group consisting of toll-like receptor (TLR) agonists, monophosphoryl lipid A (MPL) , synthetic lipid A, lipid A mimetics or analogs, aluminum salts, cytokines, saponins, muramyl dipeptide (MDP) derivatives, CpG oligos, lipopolysaccharide (LPS) of gram-negative bacteria, polyphosphazenes, emulsions, virosomes, cochleates, poly(lactide-co-glycolides) (PLG) microparticles, poloxamer particles, microparticles, and liposomes.
3. The composition of claim 2, wherein the adjuvant is MPL.
4. The composition of claim 1, further comprising a delivery agent.
5. The composition of claim 4, wherein the delivery agent functions to enhance antigen uptake, provide a depot effect, or increase antigen retention time at the site of delivery.
6. The composition of claim 4, wherein the delivery agent is a bioadhesive.
7. The composition of claim 6, wherein said bioadhesive is a mucoadhesive.
8. The composition of claim 7, wherein said mucoadhesive is selected from the group consisting of glycosaminoglycans, carbohydrate polymers, cross-linked derivatives of poly(acrylic acid), polyvinyl alcohol, polyvinyl pyrrolidone, polysaccharides, polyions, cellulose derivatives, proteins, and deoxyribonucleic acid.

9. The composition of claim 8 wherein said mucoadhesive is a polysaccharide.
10. The composition of claim 9 wherein said polysaccharide is chitosan, chitosan salt, or chitosan base.
11. The composition of claim 4, wherein said adjuvant is MPL, and said delivery agent is chitosan, chitosan salt or chitosan base.
12. The composition of claim 1, wherein the composition has an average particle size from about 10 to 500 micrometers in diameter.
13. The composition of claim 1 in combination with one or more devices for administering one or more doses of said composition.
14. The composition of claim 13, wherein said one or more doses are unit doses.
15. The composition of claim 13, wherein the device is a single-use nasal administration device.
16. The composition of claim 13, wherein said composition is stored in said device.
17. The composition of claim 1, wherein said composition is formulated for mucosal administration.
18. The composition of claim 17, wherein the mucosal route of administration is intranasal, oral, or vaginal.
19. The composition of claim 18, wherein the composition is administered to the nasal mucosa by rapid deposition within the nasal passage from a device of the formulation held close or inserted into the nasal passageway.

20. The composition of claim 19, wherein the composition is administrated to one or both nostrils.
21. A composition comprising at least one Norovirus antigen and at least one adjuvant, wherein the adjuvant is a toll-like receptor (TLR) agonist, and wherein the composition is formulated as a liquid.
22. The composition of claim 21, wherein the adjuvant is a toll-like receptor 4 (TLR-4) agonist.
23. The composition of claim 22, wherein the TLR-4 agonist is lipid A, synthetic lipid A, a lipid A mimetic, or a lipid A analog.
24. The composition of claim 22, wherein the TLR-4 agonist is MPL.
25. The composition of claim 21, wherein the composition is formulated for parenteral administration.
26. The composition of claim 21, further comprising oil.
27. The composition of claim 21, further comprising an aluminum salt.
28. The composition of claim 21, wherein the composition is formulated for intranasal administration.
29. The composition of claim 28, wherein the formulation is in the form of a nasal spray or nasal drops.
30. The composition of claim 28, further comprising chitosan.

31. The composition of any one of claims 1-30, wherein said Norovirus antigen comprises peptides, proteins Norovirus virus-like particles (VLPs), denatured VLPs, capsid monomers, capsid multimers, aggregates, or mixtures thereof.
32. The composition of claim 31, wherein said Norovirus antigen comprises Norovirus VLPs.
33. The composition of claim 32, wherein said Norovirus virus-like particles (VLPs) comprise a capsid protein from a Norovirus genogroup I or genogroup II viral strain.
34. The composition of claim 32, wherein said Norovirus VLPs are recombinant VLPs produced in an expression system using a Norovirus nucleic acid sequence.
35. The composition of claim 34, wherein said nucleic acid sequence encodes a capsid protein.
36. The composition of claim 35, wherein said capsid protein is selected from the group consisting of VP1 and VP2.
37. The composition of claim 32, wherein the VLPs are monovalent VLPs or multivalent VLPs.
38. The composition of claim 37, wherein the multivalent VLPs comprise capsid proteins from genogroup I and genogroup II Noroviruses.
39. The composition of claim 34, wherein the expression system is a recombinant cellular expression system or a baculovirus-infected cellular expression system.
40. The composition of claim 39, wherein the cellular expression system is selected from the group consisting of yeast, bacterial, insect, and mammalian expression system.

41. The composition of any one of claims 1-30, further comprising a second Norovirus antigen.
42. The composition of claim 41, wherein said first and second Norovirus antigens are monovalent VLPs from different genogroups.
43. The composition of claim 42, wherein said first Norovirus antigen is a monovalent VLP comprising at least one capsid protein from a genogroup I Norovirus and said second Norovirus antigen is a monovalent VLP comprising at least one capsid protein from a genogroup II Norovirus.
44. The composition of claim 43, wherein the genogroup II Norovirus is a GII.4 Norovirus.
45. The composition of any one of claims 1-40, wherein the Norovirus antigen is present in a concentration of from about 0.01% (w/w) to about 80% (w/w).
46. The composition of any one of claims 1-40, wherein the dosage of the Norovirus antigen is present in an amount of from about 1 µg to about 100 mg per dose, or is from about 1 µg to about 1 mg per dose, or is from about 1 µg to about 500 µg per dose, or is from about 1 µg to about 100 µg per dose.
47. Use of the composition of any one of claims 1-46 for use in inducing an immune response to Norovirus in a mammal.
48. Use of the composition of any one of claims 1-46 for preparation of a medicament for treating a Norovirus infection in a mammal.

Claims:

1. A composition comprising at least one Norovirus antigen and at least one adjuvant, wherein the adjuvant is a toll-like receptor (TLR) agonist, and wherein the composition is formulated as a liquid.
2. The composition of claim 1, wherein the adjuvant is a toll-like receptor 4 (TLR-4) agonist.
3. The composition of claim 2, wherein the TLR-4 agonist is lipid A, synthetic lipid A, a lipid A mimetic, or a lipid A analog.
4. The composition of claim 2, wherein the TLR-4 agonist is monophosphoryl lipid A (MPL).
5. The composition of claim 1, wherein said Norovirus antigen comprises peptides, proteins, Norovirus virus-like particles (VLPs), denatured VLPs, capsid monomers, capsid multimers, aggregates, or mixtures thereof.
6. The composition of claim 5, wherein said Norovirus antigen is selected from the group consisting of Norovirus genogroup I and genogroup II viral strains.
7. The composition of claim 5, wherein said Norovirus antigen comprises Norovirus VLPs.
8. The composition of claim 7, wherein said Norovirus VLPs comprise a capsid protein.
9. The composition of claim 8, wherein said capsid protein is selected from the group consisting of VP1 and VP2.
10. The composition of claim 7, wherein the VLPs are monovalent VLPs.
11. The composition of claim 7, wherein the VLPs are multivalent VLPs.

12. The composition of claim 11, wherein the multivalent VLPs are selected from the group consisting of genogroup I and genogroup II Noroviruses.
13. The composition of claim 7, wherein the Norovirus VLPs are produced in a recombinant cellular expression system or a baculovirus-infected cellular expression system.
14. The composition of claim 13, wherein the cellular expression system is selected from the group consisting of yeast, bacterial, insect, and mammalian expression system.
15. The composition of claim 1, further comprising a second Norovirus antigen.
16. The composition of claim 15, wherein said first and second Norovirus antigens are monovalent VLPs from different genogroups.
17. The composition of claim 16, wherein said first Norovirus antigen is a monovalent VLP comprising at least one capsid protein from a genogroup I Norovirus and said second Norovirus antigen is a monovalent VLP comprising at least one capsid protein from a genogroup II Norovirus.
18. The composition of claim 17, wherein the genogroup II Norovirus is a GII.4 Norovirus.
19. A vaccine formulation comprising the composition of claim 1.
20. The formulation of claim 19, wherein the Norovirus antigen is present in a concentration of from about 0.01% (w/w) to about 80% (w/w).
21. The formulation of claim 19, wherein the dosage of the Norovirus antigen is present in an amount of from about 1 .mu.g to about 100 mg per dose.
22. The formulation of claim 21, wherein the dosage of the Norovirus antigen is from about 1 µg to about 1 mg per dose.

23. The formulation of claim 21, wherein the dosage of the Norovirus antigen is from about 1 μg to about 500 μg per dose.
24. The formulation of claim 21, wherein the dosage of the Norovirus antigen is from about 1 μg to about 150 μg per dose.
25. The composition of claim 1, wherein the composition is formulated for parenteral administration.
26. The composition of claim 1, further comprising oil.
27. The composition of claim 1, further comprising an aluminum salt.
28. The composition of claim 1, wherein the composition is formulated for intranasal administration.
29. The composition of claim 28, wherein the formulation is in the form of a nasal spray or nasal drops.
30. The composition of claim 28, further comprising chitosan.
31. A composition comprising at least one Norovirus antigen and an aluminum salt, wherein the composition is formulated as a liquid.
32. The formulation of any one of claims 19 to 24, for use in a method of inducing an immune response in a subject experiencing a Novovirus infection wherein the formulation is for administering to the subject.