

CLAIMS

What is Claimed is:

1. ~~A polynucleotide having the formula:~~

~~Signal/Leader—payload—TMD—CYD~~

~~wherein~~

~~the Signal/Leader encodes a signal sequence, a leader sequence, or a sorting sequence, in frame with and upstream of a payload;~~

~~the payload is selected from the group consisting of an antigenic payload region, a detectable agent, and a therapeutic agent;~~

~~the TMD encodes a portion of a transmembrane region from one or more proteins or isoforms selected from the group consisting of CD1d, CD1e, LDLR, LDLRP, and LRP1 proteins; and~~

~~the CYD encodes all or a portion of a cytoplasmic region from one or more proteins or isoforms selected from the group consisting of CD1d, CD1e, LDLR, LDLRP, and LRP1 proteins.~~

2. The polynucleotide of claim 1, wherein the payload is an antigenic payload region having the formula (An1)_n-X_o-(An2)_p comprising:

(a) a first encoded antigenic payload (An1), wherein n is an integer from 1 to 10

(b) an encoded linker region (X), wherein o is an integer from 0 to 10, and

(c) a second encoded antigenic payload (An2), wherein p is an integer from 0 to 10.

3. The polynucleotide of claim 2, wherein the first encoded or second encoded antigenic payload encodes all or a portion of a tumor antigen or an infectious agent antigen.

4. The polynucleotide of claim 2 or claim 3, wherein the first encoded or second encoded antigenic payload comprises sequence SIINFEKL.

5. ~~The polynucleotide of claim 1, wherein the payload is a detectable agent selected from the group consisting of organic small molecules, inorganic compounds, nanoparticles, enzymes or enzyme substrates, fluorescent materials, luminescent materials, bioluminescent materials, chemiluminescent materials, radioactive materials, contrast agents, gadolinium, iron oxides, monocrystalline iron oxide nanoparticles, ultrasmall superparamagnetic iron oxide, manganese chelates, barium sulfate, iodinated contrast media, microbubbles, and perfluorocarbons.~~
6. ~~The polynucleotide of any one of the preceding claims, wherein the TMD and the CYD are derived from the same isoform or protein.~~
7. ~~The polynucleotide of any one of claims 1-5, wherein the TMD and the CYD are derived from different isoforms or proteins.~~
8. ~~The polynucleotide of any one of the preceding claims, wherein the Signal/Leader encodes a signal sequence, a leader sequence, or a sorting sequence from the same isoform or protein as the TMD, the CYD, or both.~~
9. ~~The polynucleotide of any one of the preceding claims, wherein the TMD encodes the sequence MGLIALAVLACLLFLLIVGFT.~~
10. ~~The polynucleotide of any one of the preceding claims, wherein the CYD encodes the sequence SRFKRQTSYQGVL.~~
11. ~~The polynucleotide of any one of the preceding claims, wherein the signal sequence encodes the sequence MGCLLFLLLWALLQAWGSA.~~

~~121.~~ A polynucleotide having the formula:

Signal/Leader—payload—PRM

wherein

the Signal/Leader encodes a signal sequence, a leader sequence, or a sorting sequence, in frame with and upstream of a payload;

the payload is selected from the group consisting of an antigenic payload region, a detectable agent, and a therapeutic agent; and

the PRM encodes all or a portion of at least one parental receptor molecule region from one or more proteins or isoforms selected from the group consisting of CD1d, CD1e, LDLR, LDLRP, and LRP1 proteins.

- ~~132~~. The polynucleotide of claim ~~121~~, wherein the parental receptor molecule region is selected from the group consisting of an extracellular region, a transmembrane region, and a cytoplasmic region.
- ~~143~~. A host cell comprising the polynucleotide of any one of the preceding claims.
- ~~154~~. A pharmaceutical composition comprising ~~a the~~ polynucleotide of ~~any one of claims 1-13~~claim 1 or 2 or ~~a the~~ host cell of claim ~~143~~.
- ~~165~~. The pharmaceutical composition of claim ~~154~~, wherein the pharmaceutical composition is in the form of a vaccine.
- ~~176~~. The pharmaceutical composition of claim ~~15-4~~ or claim ~~165~~, further comprising one or more pharmaceutically acceptable excipients or one or more additional pharmaceutically active ingredients, wherein the pharmaceutically acceptable excipients are selected from the group consisting of antiadherents, antioxidants, binders, coatings, compression aids, disintegrants, dyes, emollients, emulsifiers, fillers, film formers or coatings, flavors, fragrances, glidants, lubricants, preservatives, printing inks, sorbents, suspending or dispersing agents, sweeteners, and waters of hydration.

~~18. The pharmaceutical composition of claim 17, wherein the pharmaceutically acceptable excipients are selected from the group consisting of antiadherents, antioxidants, binders, coatings, compression aids, disintegrants, dyes, emollients, emulsifiers, fillers, film formers or coatings, flavors, fragrances, glidants, lubricants, preservatives, printing inks, sorbents, suspending or dispersing agents, sweeteners, and waters of hydration~~

~~197.~~ A therapeutic polynucleotide comprising ~~a~~the polynucleotide of ~~any one of claims 1-13 or 2~~ formulated and/or encapsulated with a delivery vehicle.

~~20. The therapeutic polynucleotide of claim 19, wherein the polynucleotide is encapsulated with the delivery vehicle.~~

~~218.~~ The therapeutic polynucleotide of claim ~~19 or 207~~, wherein the delivery vehicle is selected from the group consisting of amphipathic molecules, amino-lipidated peptides, and tertiary amino lipidated cationic peptides.

~~229.~~ A therapeutic composition comprising the therapeutic polynucleotide of any one of claims ~~19-217~~ or 8.

~~2310.~~ The therapeutic composition of claim ~~229~~, wherein the therapeutic composition is in the form of a vaccine.

~~2411.~~ The therapeutic composition of claim ~~22-9~~ or claim ~~2310~~, further comprising one or more therapeutically acceptable excipients or one or more additional therapeutically active ingredients, wherein the therapeutically acceptable excipients are selected from the group consisting of antiadherents, antioxidants, binders, coatings, compression aids, disintegrants, dyes, emollients, emulsifiers, fillers, film formers or coatings, flavors, fragrances, glidants, lubricants, preservatives, printing inks, sorbents, suspending or dispersing agents, sweeteners, and waters of hydration.

~~25. The therapeutic composition of claim 24, wherein the therapeutically acceptable excipients are selected from the group consisting of antiadherents, antioxidants, binders, coatings, compression aids, disintegrants, dyes, emollients, emulsifiers, fillers, film formers or coatings,~~

~~flavors, fragrances, glidants, lubricants, preservatives, printing inks, sorbents, suspending or dispersing agents, sweeteners, and waters of hydration.~~

2612. The pharmaceutical composition of any one of claims ~~15-184-6~~, or the therapeutic composition of any one of claims ~~22-259-11~~, for use in therapy, wherein a therapeutically effective dose, prophylactically effective dose, or appropriate imaging dose of the pharmaceutical composition or therapeutic composition is to be administered to a subject in need thereof.

~~27. — A method of treating, vaccinating, or immunizing a subject in need thereof, the method comprising administering to the subject a polynucleotide of any one of claims 1-13, a host cell of claim 14, a pharmaceutical composition of any one of claims 15-18, or a therapeutic composition of any one of claims 22-25.~~

~~28. — The pharmaceutical composition or therapeutic composition of claim 26 or the method of claim 27, wherein the subject is a mammal.~~

~~29. — The pharmaceutical composition or therapeutic composition of claim 26 or the method of claim 27, wherein the subject is a human.~~

3013. The polynucleotide of ~~any one of claims 1-13~~ 1 or 2, the host cell of claim ~~143~~, the pharmaceutical composition of any one of claims ~~15-184-6~~, the therapeutic polynucleotide of any one of claims ~~19-217-8~~, the therapeutic composition of any one of claims ~~22-259-12~~, or the method of any one of claims 27-29, wherein the polynucleotide is to perform one of the following:

- a) enable antigen processing and presentation;
- b) traffic protein to the antigen presentation pathway;
- c) improve T cell activation;
- d) increase clonal diversity; and
- e) any combination thereof.

14. The polynucleotide of claim 1, wherein the PRM encodes all or a portion of a transmembrane region from one or more proteins or isoforms selected from the group consisting of CD1d, CD1e, LDLR, LDLRP, and LRP1 proteins and all or a portion of a cytoplasmic region from one or more proteins or isoforms selected from the group consisting of CD1d, CD1e, LDLR, LDLRP, and LRP1 proteins.
15. The polynucleotide of claim 1, wherein the payload is an antigenic payload region having the formula (An1)n-Xo-(An2)p comprising:
 - (a) a first encoded antigenic payload (An1), wherein n is an integer from 1 to 10
 - (b) an encoded linker region (X), wherein o is an integer from 0 to 10, and
 - (c) a second encoded antigenic payload (An2), wherein p is an integer from 0 to 10.
16. The polynucleotide of claim 15, wherein the first encoded or second encoded antigenic payload encodes all or a portion of a tumor antigen or an infectious agent antigen.
17. The polynucleotide of claim 1, wherein the payload is a detectable agent selected from the group consisting of organic small molecules, inorganic compounds, nanoparticles, enzymes or enzyme substrates, fluorescent materials, luminescent materials, bioluminescent materials, chemiluminescent materials, radioactive materials, contrast agents, gadolinium, iron oxides, monocrystalline iron oxide nanoparticles, ultrasmall superparamagnetic iron oxide, manganese chelates, barium sulfate, iodinated contrast media, microbubbles, and perfluorocarbons.
18. The pharmaceutical composition or the therapeutic composition of claim 12, wherein administration of the therapeutic composition results in the generation of functional T cells in the subject.
19. The pharmaceutical composition or the therapeutic composition of claim 12, wherein administration of the therapeutic composition results in improved IFN γ T cell responses in the subject.

20. The pharmaceutical composition or the therapeutic composition of claim 12, wherein administration of the therapeutic composition results in increased antigen processing and presentation in the subject.