to be under 50%. Accordingly, it is desirable to improve HPV vaccination rates by generating immunity against HPV through a single administration that provides a comparable immune response to an existing 2-3 dose HPV vaccine.

It was surprisingly found that a single-injection of an LNP adjuvant combined with a HPV vaccine provided a comparable or enhanced initial anti-HPV immune response when compared to the standard multi-dose protocol of known aluminum adjuvant-containing multivalent HPV vaccine.

SUMMARY

The present ~~invention~~ disclosure provides a pharmaceutical composition comprising at least one type of VLPs from human papillomavirus (HPV) selected from the group consisting of HPV types: 6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 55, 56, 58, 59, 66, 68, 73, and 82, a lipid nanoparticle (LNP) adjuvant, and a pharmaceutically acceptable carrier. In one aspect, the present disclosure provides a pharmaceutical composition comprising virus-like particles (VLPs) of at least one type of human papillomavirus (HPV) selected from the group consisting of HPV types: 6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 55, 56, 58, 59, 66, 68, 73, and 82, a lipid nanoparticle (LNP) adjuvant, and a pharmaceutically acceptable carrier. ~~In one aspect, t~~The present disclosure ~~invention~~ also provides a pharmaceutical composition comprising an aluminum adjuvant and VLPs of at least one type of HPV selected from the group consisting of HPV types: 6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 55, 56, 58, 59, 66, 68, 73, and 82, an LNP adjuvant, and a pharmaceutically acceptable carrier.

The present disclosure ~~invention~~ further provides a pharmaceutical composition comprising: (a) VLPs of at least one HPV type (HPV VLPs), wherein at least one type of HPV is selected from the group consisting of HPV types: 6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 55, 56, 58, 59, 66, 68, 73, and 82; and (b) about 1 μg to about 200 mg of an LNP adjuvant, where the HPV VLPs comprise recombinant Ll or recombinant Ll + L2 protein of the at least one HPV; where the VLPs of any one of the at least one HPV type are present in a concentration of about 1 μg to about 100 μg per 0.5 mL of the pharmaceutical composition; where the total VLP concentration is between 1 μg and 2000 μg per 0.5 mL of pharmaceutical composition.

In another aspect, the present disclosure provides a pharmaceutical composition comprising: (a) virus like particles (VLPs) of at least one type of human papillomavirus (HPV), wherein the at least one type of HPV is selected from the group consisting of HPV types: 6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 55, 56, 58, 59, 66, 68, 73, and 82; (b) about 100 μg to

about 900 µg of an aluminum adjuvant; and (c) about 10 µg to about 200 mg of a lipid nanoparticle (LNP) adjuvant, wherein each of the HPV VLPs comprise recombinant Ll or recombinant Ll + L2 protein; wherein each of the HPV VLPs are present in a concentration of about 10 µg to about 100 µg per 0.5 mL of the pharmaceutical composition; wherein the total HPV VLP concentration is between 10 µg and 2000 µg per 0.5 mL of the pharmaceutical composition; and wherein the HPV VLPs are adsorbed onto the aluminum adjuvant.

The present disclosure ~~invention~~ further provides a pharmaceutical composition comprising: (a) HPV VLPs of at least one HPV type, wherein at least one type of HPV is selected from the group consisting of HPV types: 6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 55, 56, 58, 59, 66, 68, 73, and 82; (b) about 100 µg to about 900 µg of an aluminum adjuvant; and (c) about 1 µg to about 200 mg of a lipid nanoparticle (LNP) adjuvant, where the HPV VLPs comprise recombinant Ll or recombinant Ll + L2 protein of the at least one HPV; where the VLPs of any one of the at least one HPV type are present in a concentration of about 1 µg to about 100 µg per 0.5 mL of the pharmaceutical composition; wherein the total VLP concentration is between 1 µg

and 2000 μg per 0.5 mL of pharmaceutical composition; and wherein the HPV VLPs are adsorbed onto the aluminum adjuvant.

The present disclosure ~~invention~~ further provides a single-dose vaccine composition that includes (a) a lipid nanoparticle (LNP) adjuvant, wherein the LNP adjuvant comprises one or more cationic lipids in the amount of about 30 mole% to about 65 mole%, one or more polymer-lipid conjugates in the amount of about 0.5 mole% to about 4.0 mole%, one or more phospholipids in the amount of about 5 mole% to about 30 mole%, cholesterol in the amount of about 10 mole% to about 40 mole%, (b) a HPV vaccine composition comprising VLPs at least one type of HPV selected from the group consisting of HPV types: 6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 55, 56, 58, 59, 66, 68, 73, and 82, or HPV VLPs of at least one type of HPV selected from the group consisting of HPV types 6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 55, 56, 58, 59, 66, 68, 73, and 82, wherein the single-dose vaccine composition provides an elevated or comparable anti-HPV immune response relative to multiple doses of the same composition formulated, or administered, without the LNP adjuvant.

In another aspect, the present disclosure provides a single-dose vaccine composition comprising: a lipid nanoparticle (LNP) adjuvant, wherein the adjuvant comprises 30-65 mole% cationic lipid, 5-30 mole% phospholipid, 10-40 mole% cholesterol, and 0.5-4 mole% PEG-lipid, virus-like particles (VLPs) of at least one type of human papillomavirus (HPV) selected from the group consisting of HPV types: 6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 55, 56, 58, 59, 66, 68, 73, and 82, wherein the single-dose vaccine composition provides an elevated or comparable anti-HPV immune response relative to multiple doses of the same composition formulated without an LNP adjuvant.

In another aspect, the present disclosure provides a pharmaceutical composition as defined herein or a single-dose vaccine composition as defined herein for use in therapy.

The present disclosure ~~invention~~ also provides a method of inducing an immune response to an HPV in a human patient comprising administering to the patient a pharmaceutical composition comprising HPV VLPs of at least one type of HPV selected from the group consisting of HPV types: 6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 55, 56, 58, 59, 66, 68, 73, and 82, an LNP adjuvant, a pharmaceutically acceptable carrier, and, optionally, an aluminum adjuvant.

In another aspect, the present disclosure provides use of a pharmaceutical composition as defined herein or a single-dose vaccine composition as defined herein in the manufacture of a medicament for inducing an immune response to a human papillomavirus (HPV).

The present disclosure ~~invention~~ also provides a method of inducing an immune response to an HPV in a human patient comprising administering to the patient pharmaceutical composition comprising: (a) HPV VLPs of at least one HPV type, wherein the at least one type of human papillomavirus (HPV) is selected from the group consisting of HPV types: 6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 55, 56, 58, 59, 66, 68, 73, and 82; (b) optionally, about 100 µg to about 900 µg of an aluminum adjuvant; and (c) about 1 µg to about 200 mg of a lipid nanoparticle (LNP) adjuvant, where the HPV VLPs comprise recombinant Ll or recombinant Ll + L2 protein of the at least one HPV type; where the HPV VLPs of any one of the at least one HPV type are present in a concentration of about 1 µg to about 100 µg per 0.5 mL of the pharmaceutical composition; wherein the total VLP concentration is between 1 µg and 2000 µg per 0.5 mL of the pharmaceutical composition; and wherein the HPV VLPs are adsorbed onto the aluminum adjuvant when the aluminum adjuvant is present.

The present disclosure ~~invention~~ also provides a method of inducing an immune response to a an HPV in a human patient comprising administering to the patient a single-dose vaccine

composition that includes (a) an LNP adjuvant, wherein the LNP adjuvant comprises one or more cationic lipids in the amount of about 30 mole% to about 65 mole%, one or more polymer-lipid conjugates in the amount of about 0.5 mole% to about 4.0 mole%, one or more phospholipids in the amount of about 5 mole% to about 30 mole%, cholesterol in the amount of about 10 mole% to about 40 mole%, (b) (i) an HPV vaccine composition comprising HPV VLPs of at least one type of HPV selected from the group consisting of HPV types: 6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 55, 56, 58, 59, 66, 68, 73, and 82 or (ii) HPV VLPs of at least one type of human papillomavirus (HPV) selected from the group consisting of HPV types: 6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 55, 56, 58, 59, 66, 68, 73, and 82, wherein the single-dose vaccine composition provides an elevated or comparable anti-HPV immune response relative to multiple doses of the same composition formulated, or administered, without the LNP adjuvant.

In another aspect, the present disclosure provides use of (a) a pharmaceutical composition comprising virus-like particles (VLPs) of at least one type of human papillomavirus (HPV) selected from the group consisting of HPV types: 6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 55, 56, 58, 59, 66, 68, 73, and 82 and (b) an LNP adjuvant in the manufacture of a medicament for inducing an immune response to a human papillomavirus (HPV), wherein the pharmaceutical composition and the LNP adjuvant are to be co-administered to a human patient.

The present disclosure ~~invention~~ also provides a method of inducing an immune response to an HPV in a human patient comprising administering to the patient (a) a pharmaceutical composition comprising HPV VLPs of at least one type of HPV selected from the group consisting of HPV types: 6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 55, 56, 58, 59, 66, 68, 73, and 82 and (b) an LNP adjuvant.

The present disclosure ~~invention~~ also provides a method of preventing infection of a human patient by an HPV comprising administering to the patient a pharmaceutical composition comprising HPV VLPs of at least one type of human papillomavirus (HPV) selected from the group consisting of HPV types: 6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 55, 56, 58, 59, 66, 68, 73, and 82 and, an LNP adjuvant, a pharmaceutically acceptable carrier, and, optionally, an aluminum adjuvant.

In another aspect, the present disclosure provides use of a pharmaceutical composition as defined herein or a single-dose vaccine composition as defined herein in the manufacture of a medicament for preventing infection of a human patient by a human papillomavirus (HPV).

The present disclosure ~~invention~~ also provides a method of preventing infection of a human patient by an HPV comprising administering to the patient a pharmaceutical composition comprising: (a) HPV VLPs of at least one HPV type, wherein the at least one type of HPV is selected from the group consisting of HPV types: 6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 55, 56, 58, 59, 66, 68, 73, and 82; (b) optionally about 100 μg to about 900 μg of an aluminum adjuvant; and (c) about 1 μg to about 200 mg of a lipid nanoparticle (LNP) adjuvant, where the HPV VLPs comprise recombinant Ll or recombinant Ll + L2 protein of the at least one HPV; where the VLPs of any one of the at least one HPV type are present in a concentration of about 1 μg to about 100 μg per 0.5 mL of the pharmaceutical composition; wherein the total VLP concentration is between 1 μg and 2000 μg per 0.5 mL of the pharmaceutical composition; and

wherein the HPV VLPs are adsorbed onto the aluminum adjuvant when the aluminum adjuvant is present.

The present disclosure ~~invention~~ also provides a method of preventing infection of a human patient by an HPV comprising administering to the patient a single-dose vaccine composition that includes (a) an LNP adjuvant, wherein the adjuvant comprises one or more cationic lipids in the amount of about 30 mole% to about 65 mole%, one or more polymer-lipid conjugates in the amount of about 0.5 mole% to about 4.0 mole%, one or more phospholipids in the amount of about 5 mole% to about 30 mole%, cholesterol in the amount of about 10 mole% to about 40 mole%, (b) (i) an HPV vaccine composition comprising VLPs of at least one type of HPV selected from the group consisting of HPV types: 6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 55, 56, 58, 59, 66, 68, 73, and 82 or (ii) HPV VLPs of at least one type of HPV selected from the group consisting of HPV types: 6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 55, 56, 58, 59, 66, 68, 73, and 82, wherein the single-dose vaccine composition provides an elevated or comparable anti-HPV immune response relative to multiple doses of the same composition formulated, or administered, without the LNP adjuvant.

The present disclosure ~~invention~~ also provided a method of preventing infection of a human patient by an HPV comprising co-administering to the patient (a) a pharmaceutical composition comprising HPV VLPs of at least one type of HPV selected from the group consisting of HPV types: 6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 55, 56, 58, 59, 66, 68, 73, and 82 and (b) an LNP adjuvant.

In another aspect, the present disclosure provides use of (a) a pharmaceutical composition comprising virus-like particles (VLPs) of at least one type of human papillomavirus (HPV) selected from the group consisting of HPV types: 6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 55, 56, 58, 59, 66, 68, 73, and 82 and (b) an LNP adjuvant in the manufacture of a medicament for preventing infection of a human patient by a human papillomavirus (HPV), wherein the pharmaceutical composition and the LNP adjuvant are to be co-administered to the human patient.

The present disclosure ~~invention~~ also provides a method of delivering a pharmaceutical composition that induces a neutralizing titer against an HPV antigen in a host including: administering a single-dose vaccine composition comprising: (a) an LNP adjuvant, and (b) (i) an HPV composition comprising VLPs of at least one type of HPV selected from the group consisting of HPV types: 6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 55, 56, 58, 59, 66, 68, 73, and 82, or (ii) VLPs of at least one type of HPV selected from the group consisting of HPV

types: 6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 55, 56, 58, 59, 66, 68, 73, and 82 and, (c) optionally, an aluminum adjuvant, and inducing a neutralizing titer against an antigen in the host, where the single-dose vaccine composition provides enhanced or comparable neutralizing titers when compared to multiple doses of the same composition formulated, or administered, without the LNP adjuvant.

The present disclosure ~~invention~~ also provides a method of delivering a pharmaceutical composition that induces a neutralizing titer against an HPV antigen in a host including: co-administering (a)

an LNP adjuvant, and (b) a composition comprising HPV VLPs of at least one type of HPV selected from the group consisting of HPV types: 6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 55, 56, 58, 59, 66, 68, 73, and 82, and inducing a neutralizing titer against the HPV antigen in the host, where a single co-administration of (a) and (b) provides enhanced or comparable neutralizing titers when compared to multiple doses of the same composition of (b) administered without the LNP adjuvant.

In another aspect, the present disclosure provides a method of delivering a pharmaceutical composition that induces a neutralizing titer against an HPV antigen in a host comprising inducing a neutralizing titer against the HPV antigen in the host after administration of a pharmaceutical composition that comprises: a lipid nanoparticle (LNP) adjuvant, and virus-like particles (VLPs) of at least one type of human papillomavirus (HPV) selected from the group consisting of HPV types: 6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 55, 56, 58, 59, 66, 68, 73, and 82, where a single dose of the pharmaceutical composition provides enhanced or comparable neutralizing titers when compared to multiple doses of the same pharmaceutical composition when the anti-HPV composition is formulated without an adjuvant.

The present disclosure ~~invention~~ also provides a kit comprising an HPV vaccine composition and an LNP adjuvant. In another aspect, the present disclosure provides a kit comprising: (a) a human papilloma virus (HPV) vaccine; and (b) an LNP adjuvant.

DEFINITIONS

As used throughout the specification and in the appended claims, the singular forms "a," "an," and "the" include the plural reference unless the context clearly dictates otherwise.

As used throughout the specification and appended claims, the following definitions and abbreviations apply:

About: As used herein, the term "about," when used herein in reference to a value, refers to a value that is the same as or, in context, is similar to the referenced value. In general, those skilled in the art, familiar with the context, will appreciate the absolute amount and/or relative degree of difference encompassed by "about" in that context. For example, in some embodiments, the term "about" can encompass a range of values that within 25%, 20%, 19%, 18%, 17%, 16%, 15%, 14%, 13%, 12%, 11%, 10%, 9%, 8%, 7%, 6%, 5%, 4%, 3%, 2%, 1%, or less of the referenced value.

Adjuvant: As used herein, the term “adjuvant” refers to a composition or compound that is capable of enhancing the immune response against an antigen of interest. Adjuvants are substances or combinations of substances that are used in conjunction with a vaccine antigen to enhance (e.g., increase, accelerate, prolong and/or possibly target) or modulate to a different type (e.g., switch a Th1 immune response to a Th2 response, or a humoral response to a cytotoxic T cell response) the specific immune response to the vaccine antigen in order to enhance the clinical effectiveness of the vaccine. In some embodiments, the adjuvant may modify (Th1/Th2) the immune response. In some embodiments, the adjuvant may boost the strength and longevity of the immune response. In some embodiments, the adjuvant may broaden the immune response to a concomitantly administered antigen. In some embodiments, the adjuvant may be capable of inducing strong antibody and T cell responses. In some embodiments, the adjuvant may be used to

CLAIMS

WHAT IS CLAIMED:

1. A pharmaceutical composition comprising:

virus-like particles (VLPs) of at least one type of human papillomavirus (HPV) selected from the group consisting of HPV types: 6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 55, 56, 58, 59, 66, 68, 73, and 82,

a lipid nanoparticle (LNP) adjuvant, and

a pharmaceutically acceptable carrier.

2. The pharmaceutical composition of claim 1, wherein the pharmaceutical composition comprises VLPs of at least HPV types 16 and 18.

3. The pharmaceutical composition of claim 1, wherein the pharmaceutical composition comprises VLPs of at least HPV types 6, 11, 16, and 18.

4. The pharmaceutical composition of claim 1, wherein the pharmaceutical composition comprises VLPs of at least HPV types 31, 45, 52, and 58.

5. The pharmaceutical composition of claim 1, wherein the pharmaceutical composition comprises VLPs of at least HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58.

6. The pharmaceutical composition of any of claims 1-5, wherein the LNP adjuvant comprises a cationic lipid, a phospholipid, cholesterol, and a PEG-lipid.

7. The pharmaceutical composition of any of claims 1-6, wherein the LNP adjuvant comprises 30-65 mole% cationic lipid, 5-30 mole% phospholipid, 10-40 mole% cholesterol, and 0.5-4 mole% PEG-lipid.

8. The pharmaceutical composition of any of claims 1-7, wherein the LNP adjuvant comprises 55-65 mole% cationic lipid, 5-15 mole% phospholipid, 25-35 mole% cholesterol, and 1-2.5 mole% PEG-lipid.

9. The pharmaceutical composition of any of claims 1-8, wherein the LNP adjuvant comprises DSPC, cholesterol, ePEG2000-DMG, and (13Z, 16Z) – N, N-dimethyl-3-nonyldocosa 13, 16-dien-1-amine.

10. The pharmaceutical composition of any of claims 1-9, wherein the LNP adjuvant comprises 5-15 mole% DSPC, 25-35 mole% cholesterol, 1-2.5 mole% ePEG2000-DMG, and 55-65 mole% (13Z, 16Z) – N, N-dimethyl-3-nonyldocosa 13, 16-dien-1-amine.

11. The pharmaceutical composition of any of claims 1-10, further comprising an aluminum adjuvant.

12. A pharmaceutical composition comprising:

(a) virus like particles (VLPs) of at least one type of human papillomavirus (HPV), wherein the at least one type of HPV is selected from the group consisting of HPV types: 6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 55, 56, 58, 59, 66, 68, 73, and 82;

(b) about 100 μg to about 900 μg of an aluminum adjuvant; and

(c) about 10 μg to about 200 mg of a lipid nanoparticle (LNP) adjuvant,

wherein each of the HPV VLPs comprise recombinant Ll or recombinant Ll + L2 protein;

wherein each of the HPV VLPs are present in a concentration of about 10 μg to about 100 μg per 0.5 mL of the pharmaceutical composition;

wherein the total HPV VLP concentration is between 10 μg and 2000 μg per 0.5 mL of the pharmaceutical composition; and

wherein the HPV VLPs are adsorbed onto the aluminum adjuvant.

13. The pharmaceutical composition of claim 12, wherein the pharmaceutical composition comprises HPV VLPs of at least HPV types 16 and 18.

14. The pharmaceutical composition of claim~~s~~ 12, wherein the pharmaceutical composition comprises HPV VLPs of at least HPV types 6, 11, 16, and 18.

15. The pharmaceutical composition of claim~~s~~ 12, wherein the pharmaceutical composition comprises HPV VLPs of at least HPV types 31, 45, 52, and 58.

16. The pharmaceutical composition of claim 12, wherein the pharmaceutical composition comprises HPV VLPs of at least HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58.

17. The pharmaceutical composition of any of claims 12-16, wherein the LNP adjuvant comprises a cationic lipid, a phospholipid, cholesterol, and a PEG-lipid.

18. The pharmaceutical composition of claim 17, wherein the LNP adjuvant comprises 30-65 mole% cationic lipid, 5-30 mole% phospholipid, 10-40 mole% cholesterol, and 0.5-4 mole% PEG-lipid.

19. The pharmaceutical composition of claim 18, wherein the LNP adjuvant comprises DSPC, cholesterol, ePEG2000-DMG, and (13Z, 16Z) – N, N-dimethyl-3-nonyldocosa 13, 16-dien-1-amine.

20. The pharmaceutical composition of claim 19, wherein the LNP adjuvant comprises 5-15 mole% DSPC, 25-35 mole% cholesterol, 1-2.5 mole% ePEG2000-DMG, and 55-65 mole% (13Z, 16Z) – N, N-dimethyl-3-nonyldocosa 13, 16-dien-1-amine.

21. The pharmaceutical composition of any of claims 1-20, wherein the HPV VLPs comprise HPV L1 protein and do not comprise HPV L2 protein.

22. The pharmaceutical composition of any of claims 1-20, wherein the HPV VLPs consists of HPV L1 protein.

23. A single-dose vaccine composition comprising:

a lipid nanoparticle (LNP) adjuvant, wherein the adjuvant comprises 30-65 mole% cationic lipid, 5-30 mole% phospholipid, 10-40 mole% cholesterol, and 0.5-4 mole% PEG-lipid,

virus-like particles (VLPs) of at least one type of human papillomavirus (HPV) selected from the group consisting of HPV types: 6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 55, 56, 58, 59, 66, 68, 73, and 82,

wherein the single-dose vaccine composition provides an elevated or comparable anti-HPV immune response relative to multiple doses of the same composition formulated without an LNP adjuvant.

24. The single-dose vaccine composition of claim 23, wherein the vaccine further comprises an aluminum adjuvant.

25. The single-dose vaccine composition of claim 24, wherein the HPV VLPs are adsorbed onto the aluminum adjuvant.

26. The single-dose vaccine composition of any of claims 23-25, wherein each of the HPV VLPs are present in a concentration of about 10 µg to about 100 µg per 0.5 mL of the pharmaceutical composition and wherein the total HPV VLP concentration is between 10 µg and 2000 µg per 0.5 mL of the pharmaceutical composition.

27. Use of a pharmaceutical composition of any of claims 1-22 or a single-dose vaccine composition of any of claims 23-26 in the manufacture of a medicament for ~~A method of~~ inducing an immune response to a human papillomavirus (HPV). ~~in a human patient comprising administering to the patient the pharmaceutical composition of any of claims 1-22 or the single-dose vaccine composition of any of claims 23-26.~~

28. Use of (a) a pharmaceutical composition comprising virus-like particles (VLPs) of at least one type of human papillomavirus (HPV) selected from the group consisting of HPV types: 6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 55, 56, 58, 59, 66, 68, 73, and 82 and (b) an LNP adjuvant in the manufacture of a medicament for ~~A method of~~ inducing an immune response to a human papillomavirus (HPV), wherein the pharmaceutical composition and the LNP adjuvant are to be co-administered to~~in~~ a human patient. ~~comprising co-administering to the patient (a) a pharmaceutical composition comprising virus-like particles (VLPs) of at least one type of human papillomavirus (HPV) selected from the group consisting of HPV types: 6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 55, 56, 58, 59, 66, 68, 73, and 82 and (b) an LNP adjuvant.~~

29. Use of a pharmaceutical composition of any of claims 1-22 or a single-dose vaccine composition of any of claims 23-26 in the manufacture of a medicament for ~~A method of~~ preventing infection of a human patient by a human papillomavirus (HPV). ~~comprising administration to the patient the pharmaceutical composition of any of claims 1-22 or the single-dose vaccine composition of any of claims 23-26.~~

30. Use of (a) a pharmaceutical composition comprising virus-like particles (VLPs) of at least one type of human papillomavirus (HPV) selected from the group consisting of HPV types: 6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 55, 56, 58, 59, 66, 68, 73, and 82 and (b) an LNP adjuvant in the manufacture of a medicament for ~~A method of~~ preventing infection of a human patient by a human papillomavirus (HPV), wherein the pharmaceutical composition and the LNP adjuvant are to be co-administered to the human patient. ~~comprising co-administering to the patient (a) a pharmaceutical composition comprising virus-like particles (VLPs) of at least one type of human papillomavirus (HPV) selected from the group consisting of HPV types: 6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 55, 56, 58, 59, 66, 68, 73, and 82 and (b) an LNP adjuvant.~~

31. A kit comprising:

(a) a human papilloma virus (HPV) vaccine; and

(b) an LNP adjuvant.

32. The kit of claim 31, further comprising instructions for administering to a human patient the HPV vaccine and the LNP adjuvant.

33. The kit of any of claims ~~25~~ 31 and ~~26~~32, wherein the HPV vaccine comprises virus-like particles (VLPs) of at least one type of human papillomavirus (HPV) selected from the group consisting of HPV types: 6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 55, 56, 58, 59, 66, 68, 73, and 82.

34. A method of delivering a pharmaceutical composition that induces a neutralizing titer against an HPV antigen in a host comprising~~:~~

~~administering a pharmaceutical composition comprising:~~

~~a lipid nanoparticle (LNP) adjuvant, and~~

~~virus-like particles (VLPs) of at least one type of human papillomavirus (HPV) selected from the group consisting of HPV types: 6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 55, 56, 58, 59, 66, 68, 73, and 82,~~

~~and~~

inducing a neutralizing titer against the HPV antigen in the host after administration of a pharmaceutical composition that comprises: ~~,~~

a lipid nanoparticle (LNP) adjuvant, and

virus-like particles (VLPs) of at least one type of human papillomavirus (HPV) selected from the group consisting of HPV types: 6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 55, 56, 58, 59, 66, 68, 73, and 82,

where a single dose of the pharmaceutical composition provides enhanced or comparable neutralizing titers when compared to multiple doses of the same pharmaceutical composition when the anti-HPV composition is formulated without an adjuvant.

35. The method of claim 34, further comprising an aluminum adjuvant.

36. A pharmaceutical composition of any of claims 1-22 or a single-dose vaccine composition of any of claims 23-26 for use in therapy.