

CLAIMS

What is claimed is:

1. An injectable composition for use in therapy, the injectable composition comprising:
 - an HPV vaccine comprising at least one purified viral L1 protein, wherein the at least one purified viral L1 is a human papilloma virus (HPV) L1 protein or fragment thereof and is free of host-cell and/or non-L1 HPV peptide;
 - a second active pharmaceutical ingredient selected from the group consisting of a local anesthetic, sirolimus, ingenol mebutate, T4 endonuclease, and a cyclooxygenase inhibitor; and
 - a pharmaceutically-acceptable carrier,wherein the injectable composition is suitable for treating a patient having skin cancer, cancerous tumor, or a human papilloma virus (HPV)-associated cancerous lesion, and wherein:
 - a) a first dose of the injectable composition is to be administered to the patient;
 - b) a second dose of the injectable composition is to be administered to the patient one month to three months after the first dose; and
 - c) optionally, a third dose of the injectable composition is to be administered to the patient five months to seven months after the first dose.
2. The injectable composition of claim 1 wherein the second dose of the injectable composition is to be administered two months after administering the first dose and the optional third dose of the injectable composition is to be administered six months after the first dose.
3. The injectable composition of claim 1 wherein the HPV vaccine is selected from the group consisting of HPV quadrivalent (types 6, 11, 16, and 18) recombinant vaccine comprising

HPV L1 proteins and HPV multivalent (types 16, 18, 31, 33, 45, 52, and 58) recombinant vaccine comprising HPV L1 proteins.

4. The injectable composition of claim 1 wherein the HPV vaccine is substantially free of host-cell early antigen, E6 or E7.

5. The injectable composition of claim 1 wherein the injectable composition does not comprise or excludes an immunomodulatory agent or adjuvant to be administered to the patient.

6. The injectable composition of claim 1 wherein the skin cancer, cancerous tumor, or HPV-associated cancerous lesion is substantially reduced in size or eliminated.

7. The injectable composition of claim 1 wherein each dose comprises 0.5ml of HPV vaccine.

8. The injectable composition of claim 1 wherein the cancer or HPV-associated cancerous lesion is selected from the group consisting of squamous cell carcinoma, basal cell carcinoma, melanoma, glandular tumor, adenoma, verruca vulgaris, and condyloma accuminata.

9. The injectable composition of claim 1, wherein the patient is 27 years of age or older or is previously not immunized with an HPV vaccine.

10. The injectable composition of claim 1 wherein
a positive diagnosis of skin cancer, diagnosis of cancerous tumor, or diagnosis of HPV infection, is to be established prior to administration of the first dose of the injectable composition.

11. The injectable composition of claim 1, wherein the injectable composition is to be administered directly to a tumor or skin cancer lesion or an area immediately surrounding the tumor, or skin cancer lesion.
12. The injectable composition of claim 1 whereby the incidence of recurrence of the tumor, skin cancer lesion, or HPV-associated cancerous lesion is reduced.
13. The injectable composition of claim 11 wherein the injectable composition is to be administered by injection.
14. The injectable composition of claim 11 wherein an immunomodulatory agent or adjuvant is to be administered to the patient.
15. The injectable composition of claim 11 wherein the injectable composition does not comprise or excludes an immunomodulatory agent or adjuvant to be administered to the patient.
16. An injectable pharmaceutical composition comprising:
 - at least one purified viral L1 protein wherein the at least one purified viral L1 is a human papilloma virus (HPV) L1 protein or fragment thereof and is free of host-cell and/or non-L1 HPV peptide;
 - a second active pharmaceutical ingredient selected from the group consisting of a local anesthetic, sirolimus, ingenol mebutate, T4 endonuclease, and a cyclooxygenase inhibitor; and
 - a pharmaceutically-acceptable carrier.
17. The pharmaceutical composition of claim 16, wherein the cyclooxygenase inhibitor is diclofenac.

18. The pharmaceutical composition of claim 16, comprising a purified viral L1 protein or fragment thereof from each of HPV types 6, 11, 16 and 18.
19. The pharmaceutical composition of claim 16, comprising a purified viral L1 protein or fragment thereof from each of HPV types 16, 18, 31, 33, 45, 52 and 58.
20. The pharmaceutical composition of claim 16, wherein the at least one purified viral L1 protein or fragment thereof is present in a virus-like particle (VLP).
21. The pharmaceutical composition of claim 16, wherein the at least one purified viral L1 protein and the second active pharmaceutical ingredient and pharmaceutically acceptable carrier are in a unitary dosage form.
22. The pharmaceutical composition of clam 16, wherein the local anesthetic is lidocaine.