

CLAIMS

What is claimed is:

1. A HPV vaccine for use in treating a patient having skin cancer, benign or cancerous tumor, or a human papilloma virus (HPV)-associated lesion, said use comprising the steps of:
 - a) administering to the patient, a first dose of the HPV vaccine which is free of host-cell peptide, polypeptide, or protein or a degradant product thereof;
 - b) administering to the patient a second dose of the HPV vaccine about one month to about three months after the first administration; and
 - c) optionally, administering to the patient a third dose of the HPV vaccine about five months to about seven months after the first dose.
2. The use of claim 1 wherein the second dose of HPV vaccine is administered about two months after administering the first dose and the optional third dose of HPV vaccine is administered about six months after administering the first dose.
3. The HPV vaccine 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 HPV vaccine of claim 1 wherein the vaccine is substantially free of host-cell early antigen, E6 or E7.
5. The use of claim 1 wherein the use does not comprise or excludes administering to the patient an immunomodulatory agent or adjuvant.

6. The use of claim 1 wherein the skin cancer, benign or cancerous tumor, or HPV-associated lesion is substantially reduced in size or eliminated.
7. The use of claim 1 wherein each dose of HPV vaccine is 0.5 ml.
8. The use of claim 1 wherein the cancer or HPV-associated 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 use of claim 1, wherein the patient is 27 years of age or older or is previously not immunized with an HPV vaccine.
10. The use of claim 1 wherein the use further comprises:
establishing a positive diagnosis of skin cancer, diagnosis of benign or cancerous tumor, or diagnosis of HPV infection, prior to administering the first dose of HPV vaccine.
11. The use of claim 1, said use comprising the step of:
 - a) administering a dose of an HPV vaccine directly to a tumor or skin cancer lesion or an area immediately surrounding the tumor, or skin cancer lesion.
12. The use of claim 1 whereby the incidence of recurrence of the tumor, skin cancer lesion, or HPV-associated lesion is reduced.
13. The use of claim 11 wherein the vaccine is administered by injection.
14. The use of claim 11 wherein the use comprises administering an immunomodulatory agent or adjuvant to the patient.

15. The use of claim 11 wherein the use does not comprise or excludes administering to the patient an immunomodulatory agent or adjuvant.
16. The use of claim 1 wherein the use does not comprise or excludes administering a second composition comprising an immunostimulant or an adjuvant.
17. A pharmaceutical composition comprising:
 - at least one purified viral L1 protein or fragment thereof;
 - a second active pharmaceutical ingredient; and
 - a pharmaceutically-acceptable carrier.
18. The pharmaceutical composition of claim 17, wherein the second active pharmaceutical ingredient is a local anesthetic agent.
19. The pharmaceutical composition of claim 18, wherein the local anesthetic agent is selected from the group consisting of: procaine, benzocaine, chloroprocaine, cocaine, cyclomethycaine, dimethocaine/larocaine, piperocaine, propoxycaine, procaine, proparacaine, and tetracaine, lidocaine, articaine, bupivacaine, cinchocaine, etidocaine, levobupivacaine, lignocaine, mepivacaine, prilocaine, ropivacaine, and trimecaine.
20. The pharmaceutical composition of claim 18, wherein the local anesthetic agent is lidocaine.
21. The pharmaceutical composition of claim 17, wherein the second active pharmaceutical ingredient is an immunomodulatory agent selected from the group consisting of vitamin D, a

vitamin D analogue, vitamin A, a vitamin A analogue, sirolimus, interferon, an interferon analogue, imiquimod, ingenol mebutate, T4 endonuclease, an anti-metabolite and a cyclooxygenase inhibitor.

22. The pharmaceutical composition of claim 21, wherein the anti-metabolite is 5-fluorouracil or methotrexate.

23. The pharmaceutical composition of claim 21, wherein the cyclooxygenase inhibitor is diclofenac.

24. The pharmaceutical composition of claim 17, in an injectable form.

25. The pharmaceutical composition of claim 17, in a topical form.

26. The pharmaceutical composition of claim 17, wherein the at least one purified viral L1 protein or fragment thereof is a human papilloma virus (HPV) L1 protein or fragment thereof.

27. The pharmaceutical composition of claim 26, comprising a purified viral L1 protein or fragment thereof from each of HPV types 6, 11, 16 and 18.

28. The pharmaceutical composition of claim 26, comprising a purified viral L1 protein or fragment thereof from each of HPV types 16, 18, 31, 33, 45, 52 and 58.

29. The pharmaceutical composition of claim 1, wherein the at least one purified viral L1 protein or fragment thereof is present in a virus-like particle (VLP).

30. A HPV vaccine for use in treating a patient having skin cancer, benign or cancerous tumor, or a human papilloma virus (HPV)-associated lesion, said use comprising the steps of:

- a) administering to the patient, a first dose of the HPV vaccine which is free of non-L1 viral peptide, polypeptide, or protein or a degradant product thereof;
- b) administering to the patient a second dose of the HPV vaccine about one month to about three months after the first administration; and
- c) optionally, administering to the patient a third dose of the HPV vaccine about five months to about seven months after the first dose.