

CLAIMS

What is claimed is:

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

6. The use of claim 1 wherein the skin cancer, cancerous tumor, or HPV-associated cancerous lesion is substantially reduced in size or eliminated.
7. The use of claim 1 wherein each dose of the HPV vaccine is 0.5 ml.
8. The use 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 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
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 HPV vaccine.
11. The use of claim 1, wherein the HPV vaccine 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 use of claim 1 whereby the incidence of recurrence of the tumor, skin cancer lesion, or HPV-associated cancerous lesion is reduced.
13. The use of claim 11 wherein the HPV vaccine is to be administered by injection.
14. The use of claim 11 wherein the pharmaceutical composition comprises an immunomodulatory agent or adjuvant to be administered to the patient.
15. The use of claim 11 wherein the pharmaceutical composition does not comprise or excludes an immunomodulatory agent or adjuvant to be administered to the patient.

16. The use of claim 1 wherein the pharmaceutical composition does not comprise or excludes a second composition comprising an immunostimulant or an adjuvant to be administered to the patient.

17. A pharmaceutical composition for treating a patient having skin cancer, cancerous tumor, or a human papilloma virus (HPV)-associated cancerous lesion, said 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 17, wherein the at least one purified viral L1 protein or fragment thereof is present in a virus-like particle (VLP).

30. Use of a HPV vaccine in the preparation of a pharmaceutical composition for treating a patient having skin cancer, cancerous tumor, or a human papilloma virus (HPV)-associated cancerous lesion, wherein :

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