CLAIMS

WHAT IS CLAIMED IS:

1. A composition comprising a replication-defective virus vector comprising a nucleic acid sequence encoding a prostate specific antigen (PSA) and/or a nucleic acid sequence encoding prostate-specific membrane antigen (PSMA), wherein the PSA has an amino acid sequence at least 85% identical with SEQ ID NO: 1 or SEQ ID NO: 34 or the PSMA has an amino acid sequence at least 85% identical with SEQ ID NO: 11, and wherein the replication-defective virus vector is an adenovirus vector having deletions in the E1 gene region and the E2b gene region.

2. The composition of claim 1, wherein the vector comprises a nucleic acid sequence encoding a PSA having a nucleic acid sequence at least 85% identical with SEQ ID NO: 35 or the nucleic acid sequence encoding PSA has at least 99% identical with SEQ ID NO: 2.

3. The composition of claim 1, wherein the vector comprises a nucleic acid sequence encoding a PSMA having an amino acid sequence at least 85% identical with SEQ ID NO: 36.

4. The composition of claim 1, further comprising a second replication-defective virus vector comprising a second nucleic acid sequence encoding a Brachyury antigen, a third replication-defective virus vector comprising a third nucleic acid sequence encoding a MUC1 antigen, or a combination thereof.

5. The composition of claim 4, wherein the Brachyury antigen binds to HLA-A2, HLA-A3, HLA-A24, or a combination thereof.

6. The composition of claim 4 or 5, wherein the Brachyury antigen is a modified Brachyury antigen comprising an amino acid sequence set forth in WLLPGTSTV (SEQ ID NO: 7).

7. The composition of any of claims 4-6, wherein the Brachyury antigen is a modified Brachyury antigen comprising an amino acid sequence at least 85% identical to SEQ ID NO: 5, SEQ ID NO: 6, or SEQ ID NO: 42.

8. The composition of any of claims 4-7, wherein the second replication-defective vector comprises a nucleotide sequence at least 99% identical with SEQ ID NO: 3, SEQ ID NO: 4, positions 13 to 1242 of SEQ ID NO: 4, SEQ ID NO: 42.

9. The composition of any of claims 4-8, wherein the second replication-defective vector comprises a nucleotide sequence at least 99% to SEQ ID NO: 12 (Ad vector with sequence encoding a modified Brachyury antigen), positions 1033-2083 of SEQ ID NO: 12, or SEQ ID NO: 42.

10. The composition of any of claims 4-9, wherein the MUC1 antigen comprises a sequence at least 80%, at least 85%, at least 90%, at least 92%, at least 95%, at least 97%, or at least 99% identical to SEQ ID NO: 10 or SEQ ID NO: 41.

11. The composition of any of claims 4-10, wherein the third nucleic acid sequence encoding a MUC1 antigen comprises at least 99% identity to SEQ ID NO: 8, SEQ ID NO: 9, or SEQ ID NO: 41.

12. The composition of any of claims 4-11, wherein the MUC-1 antigen binds to HLA-A2, HLA-A3, HLA-A24, or a combination thereof.

13. The composition of any of claims 4-12, wherein the replication-defective virus vector, the second replication-defective virus vector, and/or the third replication-defective virus vector is an adenovirus vector.

14. The composition of claim 13, wherein the adenovirus vector also comprises a deletion in an E3 region, an E4 region, or a combination thereof.

15. The composition of claim 13 or 14, wherein the adenovirus vector comprises a deletion in an E4 region.

16. The composition of any of claims 13-15, wherein the adenovirus vector comprises a deletion in an E1 region, an E2b region, and an E3 region.

17. The composition of any one of claims 1-16, wherein the composition comprises from at least $1x10^9$ virus particles to at least $5x10^{12}$ virus particles.

18. The composition of any of claims 1-17, wherein the composition comprises at least $5x10^9$ virus particles.

19. The composition of any of claims 1-18, wherein the composition comprises at least $5x10^{10}$ virus particles.

20. The composition of any of claims 1-19, wherein the composition comprises at least $5x10^{11}$ virus particles.

21. The composition of any one of claims 1-20, wherein the composition comprises at least $5x10^{12}$ virus particles.

22. The composition of any of claims 1-21, wherein the composition or the replication-defective virus vector further comprises a nucleic acid sequences encoding a costimulatory molecule.

23. The composition of claim 22, wherein the costimulatory molecule comprises B7, ICAM-1, LFA-3, or a combination thereof.

24. The composition of claim 22 or 23, wherein the costimulatory molecule comprises a combination of B7, ICAM-1, and LFA-3.

25. The composition of any one of claims 1-24, wherein the composition further comprises a plurality of nucleic acid sequences encoding a plurality of costimulatory molecules positioned in the same replication-defective virus vector.

26. The composition of any one of claims 1-25, wherein the composition further comprises a plurality of nucleic acid sequences encoding a plurality of costimulatory molecules positioned in separate replication-defective virus vectors.

27. The composition of any one of claims 1-26, wherein the composition further comprises a nucleic acid sequence encoding one or more additional target antigens or immunological epitopes thereof.

28. The composition of any one of claims 1-27, wherein the replication-defective virus vector further comprises a nucleic acid sequence encoding one or more additional target antigens or immunological epitopes thereof.

29. The composition of claim 27 or 28, wherein the one or more additional target antigens is a tumor neo-antigen, tumor neo-epitope, tumor-specific antigen, tumor-associated antigen, tissue-specific antigen, bacterial antigen, viral antigen, yeast antigen, fungal antigen, protozoan antigen, parasite antigen, mitogen, or a combination thereof.

30. The composition of any one of claims 27-29, wherein the one or more additional target antigens is CEA, folate receptor alpha, WT1, HPV E6, HPV E7, p53, MAGE-A1, MAGE-A2, MAGE-A3, MAGE-A4, MAGE-A6, MAGE-A10, MAGE-A12, BAGE, DAM-6, -10, GAGE-1, -2, -8, GAGE-3, -4, -5, -6, -7B, NA88-A, NY-ESO-1, MART-1, MC1R, Gp100, PSCA, PSMA, PAP, Tyrosinase, TRP-1, TRP-2, ART-4, CAMEL, Cyp-B, Her2/neu, BRCA1, BRACHYURY, BRACHYURY(TIVS7-2, polymorphism), BRACHYURY (IVS7 T/C polymorphism), T BRACHYURY, T, hTERT, hTRT, iCE, MUC1, MUC1 (VNTR polymorphism), MUC1c, MUC1n, MUC2, PRAME,

P15, RU1, RU2, SART-1, SART-3, WT1, AFP, β-catenin/m, Caspase-8/m, CDK-4/m, Her2/neu, Her3, ELF2M, GnT-V, G250, HSP70-2M, HST-2, KIAA0205, MUM-1, MUM-2, MUM-3, Myosin/m, RAGE, SART-2, TRP-2/INT2, 707-AP, Annexin II, CDC27/m, TPI/mbcr-abl, ETV6/AML, LDLR/FUT, Pml/RARα, or TEL/AML1, a splice variant, a functional epitope, or a combination thereof.

31. The composition of any one of claims 27-30, wherein the one or more additional target antigens is CEA.

32. The composition of any one of claims 27-30, wherein the one or more additional target antigens is CEA, Brachyury, and MUC1.

33. The composition of claim 32, wherein CEA is at least 80%, at least 85%, at least 90%, at least 92%, at least 95%, at least 97%, or at least 99% identical to SEQ ID NO: 37 or SEQ ID NO: 38.

34. The composition of any one of claims 27-30, wherein the one or more additional target antigens is HER3.

35. The composition of any one of claims 27-30, wherein the one or more additional target antigens is HPV E6 or HPV E7.

36. The composition of any one of claims 1-35, wherein the replication-defective virus vector further comprises a selectable marker.

37. The composition of claim 36, wherein the selectable marker is a lacZ gene, thymidine kinase, gpt, GUS, or a vaccinia K1L host range gene, or a combination thereof.

38. The composition of any one of claims 1-37, wherein the replication-defective virus vector further comprises a nucleic acid sequence encoding an immunological fusion partner.

39. The composition of claim 1, wherein the PSA has an amino acid sequence at least 90%, at least 92%, at least 95%, at least 97%, or at least 99% identical with SEQ ID NO: 1 or SEQ ID NO: 34.

40. The composition of claim 2, wherein the PSA has an amino acid sequence at least 90%, at least 92%, at least 95%, at least 97%, or at least 99% identical with SEQ ID NO: 35.

41. The composition of claim 3, wherein the PSMA has an amino acid sequence at least 90%, at least 92%, at least 95%, at least 97%, or at least 99% identical with SEQ ID NO: 36.

42. The composition of claims 7, wherein the modified Brachyury antigen comprises an amino acid sequence at least 90%, at least 92%, at least 95%, at least 97%, or at least 99% identical to SEQ ID NO: 5, SEQ ID NO: 6, or SEQ ID NO: 42.

43. A pharmaceutical composition comprising the composition according to any one of claims 1-42 and a pharmaceutically acceptable carrier.

44. A host cell comprising the composition according to any one of claims 1-42.

45. A method of preparing a tumor vaccine, the method comprising preparing a pharmaceutical composition according to claim 43.

46. The composition of any of claims 1-42 for use in therapy.

47. Use of the composition according to any one of claims 1-42 in the manufacture of a pharmaceutical composition for treating a PSA-expressing or PSMA-expressing cancer in a subject in need thereof.