

Claims

1) A vaccine comprising a heterologous polynucleotide encoding a heterologous polypeptide, wherein the heterologous polypeptide is selected from the group consisting of SEQ ID NOs: 541, 543, 550, 554, 555, 556, 623, 624, 552, 557, 558, 559, 625, and 626, ~~and fragments thereof.~~

2) The vaccine of claim 1, wherein the vaccine is capable of eliciting a cellular immune response in a subject to be administered with the vaccine.

3) The vaccine of claim 2, wherein the cellular immune response is activation of vaccine-specific CD8⁺ T cells, CD4⁺ T cells, or CD8⁺ T cells and CD4⁺ T cells, wherein activation is assessed by increased production of TNF α , -IFN γ , or TNF α and IFN γ by CD8⁺ T cells, CD4⁺ T cells, or CD8⁺ T cells and CD4⁺ T cells relative to production of TNF α , IFN γ , or TNF α and IFN γ by CD8⁺ T cells, CD4⁺ T cells, or CD8⁺ T cells and CD4⁺ T cells from an unvaccinated subject.

4) ———. The vaccine of any one of claims 1-3, wherein the heterologous polynucleotide comprises a promoter, an enhancer, a polyadenylation site, a Kozak sequence, a stop codon, a T cell enhancer (TCE), or any combination thereof.

5) The vaccine of claim 4, wherein the promoter comprises a CMV promoter or a vaccinia P7.5 promoter.

6) The vaccine of claim 4 or 5, wherein the TCE is encoded by a polynucleotide of SEQ ID NO: 546, the CMV promoter comprises a polynucleotide of SEQ ID NO: 628, the vaccinia P7.5 promoter comprises a polynucleotide of SEQ ID NO: 630 and the polyadenylation site comprises a bovine growth hormone polyadenylation site of SEQ ID NO: 629.

7) The vaccine of any one of claims 1-6, wherein the heterologous polynucleotide is DNA or RNA.

8)₂ The vaccine of claim 7, wherein RNA is mRNA or self-replicating RNA.

9)₂ The vaccine of any one of claims 1-7, wherein the vaccine is a recombinant virus derived from adenovirus (Ad), poxvirus, adeno-associated virus (AAV) or retrovirus.

10)₂ The vaccine of claim 9, wherein the recombinant virus is derived from hAd5, hAd7, hAd11, hAd26, hAd34, hAd35, hAd48, hAd49, hAd50, GAd20, ~~Gad19~~GAd19, GAd21, GAd25, GAd26, GAd27, GAd28, GAd29, GAd30, GAd31, ChAd3, ChAd4, ChAd5, ChAd6, ChAd7, ChAd8, ChAd9, ChAd10, ChAd11, ChAd16, ChAd17, ChAd19, ChAd20, ChAd22, ChAd24, ChAd26, ChAd30, ChAd31, ChAd37, ChAd38, ChAd44, ChAd55, ChAd63, ChAd73, ChAd82, ChAd83, ChAd146, ChAd147, PanAd1, PanAd2, PanAd3, Copenhagen vaccinia virus (W), New York Attenuated Vaccinia Virus (NYVAC), ALVAC, TROVAC-, or modified vaccinia ankara (MVA).

11)₂ The vaccine of claim 10, wherein the recombinant virus is derived from GAd20.

12)₂ The vaccine of claim 10, wherein the recombinant virus is derived from MVA.

13)₂ The vaccine of claim 10, wherein the recombinant virus is derived from hAd26.

14)₂ A vaccine comprising a heterologous polynucleotide encoding a heterologous polypeptide of SEQ ID NOs: 541, 550, 554, 555, 556, 623 or 624, wherein the vaccine is a recombinant virus derived from GAd20 or Ad26.

15)₂ A vaccine comprising a heterologous polynucleotide encoding a heterologous polypeptide of SEQ ID NOs: 543, 552, 557, 558, 559, 625 or 626, wherein the vaccine is a recombinant virus derived from MVA.

16)₂ Use of a therapeutically effective amount of one or more vaccines of any one of claims 1-15 in the manufacture of a medicament for the treatment or prevention of a prostate cancer in a

subject.

17) A vaccine as claimed in any one of claims 1-15 for use in inducing an immune response in a subject.

18) The use of claim 16, wherein the prostate cancer is a relapsed prostate cancer, a refractory prostate cancer, a metastatic prostate cancer or a castration resistant prostate cancer, or any combination thereof.

19) The use of claim 16 or claim 18, wherein an additional cancer therapeutic agent is to be administered to the subject.

20) The use of claim 19, wherein the additional cancer therapeutic agent is a CTLA-4 antibody, a CTLA4 ligand, a PD-1 axis inhibitor, a PD-L1 axis inhibitor, a TLR agonist, a CD40 agonist, an OX40 agonist, hydroxyurea, ruxolitinib, fedratinib, a 41BB agonist, ~~aa~~ CD28 agonist, a STING antagonist, a RIG-1 antagonist, TCR-T therapy, CAR-T therapy, FLT3 ligand, aluminum sulfate, BTK inhibitor, CD38 antibody, -CDK inhibitor, CD33 antibody, CD37 antibody, CD25 antibody, GM-CSF inhibitor, IL-2, IL-15, IL-7, CD3 redirection molecules, pomalimib, IFN γ , IFN α , TNF α , VEGF antibody, CD70 antibody, CD27 antibody, BCMA antibody, ~~or~~ GPRC5D antibody, or any combination thereof.

~~21) Use of a heterologous polynucleotide encoding a first heterologous polypeptide, wherein the first heterologous polypeptide comprises two or more polypeptides selected from the group consisting of SEQ ID NOs: 275, 381, 333, 337, 269, 253, 309, 325, 271, 305, 251, 245, 261, 265, 317, 255, 277, 297, 285, 437, 439, 442, 444, 379, 343, 211, 349, 213, 215, 221, 219, 225, 345, 353, 235, 223, 167, 171, 19, 23 and 177 in the manufacture of a medicament in the form of a first vaccine, which when used in combination with a second vaccine, is for the treatment or prevention of a prostate cancer in a subject, wherein~~

~~a) the first vaccine is to be administered to the subject, in conjunction with~~

~~b) the second vaccine, which comprises a second heterologous polynucleotide encoding a second heterologous polypeptide, wherein the second heterologous polypeptide comprises two or more polypeptides selected from the group consisting of SEQ ID NOs: 275, 381, 333, 337, 269, 253, 309, 325,~~

~~271, 305, 251, 245, 261, 265, 317, 255, 277, 297, 285, 437, 439, 442, 444, 379, 343, 211, 349, 213, 215, 221, 219, 225, 345, 353, 235, 223, 167, 171, 19, 23 and 177.~~

~~22) — Use of a heterologous polynucleotide encoding a first heterologous polypeptide, wherein the first heterologous polypeptide comprises two or more polypeptides selected from the group consisting of SEQ ID NOs: 275, 381, 333, 337, 269, 253, 309, 325, 271, 305, 251, 245, 261, 265, 317, 255, 277, 297, 285, 437, 439, 442, 444, 379, 343, 211, 349, 213, 215, 221, 219, 225, 345, 353, 235, 223, 167, 171, 19, 23 and 177 in the manufacture of a medicament in the form of a first vaccine which when used in combination with a second vaccine, is for inducing an immune response in a subject, wherein~~

~~a) the first vaccine is to be administered to the subject in conjunction with~~

~~b) the second vaccine, which comprises a second heterologous polynucleotide encoding a second heterologous polypeptide, wherein the second heterologous polypeptide comprises two or more polypeptides selected from the group consisting of SEQ ID NOs: 275, 381, 333, 337, 269, 253, 309, 325, 271, 305, 251, 245, 261, 265, 317, 255, 277, 297, 285, 437, 439, 442, 444, 379, 343, 211, 349, 213, 215, 221, 219, 225, 345, 353, 235, 223, 167, 171, 19, 23 and 177.~~

~~23) — The use of claim 21 or claim 22, wherein the first heterologous polypeptide and the second heterologous polypeptide have distinct amino acid sequences.~~

~~24) — The use of any one of claims 21-23, wherein the first heterologous polypeptide comprises an amino acid sequence of SEQ ID NOs: 541, 550, 554, 555, 556, 623 or 624.~~

~~25) — The use of any one of claims 21-23, wherein the second heterologous polypeptide comprises the amino acid sequence of SEQ ID NOs: 543, 552, 557, 558, 559, 625 or 626.~~

~~26) — The use of any one of claims 21-25, wherein the first vaccine, the second vaccine, or both the first vaccine and the second vaccine is a DNA vaccine.~~

~~27) — The use of any one of claims 21-25, wherein the first vaccine, the second vaccine, or both the first vaccine and the second vaccine is a RNA vaccine.~~

~~28) — The use of any one of claims 21-25, wherein the first vaccine, the second vaccine or both the first vaccine and the second vaccine is a recombinant virus.~~

29) — The use of claim 28, wherein the recombinant virus is derived from hAd5, hAd7, hAd11, hAd26, hAd34, hAd35, hAd48, hAd49, hAd50, GAd20, Gad19, GAd21, GAd25, GAd26, GAd27, GAd28, GAd29, GAd30, GAd31, ChAd3, ChAd4, ChAd5, ChAd6, ChAd7, ChAd8, ChAd9, ChAd10, ChAd11, ChAd16, ChAd17, ChAd19, ChAd20, ChAd22, ChAd24, ChAd26, ChAd30, ChAd31, ChAd37, ChAd38, ChAd44, ChAd55, ChAd63, ChAd73, ChAd82, ChAd83, ChAd146, ChAd147, PanAd1, PanAd2, PanAd3, Copenhagen vaccinia virus (W), New York Attenuated Vaccinia Virus (NYVAC), ALVAC, TROVAC, or MVA.

30) — The use of any one of claims 21-29, wherein the first vaccine is a recombinant virus derived from GAd20 or Ad26 comprising a heterologous polynucleotide encoding a heterologous polypeptide of SEQ ID NOs: 541, 550, 554, 555, 556, 623 or 624.

31) — The use of any one of claims 21-29, wherein the second vaccine is a recombinant virus derived from MVA comprising a heterologous polynucleotide encoding a heterologous polypeptide of SEQ ID NOs: 543, 552, 557, 558, 559, 625 or 626.

32) — The use of any one of claims 21-31, wherein an additional cancer therapeutic agent is also to be administered to the subject.

33) — The use of claim 32, wherein the additional cancer therapeutic agent is a CTLA-4 antibody, a CTLA4 ligand, a PD-1 axis inhibitor, a PD-L1 axis inhibitor, a TLR agonist, a CD40 agonist, an OX40 agonist, hydroxyurea, ruxolitinib, fedratinib, a 41BB agonist, a CD28 agonist, a STING antagonist, a RIG-1 antagonist, TCR-T therapy, CAR-T therapy, FLT3 ligand, aluminum sulfate, BTK inhibitor, CD38 antibody, CDK inhibitor, CD33 antibody, CD37 antibody, CD25 antibody, GM-CSF inhibitor, IL-2, IL-15, IL-7, CD3 redirection molecules, pomalimab, IFN γ , IFN α , TNF α , VEGF antibody, CD70 antibody, CD27 antibody, BCMA antibody or GPRC5D antibody or any combination thereof.

34) — The use of claim 33, wherein the checkpoint inhibitor is ipilimumab, cetrelimab, pembrolizumab, nivolumab, sintilimab, cemiplimab, toripalimab, camrelizumab, tislelizumab, dostalimab, spartalizumab, prolgolimab, balstilimab, budigalimab, sasanlimab, avelumab, atezolizumab, durvalumab, envafolimab, or iodapolimab, or any combination thereof.

35) — The use of any one of claims 21-31, wherein the first vaccine is to be administered one or more times to the subject.

36) — The use of any one of claims 21-31, wherein the second vaccine is to be administered one or more times to the subject.

37) — The use of any one of claims 21-31, wherein the first vaccine is to be administered between about 1-16 weeks prior to the administration of the second vaccine.

38) — An isolated heterologous polynucleotide encoding two or more polypeptides selected from the group consisting of SEQ ID NOs: 275, 381, 333, 337, 269, 253, 309, 325, 271, 305, 251, 245, 261, 265, 317, 255, 277, 297, 285, 437, 439, 442, 444, 379, 343, 211, 349, 213, 215, 221, 219, 225, 345, 353, 235, 223, 167, 171, 19, 23 and 177, and fragments thereof.

39) — The isolated heterologous polynucleotide of claim 38, comprising two or more polynucleotides selected from the group consisting of SEQ ID NOs: 276, 382, 334, 338, 270, 254, 310, 326, 272, 306, 252, 246, 262, 266, 318, 256, 278, 298, 286, 448, 450, 453, 455, 380, 344, 212, 350, 214, 216, 222, 220, 226, 346, 354, 236, 224, 168, 172, 20, 24 and 178, and fragments thereof.

40) — A vector comprising the heterologous polynucleotide of claim 39.

41) — The vector of claim 40, wherein the vector is a recombinant viral vector derived from hAd5, hAd7, hAd11, hAd26, hAd34, hAd35, hAd48, hAd49, hAd50, GAd20, Gad19, GAd21, GAd25, GAd26, GAd27, GAd28, GAd29, GAd30, GAd31, ChAd3, ChAd4, ChAd5, ChAd6, ChAd7, ChAd8, ChAd9, ChAd10, ChAd11, ChAdI6, ChAdI7, ChAdI9, ChAd20, ChAd22, ChAd24, ChAd26, ChAd30, ChAd31, ChAd37, ChAd38, ChAd44, ChAd55, ChAd63, ChAd73, ChAd82, ChAd83, ChAd146, ChAd147, PanAd1, PanAd2, PanAd3, Copenhagen vaccinia virus (W), New York Attenuated Vaccinia Virus (NYVAC), ALVAC, TROVAC, or MVA.

42) — The vector of claim 41, wherein the recombinant virus is derived from GAd20.

43) — The vector of claim 41, wherein the recombinant virus is derived from MVA.

44) — An isolated polynucleotide

a) — encoding a polypeptide of SEQ ID NOs: 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, 35, 37, 39, 41, 43, 45, 47, 49, 51, 53, 55, 57, 59, 61, 63, 65, 67, 69, 71, 73, 75, 77, 79,

81, 83, 85, 87, 89, 91, 93, 95, 97, 99, 101, 103, 105, 107, 109, 111, 113, 115, 117, 119, 121, 123, 125, 127, 129, 131, 133, 135, 137, 139, 141, 143, 145, 147, 149, 151, 153, 155, 157, 159, 161, 163, 165, 167, 169, 171, 173, 175, 177, 179, 181, 183, 185, 187, 189, 191, 193, 195, 197, 199, 201, 203, 205, 207, 209, 211, 213, 215, 217, 219, 221, 223, 225, 227, 229, 231, 233, 235, 237, 239, 241, 243, 245, 247, 249, 251, 253, 255, 257, 259, 261, 263, 265, 267, 269, 271, 273, 275, 277, 279, 281, 283, 285, 287, 289, 291, 293, 295, 297, 299, 301, 303, 305, 307, 309, 311, 313, 315, 317, 319, 321, 323, 325, 327, 329, 331, 333, 335, 337, 339, 341, 343, 345, 347, 349, 351, 353, 355, 357, 359, 361, 363, 365, 367, 369, 371, 373, 375, 379, 381, 383, 385, 387, 388, 389, 390, 391, 392, 393, 394, 395, 396, 397, 398, 399, 400, 401, 402, 403, 404, 405, 406, 407, 408, 426, 427, 428, 429, 430, 431, 432, 433, 434, 435, 436, 437, 438, 439, 440, 441, 442, 443, 444, 445, 446 or 447, or fragments thereof;

b) — encoding a polypeptide that is at least 90% identical to the polypeptide of SEQ ID NOs: 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, 35, 37, 39, 41, 43, 45, 47, 49, 51, 53, 55, 57, 59, 61, 63, 65, 67, 69, 71, 73, 75, 77, 79, 81, 83, 85, 87, 89, 91, 93, 95, 97, 99, 101, 103, 105, 107, 109, 111, 113, 115, 117, 119, 121, 123, 125, 127, 129, 131, 133, 135, 137, 139, 141, 143, 145, 147, 149, 151, 153, 155, 157, 159, 161, 163, 165, 167, 169, 171, 173, 175, 177, 179, 181, 183, 185, 187, 189, 191, 193, 195, 197, 199, 201, 203, 205, 207, 209, 211, 213, 215, 217, 219, 221, 223, 225, 227, 229, 231, 233, 235, 237, 239, 241, 243, 245, 247, 249, 251, 253, 255, 257, 259, 261, 263, 265, 267, 269, 271, 273, 275, 277, 279, 281, 283, 285, 287, 289, 291, 293, 295, 297, 299, 301, 303, 305, 307, 309, 311, 313, 315, 317, 319, 321, 323, 325, 327, 329, 331, 333, 335, 337, 339, 341, 343, 345, 347, 349, 351, 353, 355, 357, 359, 361, 363, 365, 367, 369, 371, 373, 375, 379, 381, 383, 385, 387, 388, 389, 390, 391, 392, 393, 394, 395, 396, 397, 398, 399, 400, 401, 402, 403, 404, 405, 406, 407, 408, 426, 427, 428, 429, 430, 431, 432, 433, 434, 435, 436, 437, 438, 439, 440, 441, 442, 443, 444, 445, 446 or 447, or fragments thereof;

c) — comprising a polynucleotide sequence of SEQ ID NOs: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76, 78, 80, 82, 84, 86, 88, 90, 92, 94, 96, 98, 100, 102, 104, 106, 108, 110, 112, 114, 116, 118, 120, 122, 124, 126, 128, 130, 132, 134, 136, 138, 140, 142, 144, 146, 148, 150, 152, 154, 156, 158, 160, 162, 164, 166, 168, 170, 172, 174, 176, 178, 180, 182, 184, 186, 188, 190, 192, 194, 196, 198, 200, 202, 204, 206, 208, 210, 212, 214, 216, 218, 220, 222, 224, 226, 228, 230, 232, 234, 236, 238, 240, 242, 244, 246, 248, 250, 252, 254, 256, 258, 260, 262, 264, 266, 268, 270, 272, 274, 276, 278, 280, 282, 284, 286, 288, 290, 292, 294, 296, 298, 300, 302, 304, 306, 308, 310, 312, 314, 316, 318, 320, 322, 324, 326, 328, 330, 332, 334, 336, 338, 340, 342, 344, 346, 348, 350, 352, 354, 356, 358, 360, 362, 364, 366, 368, 370, 372, 374, 376, 380, 382, 384, 386,

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d) ~~comprising a polynucleotide sequence that is at least 90% identical to the polynucleotide sequence of SEQ ID NOs: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76, 78, 80, 82, 84, 86, 88, 90, 92, 94, 96, 98, 100, 102, 104, 106, 108, 110, 112, 114, 116, 118, 120, 122, 124, 126, 128, 130, 132, 134, 136, 138, 140, 142, 144, 146, 148, 150, 152, 154, 156, 158, 160, 162, 164, 166, 168, 170, 172, 174, 176, 178, 180, 182, 184, 186, 188, 190, 192, 194, 196, 198, 200, 202, 204, 206, 208, 210, 212, 214, 216, 218, 220, 222, 224, 226, 228, 230, 232, 234, 236, 238, 240, 242, 244, 246, 248, 250, 252, 254, 256, 258, 260, 262, 264, 266, 268, 270, 272, 274, 276, 278, 280, 282, 284, 286, 288, 290, 292, 294, 296, 298, 300, 302, 304, 306, 308, 310, 312, 314, 316, 318, 320, 322, 324, 326, 328, 330, 332, 334, 336, 338, 340, 342, 344, 346, 348, 350, 352, 354, 356, 358, 360, 362, 364, 366, 368, 370, 372, 374, 376, 380, 382, 384, 386, 448, 449, 450, 451, 452, 453, 454, 455, 456, 457, 458, 459, 460, 461, 462, 463, 464, 465, 466, 467, 468, 469, 470, 471, 472, 473, 474, 475, 476, 477, 478, 479, 480, 481, 482, 483, 484, 485, 486, 487, 488, 489, 490, 491, 492, 493, 494, 495, 496, 497, 498, 499, 500, 501, 503, 504, 505, 506, 507, 508, 509, 510, 511, 512, 513, 514, 515, 516, 517, 519, 520, 521, 522, 523, 524, 525, 528, 529, 530, 531, 532, 533, 534, 535, 536, 537, 538, 539 or 540, or fragments thereof.~~

45) ~~A vector comprising the polynucleotide of claim 44.~~

46) ~~The vector of claim 45, wherein the vector is a viral vector selected from Ad vector, an AAV vector, a poxvirus vector, a vaccinia vector, or a MVA vector.~~