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Review article

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Vaccines as treatments for prostate cancer

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Vaccine	Antigen	Combination agent(s)	Phase	Number enrolled	Study title	NCT trial no.	Results / Comments	Ref
Antigen non-specific vaccines								
Cellular vaccines								
Irradiated autologous tumor cells		BCG adjuvant	I	50	Phase I study with an autologous tumor cell vaccine for locally advanced or metastatic prostate cancer			[1]
Irradiated, GM-CSF transfected autologous tumor cells			I	8	Induction of immunity to prostate cancer antigens: results of a clinical trial of vaccination with irradiated autologous prostate tumor cells engineered to secrete granulocyte-macrophage colony-stimulating factor using ex vivo gene transfer			[2]
Irradiated allogeneic human prostate carcinoma LNCaP cell line engineered to secrete IL-2 and IFNγ			I/II	25	Phase I/II study of immunization with MHC class I matched allogeneic human prostatic carcinoma cells engineered to secrete interleukin-2 and interferon-gamma	NCT00002637		
GVAX (irradiated GM-CSF transfected allogeneic prostate tumor cells)			I/II	80	Dose escalation and efficacy trial of GVAX® prostate cancer vaccine	NCT00140348		[3]
GVAX			I/II	50	Prime-boost dose scheduling trial for human GM-CSF gene transduced irradiated prostate allogeneic cancer vaccine (Allogeneic Prostate GVAX®) in patients with hormone-refractory prostate cancer	NCT00140400		
GVAX			I/II	36	Vaccination priming and vaccine boosting trial of allogeneic human GM-CSF gene transduced irradiated prostate cancer cell vaccines (GVAX® vaccine for prostate cancer)	NCT00140374		
GVAX			I/II	20	Prime-boost dose scheduling trial for human GM-CSF gene transduced irradiated prostate allogeneic cancer cell vaccines (Allogeneic Prostate GVAX®)	NCT00140387		

GVAX			I/II	55	Granulocyte macrophage colony-stimulating factor--secreting allogeneic cellular immunotherapy for hormone-refractory prostate cancer			[4]
GVAX		Ipilimumab	I	28	Combination immunotherapy with prostate GVAX and ipilimumab: safety toxicity and dose escalation	NCT01510288		[5]
GVAX		Cyclophosphamide +/- fludaribine and autologous PBMCs	I/II	18	GVAX in advanced prostate cancer patients made lymphopenic	NCT00122005		
GVAX		Degarelix acetate and Cyclophosphamide	I/II	29	A neoadjuvant study of androgen ablation combined with cyclophosphamide and GVAX vaccine for localized prostate cancer	NCT01696877		[6]
GVAX		Androgen ablation - bicalutamide, goserelin, leuprolide acetate	II	0	Androgen ablation therapy with or without vaccine therapy in treating patients with prostate cancer	NCT00771017	Withdrawn	
GVAX		Docetaxel	II	6	Docetaxel and immunotherapy prior to prostatectomy for high-risk prostate cancer	NCT00577356		
ONY-P1 (irradiated prostate cancer cell lines; LNCaP, P4E6, and OnyCap-23)		BCG	I/II	26	Delayed disease progression after allogeneic cell vaccination in hormone-resistant prostate cancer and correlation with immunologic variables			[7]
ONY-P1		BCG	II	54	Vaccine Therapy in Treating Patients With Stage D0 Prostate Cancer	NCT00514072		
GVAX			III	626	GVAX® vaccine for prostate cancer vs docetaxel & prednisone in patients with metastatic hormone-refractory prostate cancer	NCT00089856	Terminated (Based on futility analysis showing <30% chance of	

							meeting primary endpoint)	
GVAX		Docetaxel	III	408	Docetaxel in combination with GVAX ® immunotherapy versus docetaxel and prednisone in prostate cancer patients	NCT00133224	Terminated (Accrual and treatment with GVAX stopped due to IDMC recommend ation.)	
Non antigen-specific dendritic cell vaccines								
Autologous dendritic cells transfected with autologous prostate carcinoma RNA			I	3	Vaccine therapy in treating patients with metastatic prostate cancer	NCT00010127		
Dendritic cells transfected with RNA from autologous cancer cells			I	N/A	Tumor RNA transfected dendritic cell vaccines	NCT00108264		
DRibble vaccine (dendritic cell-targeting microvesicles containing SLiPs and DRiPs) and HPV vaccination (CERAVIX)		Cyclophosph amide and Imiquimod	I	3	A Pilot Study of DPV-001 DRibble Vaccine With Imiquimod in Advanced Prostate Cancer	NCT02234921		
Dendritic cells pulsed with apoptotic LNCaP cells			I/II	24	Safety and effectiveness of a vaccine for prostate cancer that uses each patients' own immune cells	NCT00289341		[8]
DCVAC/PCa (Dendritic cells pulsed with killed LNCaP prostate cancer cells)		Docetaxel	I/II	25	Phase I/II clinical trial of dendritic-cell based immunotherapy (DCVAC/PCa) combined with chemotherapy in patients with metastatic, castration-resistant prostate cancer			[9]
Autologous dendritic cell pulsed with apoptotic PC3 cells			I/II	13	Dendritic cell vaccine study (DC/PC3) for prostate cancer	NCT00345293		[10]

alpha-type-1-polarized dendritic cells (DC1) loaded with apoptotic allogeneic tumor (LNCap)		Androgen ablation (Lupron or Zoladex mg)	II	13	Dendritic Cell (DC)-based vaccines loaded with allogeneic prostate cell lines in combination with androgen ablation in patients with prostate cancer	NCT00970203		
Autologous dendritic cells delivered with allogeneic whole cell vaccine		allogenic whole prostate carcinoma cell vaccine	II	2	Vaccine Therapy in Treating Patients With Non-Metastatic Prostate Cancer	NCT00814892		
DCVAC/PCa		Radiotherapy	II	62	Phase II study of DCVAC/PCa after primary radiotherapy for patients with high risk localized prostate cancer	NCT02107430		
DCVAC/PCa			II	150	Phase II study of DCVAC/PCa added after radical primary prostatectomy for patients with localized prostate cancer	NCT02107404		
DCVAC/PCa		Leuprolide acetate and Goserelin Acetate	II	63	Phase II study of DCVAC/PCa added to hormone therapy for men with metastatic prostate cancer	NCT02107391		
DCVAC/PCa		Docetaxel	II	60	Phase II study of DCVAC/PCa added to standard chemotherapy for men with metastatic castration resistant prostate cancer	NCT02105675		
DCVAC/PCa		docetaxel and prednisone	III	1182	A Randomized, Double Blind, Multicenter, Parallel-group, Phase III Study to Evaluate Efficacy and Safety of DCVAC/PCa Versus Placebo in Men With Metastatic Castration Resistant Prostate Cancer Eligible for 1st Line Chemotherapy (VIABLE)	NCT02111577	Did not improve overall survival of patients with mCRPC	[11]
Antigen-specific vaccines								
Cancer-associated membrane carbohydrates								
MUC-2-Globo H-KLH conjugate	MUC-2	QS21	I	9	Vaccine therapy plus QS21 in treating patients with prostate cancer	NCT00036933		[12]

MUC-2-Globo H-KLH conjugate	MUC-2	GPI-0100	I	34	Vaccine therapy plus biological therapy in treating patients with prostate cancer	NCT00016146		
MUC-2-KLH conjugate	MUC-2	QS21	I	15	Vaccine therapy plus QS21 in treating patients with progressive prostate cancer	NCT00004929		
MUC-2-KLH conjugate	MUC-2	QS21	I	15	Vaccination of prostate cancer patients with MUC-2-KLH conjugate plus the immunological adjuvant QS21	NCT00698711		
MUC-1-KLH conjugate	MUC-1	QS21	I	27	Vaccine therapy plus QS21 in treating patients with prostate cancer	NCT00005632		
TF(c)-KLH conjugate	Thomsen-Friedenreich antigen	QS21	I	21	Vaccine therapy plus QS21 in treating patients with progressive prostate cancer	NCT00003819		[13]
Alpha (1,3) galactosyltransferase expressing irradiated allogeneic tumor cells	Alpha (1,3) galactosyltransferase		I/II	8	Vaccine treatment for hormone refractory prostate cancer	NCT00105053		
Carbohydrate or peptide constituent (conjugated with KLH)	Globohexaosylceramide (globo-H), GM2, Lewis-y, MUC-1, TF(c), and Tn(c)	QS21	II	30	Multivalent conjugate vaccine trial for patients with biochem. relapsed prostate cancer	NCT00579423		[14]
Protein vaccines								
PSA/IL-2/GM-CSF (Proscavax)	PSA (Prostate specific antigen)	IL-2 + GMCSF	I	48	Phase 1a/1b study of PSA/IL-2/GM-CSF vaccine for recurrent prostate cancer in hormone naive and hormone independent patients (PSA)	NCT02058680		
JBT 1001(PSA in liposomes)	PSA	GM-CSF	I	10	Generation of PSA-reactive effector cells after vaccination with a PSA-based vaccine in patients with prostate cancer			[15]

OVM-200	Survivin		I	36	First-in-human study of OVM-200 as a therapeutic cancer vaccine	NCT05104515	Included patients with prostate, lung, and ovarian cancers	
CPC-P501	P501	AS15 (CpG 7909, monophosphoryl lipid, and QS-21)	I	25	Safety & activity of P501-AS15 vaccine as a first-line treatment for patients with hormone-sensitive prostate cancer who show rising PSA	NCT00148928		
IMF-001 (CHP-NY-ESO-1 complex consisting of recombinant NY-ESO-1 protein and cholesteryl hydrophobized pullulan (CHP))	NY-ESO-1		I	23	Study of IMF-001 in patients With malignancies expressing NY-ESO-1	NCT01234012		
CDX-1401 (DEC-205/NY-ESO-1 fusion protein)	NY-ESO-1	Sirolimus	I	18	Vaccine therapy with or without sirolimus in treating patients with NY-ESO-1 expressing solid tumors	NCT01522820	Included multiple tumor types	
Recombinant soluble PSMA	PSMA	Alhydrogel	I	14	Vaccine therapy of prostate cancer patients with recombinant soluble prostate-specific membrane antigen (Rs-PSMA) plus the immunological adjuvant alhydrogel	NCT00705835		
Proscavax	PSA	IL-2 + GMCSF	II	120	Study of Proscavax vaccine in patients with localized prostate cancer vs active surveillance	NCT03579654		
Peptide vaccines								
PSA (146-154 peptide) or DCs pulsed with PSA (146-154)	PSA	GM-CSF	I	28	Induction of specific T cell immunity in patients with prostate cancer by vaccination with PSA146-154 peptide			[16]
E75 HLA-A2 epitope from HER-2/neu	HER2	Flt3L or GM-CSF	I	20	Pilot study of an HLA-A2 peptide vaccine using flt3 ligand as a systemic vaccine adjuvant			[17]

DPX-0907 (7 tumor-specific HLA-A2-restricted peptides, and a universal T Helper peptide) lyophilized antigen/adjuvant/liposome complex	Multiple	Polynucleotide adjuvant, liposome and montanide ISA51 VG	I	23	A phase I safety study of a cancer vaccine to treat HLA-A2 positive advanced stage ovarian, breast and prostate cancer	NCT01095848	Included patients with breast, ovarian and prostate cancers	[18]
NY-ESO-1/LAGE-1 HLA class I and/or class II peptides	NY-ESO-1, LAGE-1		I	14	Vaccine therapy in treating patients with metastatic, progressive prostate cancer	NCT00616291		
NY-ESO-1 protein	NY-ESO-1	CpG 7909	I	15	Immunization with NY-ESO-1 protein combined with CpG 7909 in patients with prostate cancer	NCT00292045		
Personalized genomic peptides (PGV-001)	variable	Poly-ICLC and/or CDX-301 (rhFlt-3L)	I	27	The safety and tolerability of PGV001-based personalized multi-peptide vaccines in the adjuvant setting. (PGV-Prostate)	NCT05010200		
Mixed peptides	Undisclosed tumor-associated antigens	tetanus-based vaccine adjuvant	I	18	TENDU vaccine in patients with relapse after primary radical prostatectomy	NCT04701021		
Bcl-XL_42	B-cell lymphoma extra-large protein (Bcl-XL)	CAF09b	I	20	Bcl-XL_42-CAF09b vaccination for patients with prostate cancer with lymph node metastases	NCT03412786		
MUC-1 Peptide	MUC-1	GM-CSF and poly-ICLC	I	14	MUC-1 vaccine in conjunction with Poly-ICLC in patients with recurrent and/or advanced prostate cancer	NCT00374049		
EGFRvIII peptide	EGFR	KLH or GMCSF	I	14	S0114 vaccine therapy in treating patients with gastric, prostate, or ovarian cancer	NCT00023634		
TARP peptides or TARP peptide pulsed DCs	TARP		I	41	A pilot study of vaccination with epitope-enhanced TARP peptide and TARP peptide-pulsed dendritic cells in the treatment of stage D0 prostate cancer	NCT00972309	This trial evaluated direct peptide immunizatio	[19]

							n versus DC-loaded peptide	
PSMA and TARP peptides	PSMA and TARP	Poly IC-LC	I	29	PSMA and TARP peptide vaccine with Poly IC-LC adjuvant in HLA-A2 (+) patients with elevated PSA after initial definitive treatment	NCT00694551		
UV1 synthetic peptide	hTERT	GM-CSF	I/II	22	A phase I/IIa study of UV1 vaccine in patients with prostate cancer (UV1/hTERT2012P)	NCT01784913		
Peptide vaccine and with or without mRNA/protamine	Multiple prostate tumor-associated peptides	Montanide ISA-51, GM-CSF, Imiquimod, and/or Protamine	I/II	36	Peptide-specific vaccination in HLA-A*02 positive patients with biochemical recurrence after radical prostatectomy	NCT02452307		[20]
CDCA1 (A24-56) peptide	CDC1 (cell division cycle associate gene-1)		I/II	30	Novel peptide vaccination for patients with advanced prostate cancer	NCT01225471		[21]
RV001 Peptide	RhoC (Ras Homolog Family Member C)	Montanide ISA 51	I/II	22	RV001V, a RhoC anticancer vaccine, against metastasis from solid tumours	NCT03199872		[22]
PEP-223 /CoVaccine HT (peptides)	Gonadotropin-releasing hormone receptor		I/II	12	Efficacy and safety study of the therapeutic vaccine PEP223 in prostate cancer patients	NCT00895466		
PSA-3 peptide	PSA	Montanide ISA-51	II	44	Vaccine therapy in treating patients with recurrent prostate cancer	NCT00030602		
PSA:154-163(155L) peptide	PSA	Incomplete freunds adjuvant	II	32	Vaccine therapy in treating patients with recurrent prostate cancer	NCT00109811		[23]

Personalized peptide vaccines	variable	EMP (estramustine phosphate)	II	28	A randomized phase II trial of personalized peptide vaccine plus low dose estramustine phosphate (EMP) versus standard dose EMP in patients with castration resistant prostate cancer			[24]
PSMA peptide	PSMA	IL-12	II	13	Vaccine therapy plus interleukin-12 in treating patients with metastatic prostate cancer that has not responded to hormone therapy	NCT00015977		
RV001 peptide	RhoC	Montanide ISA 51	II	180	Study of RV001V in biochemical failure following curatively intended therapy For localized prostate cancer (BRaVac)	NCT04114825		
GX-301 hTERT (540-548) Acetate, hTERT (611-626) Acetate, hTERT (672-686) Acetate and hTERT (766-780) Acetate peptides	hTERT	Montanide ISA-51 VG and imiquimod	II	98	A phase II randomised trial of three regimens of GX301 vaccination in castration-resistant prostate cancer	NCT02293707		[25]
Tecemotide (liposome-encapsulatedpeptide)	MUC-1	Radiation therapy, goserelin, cyclophosphamide	II	28	Tecemotide (L-BLP25) in prostate cancer	NCT01496131		
Personalized peptide vaccines	HLA-A24-restricted peptide epitopes from several proteins		III	306	A randomized phase III trial of personalized peptide vaccination for castration-resistant prostate cancer progressing after docetaxel		Did not demonstrate improved overall survival	[26]
Antigen-loaded dendritic cell / antigen-presenting cell vaccines								
Dendritic cells pulsed with recombinant mouse PAP	Xenogeneic homolog of PAP		I	21	Dendritic cell-based xenoantigen vaccination for prostate cancer immunotherapy			[27]
BPX101 (autologous DCs transduced to express	PSMA	AP1903 to induce CD40 expression	I	19	Safety study of BPX-201 dendritic cell vaccine plus AP1903 in metastatic castrate resistent prostate cancer	NCT01823978		[28]

inducible CD40, and loaded with extracellular domain of PSMA)								
rPSMA-pulsed mature autologous dendritic cells (CaPVax)	PSMA		I	60	Vaccine therapy in treating patients with metastatic prostate cancer that has not responded to hormone therapy	NCT00005992		
BP-GMAX-CD1 (autologous DC targeting PSMA)	PSMA	AP1903	I	18	MTD study of vaccine BP-GMAX-CD1 plus AP1903 to treat castrate resistant prostate cancer	NCT00868595		
Sipuleucel-T (autologous antigen-presenting cells loaded with PAP-GM-CSF fusion protein)	PAP	Ipilimumab	I	9	Sipuleucel-T and Ipilimumab for advanced prostate cancer	NCT01832870		[29]
Transgenic autologous lymphocytes	Telomerase		I	18	Evaluation of transgenic lymphocyte immunization vaccine in subjects with prostate adenocarcinoma	NCT00061035		[30]
Autologous DCs pulsed with RNA encoding PSA	PSA		I/II	17	Vaccine therapy in treating patients with metastatic prostate cancer	NCT00004211		
CreaVax-PC (antigen primed autologous DCs)	PSA, PAP and KLH		I/II	12	Autologous dendritic cell therapy for hormone-refractory metastatic prostate cancer	NCT01171729		
mRNA- transfected dendritic cells	Not disclosed		I/II	Not available	Trial of vaccine therapy with mRNA-transfected dendritic cells in patients with androgen resistant metastatic prostate cancer	NCT01278914		
Antigen loaded Dendritic Cell	PSCA, PAP, PSMA and PSA		I/II	15	Phase I/II study of vaccination with antigen loaded dendritic cells (DCs) in hormone-refractory prostate cancer	NCT01897207		
DC-Tn-MUC1 (Autologous DCs expressing Tn-MUC-1)	MUC-1		I/II	20	A study evaluating vaccination of prostate cancer patients with self dendritic cells expressing MUC-1	NCT00852007		
Autologous monocytes loaded with PAP-GM-CSF fusion protein	PAP	Delivered with PD-1 KO	I/II	30	Clinical Assessment of a Therapeutic Vaccine in Combination With PD-1	NCT03525652		

		autologous T cells			Knockout T Cells in the Treatment of Prostate Cancer			
Dendritic Cells Loaded With mRNA From Primary Prostate Cancer Tissue, hTERT and Survivin	mRNA From Primary Prostate Cancer Tissue, hTERT and Survivin		I/II	30	Vaccine therapy in curative resected prostate cancer patients	NCT01197625		
Dendritic cells (DC) pulsed with two HLA-A2-specific prostate-specific membrane antigen (PSMA) peptides (PSM-P1 and -P2)	PSMA		II	37	Phase II prostate cancer vaccine trial: report of a study involving 37 patients with disease recurrence following primary treatment			[31]
mRNA transfected dendritic cell	PSA, PAP, survivin and hTERT	Docetaxel	II	43	Dendritic cell vaccination and docetaxel for patients with prostate cancer	NCT01446731		
Peptide loaded myeloid dendritic cells (mDC) and/or plasmacytoid dendritic cells (pDC)	NY-ESO-1, MUC-1 and undisclosed tumor antigens		II	21	Natural dendritic cells for immunotherapy of chemo-naive metastatic castration-resistant prostate cancer patients	NCT02692976		[32]
T-cell Receptor Alternate Reading Frame Protein Dendritic Cell (DC) Vaccine	TARP		II	7	Multi-epitope TARP peptide autologous dendritic cell vaccination in men with stage D0 prostate cancer	NCT02362451		
Multi-Epitope TARP peptide loaded autologous dendritic cell vaccine	TARP		II	14	Long-term TARP vaccination using a multi-epitope TARP peptide autologous dendritic cell vaccination in previously vaccinated men on NCI 09-C-0139	NCT02362464		

Sipuleucel-T	PAP		II	47	Sipuleucel-T manufacturing demonstration study	NCT01477749		
Sipuleucel-T	PAP	Abiraterone acetate (ADT)	II	69	Concurrent vs. sequential sipuleucel-T & abiraterone treatment in men with metastatic castrate resistant prostate cancer	NCT01487863		[33]
Sipuleucel-T	PAP	leuprolide acetate	II	68	Sequencing of sipuleucel-T and ADT in men with non-metastatic prostate cancer	NCT01431391		[34]
Sipuleucel-T	PAP		II	21	Immunotherapy (APC8015, Provenge) targeting prostatic acid phosphatase can induce durable remission of metastatic androgen-independent prostate cancer: a Phase 2 trial			[35]
Sipuleucel-T	PAP	Radiation	II	51	Sipuleucel-T with or without radiation therapy in treating patients with hormone-resistant metastatic prostate cancer	NCT01807065		[36]
Sipuleucel-T	PAP	Radium 223	II	36	Study of sipuleucel-T W/ or W/O Radium-223 in men with asymptomatic or minimally symptomatic bone-MCRPC	NCT02463799		[37]
Sipuleucel-T	PAP	IL-7	II	54	CYT107 after vaccine treatment (Provenge®) in patients with metastatic castration-resistant prostate cancer	NCT01881867		[38]
Sipuleucel-T	PAP	pTVG-HP (plasmid encoding PAP) and rhGM-CSF	II	18	Pilot trial of sipuleucel-t, with or without pTVG-HP DNA booster vaccine, in patients with castrate-resistant, metastatic prostate cancer	NCT01706458		[39]
Sipuleucel-T	PAP	Indoximod	II	47	Phase II study of sipuleucel-T and indoximod for patients with refractory metastatic prostate cancer	NCT01560923		[40]
Sipuleucel-T	PAP	Atezolizumab (Anti-PD-L1)	II	37	Clinical study of atezolizumab (Anti-PD-L1) and sipuleucel-T in patients with asymptomatic or minimally symptomatic metastatic castrate resistant prostate cancer	NCT03024216		[41]
Sipuleucel-T	PAP		II	8	Sipuleucel-T in metastatic castrate resistant prostate cancer	NCT01338012		

Sipuleucel-T	PAP		II	104	Open label study of sipuleucel-T in metastatic prostate cancer	NCT00901342		
Sipuleucel-T	PAP		II	122	To evaluate sipuleucel-T manufactured with different concentrations of (PA2024) antigen	NCT00715078		
Sipuleucel-T	PAP	CT-011 (Anti-PD1 Ab) and Cyclophosphamide	II	7	Sipuleucel-T, CT-011, and cyclophosphamide for advanced prostate cancer	NCT01420965		
Sipuleucel-T	PAP	Tasquinimod	II	2	Sipuleucel-T with or without tasquinimod in treating patients with metastatic hormone-resistant prostate cancer	NCT02159950		
Sipuleucel-T	PAP	Docetaxel	II	0	Docetaxel followed by Provenge in metastatic prostate cancer	NCT02793765	Withdrawn	
Sipuleucel-T	PAP	Docetaxel	II	0	Provenge followed by docetaxel in castration-resistant prostate cancer	NCT02793219	Withdrawn	
Sipuleucel-T	PAP		III	176	PROvenge treatment and early cancer treatment	NCT00779402		
Sipuleucel-T	PAP		III	127	Vaccine therapy in treating patients with metastatic prostate cancer that has not responded to hormone therapy	NCT00005947		
Sipuleucel-T	PAP		III	512	A Randomized, Double Blind, Placebo Controlled Phase 3 Trial of Immunotherapy With Autologous Antigen Presenting Cells Loading With PA2024 (Provenge(R), APC8015) in Men With Metastatic Androgen Independent Prostatic Adenocarcinoma	NCT00065442	Prolonged overall survival relative to control group – led to FDA approval in 2010	[42]
Viral, bacterial, and fungal vaccines								
Adenoviral PSA vaccine, adenoviral MUC-1 vaccine, and adenoviral Brachyury vaccine	PSA, MUC-1, and Brachyury		I	18	Treatment of castration resistant prostate cancer using multi-targeted recombinant Ad5 PSA/MUC-1/Brachyury based immunotherapy vaccines	NCT03481816		[43]

Ad-sig-hMUC-1/ecdCD40L (adenoviral vector encoding MUC-1 linked to CD40L)	MUC-1		I	24	Safety study of human MUC-1 (Mucin-1) adenoviral vector vaccine for immunotherapy of epithelial cancers (MUC-1)	NCT02140996		
PROSTVAC-V/TRICOM and PROSTVAC-F/TRICOM	PSA	MDX-010 (anti-CTLA4) and GM-CSF	I	30	Vaccine and antibody treatment of prostate cancer	NCT00113984		[44]
Recombinant vaccinia-PSA (L155) /TRICOM and recombinant fowlpox-PSA (L155)/TRICOM	PSA	Recombinant fowlpox-GM-CSF	I	21	A phase I feasibility study of an intraprostatic PSA-based vaccine in men with prostate cancer with local failure following radiotherapy or cryotherapy or clinical progression on androgen deprivation therapy in the absence of local definitive therapy	NCT00096551		
Recombinant vaccinia virus expressing PSA (rV-PSA)	PSA	GM-CSF	I	46	Vaccine therapy in treating patients with metastatic prostate cancer	NCT00004029		
Adenoviral brachyury vaccine (ETBX-051), adenoviral Mucin-1 vaccine (ETBX-061), adenoviral carcinoembryonic antigen vaccine (ETBX-011)	MUC-1, CEA, and Brachyury		I	11	Multi-targeted recombinant Ad5 (CEA/MUC-1/Brachyury) based immunotherapy vaccine regimen in people with advanced cancer	NCT03384316		[45]
Recombinant vaccinia virus expressing prostate-specific antigen	PSA	GM-CSF	I	33	A phase I trial of a recombinant vaccinia virus expressing prostate-specific antigen in advanced prostate cancer			[46]
PROSTVAC-V (vaccinia)	PSA		I	75	A phase I study of recombinant vaccinia virus that expresses prostate specific antigen in adult patients with adenocarcinoma of the prostate	NCT00001382		

V935 (Adenovirus-serotype 6 vector encoding hTERT) and V934-EP (plasmid DNA encoiding hTERT, electroporated)	hTERT		I	37	A study of V934/V935 vaccine in cancer participants with selected solid tumors (V934-002)	NCT00753415		[47]
PF-06753512 (PrCa VBIR) (Adenovirus encoding 3 antigens, boosted with plasmid DNA encoding same antigens, and delivered with anti-CTLA-4 and anti-PD-1 delivered subcutaneously)	PSA PSMA PSCA		I	91	A Phase 1 Study To Evaluate Escalating Doses Of A Vaccine-Based Immunotherapy Regimen For Prostate Cancer (PrCa VBIR)	NCT02616185		[48]
ChAdOx1.5T4 and MVA.5T4 (ChAdOx1 - chimpanzee adenovirus Ox1 and MVA - modified vaccinia Ankara)	5T4	Cyclophosphamide	I	40	Vaccination in prostate cancer (VANCE)	NCT02390063		[49]
MVA-brachyury-TRICOM	Brachyury		I	38	Safety and Tolerability of a Modified Vaccinia Ankara (MVA)-Based Vaccine Modified to Express Brachyury and T-cell Costimulatory Molecules (MVA-Brachyury-TRICOM)	NCT02179515		[50]
JNJ-64041809 (live attenuated double deleted (LADD) Listeria monocytogenes)	PAP, NKX3.1, SSX2, and PSMA		I	26	Safety & immunogenicity of JNJ-64041809, a live attenuated double-deleted Listeria immunotherapy, in participants with metastatic castration-resistant prostate cancer	NCT02625857		[51]
MVA-BN-PRO (modified vaccinia Ankara-Bavarian Nordic)	PSA and PAP		I	24	A safety trial of MVA-BN®-PRO in men with androgen-insensitive prostate cancer (BNIT-PR-001)	NCT00629057		

PF-06755992 (chimpanzee adenovirus serotype 68) and PF-06755990 (pDNA)	PSA, PSMA, PSCA	Tremelimumab (anti-CTLA4 Ab) and PF-06801591 (anti-PD1 Ab)	I	91	A phase 1 study to evaluate escalating doses of a vaccine-based immunotherapy regimen for prostate cancer (PrCa VBIR)	NCT02616185		
GI-6207 (Heat-killed Saccharomyces cerevisiae modified to express CEA)	CEA		I	25	An open label phase I study to evaluate the safety and tolerability of a vaccine (GI-6207) consisting of whole, heat-killed recombinant saccharomyces cerevisiae (Yeast) genetically modified to express CEA protein in adults With metastatic CEA-expressing carcinoma	NCT00924092	Includes multiple cancer types	
MVA-BN-brachyury and FPV (fowlpox)-Brachyury	Brachyury	M7824 (TGF-β and PD-L1 fusion protein) N-803 (IL-15R agonist) and Epacadostat	I/II	113	Phase I/II study of immunotherapy combination BN-Brachyury vaccine, M7824, N-803 and epacadostat (QuEST1)	NCT03493945		[52]
BN-brachyury (MVA-BN-Brachyury + FPV-Brachyury)	Brachyury	N-803 and Bintrafusp alfa	II	28	N-803 alone or in combination with BN-Brachyury vaccine or Bintrafusp Alfa (M7824) for participants With castration resistant prostate cancer	NCT05445882		
Adenovirus PSA vaccine	PSA		II	66	Phase II study of adenovirus/PSA vaccine in men with hormone - refractory prostate cancer (APP22)	NCT00583024		
Adenovirus PSA vaccine	PSA		II	70	Phase II study of adenovirus/PSA vaccine in men with recurrent prostate cancer after local therapy APP21	NCT00583752		
Fowlpox PSA vaccine and/or recombinant vaccinia PSA vaccine	PSA		II	60	PSA vaccine therapy in treating patients with advanced prostate cancer	NCT00003871		
PROSTVAC-VF/TRICOM	PSA	GM-CSF and/or 153Sm-EDTMP radiation	II	44	153Sm-EDTMP with or without a PSA/TRICOM vaccine to treat men with androgen-insensitive prostate cancer	NCT00450619		[53]

PROSTVAC-VF/TRICOM	PSA	Flutamide and/or GM-CSF	II	64	Vaccine therapy with PROSTVAC/TRICOM and flutamide versus flutamide alone to treat prostate cancer	NCT00450463		
Recombinant fowlpox-PSA vaccine, recombinant vaccinia PSA vaccine, and recombinant vaccinia-B7.1 vaccine	PSA	GM-CSF and docetaxel	II	28 (projected)	Vaccine therapy with or without docetaxel in treating patients with metastatic prostate cancer	NCT00045227		
PROSTVAC-VF/TRICOM	PSA	Enzalutamide	II	57	Enzalutamide with or without vaccine therapy for advanced prostate cancer	NCT01867333		
PROSTVAC-VF/TRICOM	PSA	Enzalutamide	II	38	Enzalutamide in combination with PSA-TRICOM in patients with non-metastatic castration sensitive prostate cancer	NCT01875250		[54]
PROSTVAC-VF/TRICOM	PSA	Docetaxel and Prednisone	II	10	Docetaxel and prednisone with or without vaccine therapy in treating patients with metastatic hormone-resistant prostate cancer	NCT01145508		[55]
PROSTVAC-VF/TRICOM	PSA		II	27	Vaccine plus booster shots in men with prostate cancer undergoing treatment with radical prostatectomy	NCT02153918		[56]
PROSTVAC-VF/TRICOM	PSA	Recombinant fowlpox-GM-CSF and/or recombinant human GM-CSF	I/II	32	Sequential vaccinations in prostate cancer patients	NCT00060528		
PROSTVAC-VF/TRICOM	PSA	GM-CSF	II	120	PROSTVAC®-VF/TRICOM™ vaccine for the treatment of metastatic prostate cancer after failing hormone therapy	NCT00078585		[57]
MVA-MUC-1-IL2	MUC-1	IL2	II	50	Vaccine study of MVA-MUC1-IL2 in patients with prostate cancer	NCT00040170		

PROSTVAC-VF/TRICOM	PSA	Docetaxel	II	74	Docetaxel and PROSTVAC for metastatic castration-sensitive prostate cancer	NCT02649855		
PROSTVAC-VF/TRICOM	PSA		II	154	PROSTVAC (PSA-TRICOM) in preventing disease progression in patients with localized prostate cancer undergoing active surveillance	NCT02326805		[58]
PROSTVAC-VF/TRICOM	PSA		II	97	Prostvac in patients with biochemically recurrent prostate cancer	NCT02649439		
PROSTVAC-VF/TRICOM	PSA	GM-CSF and Androgen ablation	II	40	A national multicenter phase 2 study of prostate-specific antigen (PSA) pox virus vaccine with sequential androgen ablation therapy in patients with PSA progression: ECOG 9802			[59]
PROSTVAC-VF/TRICOM and CV301 (recombinant vaccinia viral vector)	PSA, carcinoembryonic antigen (CEA) and mucin-1 (MUC-1)	MSB0011359C (M7824, fusion of IgG1, anti-PD-L1 and TGFbetaRII)	II	34	Combination immunotherapy in biochemically recurrent prostate cancer	NCT03315871		
Recombinant vaccinia-PSA and rV-B7.1 plus recombinant fowlpox-PSA vaccine	PSA	GM-CSF and IL2 or nilutamide	II	78 (Projected)	Vaccine therapy plus sargramostim and interleukin-2 compared with nilutamide alone in treating patients with prostate cancer	NCT00020254		
Recombinant fowlpox-PSA vaccine and recombinant vaccinia PSA vaccine	PSA		II	86	Vaccine therapy in treating patients with advanced adenocarcinoma of the prostate (prostate cancer)	NCT00005039		
PROSTVAC-VF/TRICOM	PSA	Androgen ablation (Bicalutamide and Goserelin Acetate), and GM-CSF	II	50	A phase II study of PROSTVAC-V (Vaccinia)/TRICOM and PROSTVAC-F (Fowlpox)/TRICOM with GM-CSF in patients with PSA progression after local therapy for prostate cancer	NCT00108732		

PROSTVAC-VF/TRICOM	PSA	Nivolumab (anti-PD-1 Ab)	I/II	29	PROSTVAC in combination with nivolumab in men with prostate cancer	NCT02933255		
PROSTVAC-VF/TRICOM	PSA	Ipilimumab (anti-CTLA4 Ab)	II	15	Neoadjuvant PROSTVAC-VF with or without ipilimumab for prostate cancer	NCT02506114		
rV-PSA, rF-PSA, rV-B7.1 (V-vaccinia and F-fowlpox)	PSA and B7.1		II	48	PSA-based vaccine and radiotherapy to treat localized prostate cancer	NCT00005916		
ChAdOx1 and MVA 5T4 (ChAdOx1 - chimpanzee adenovirus Ox1 and MVA - modified vaccinia Ankara)	5T4	Nivolumab	I/II	23	Vaccination in early and advanced prostate cancer	NCT03815942		
TroVax (MVA encoding 5T4)	5T4	Docetaxel	II	25	TroVax® in subjects with hormone refractory prostate cancer (HRPC)	NCT01194960		
TroVax	5T4	Docetaxel	II	11	Study of Trovax® plus docetaxel versus docetaxel alone in patients with progressive hormone refractory prostate cancer	NCT00521274		
PROSTVAC-VF/TRICOM	PSA	GM-CSF	III	1297	Phase III trial of PROSTVAC in asymptomatic or minimally symptomatic metastatic castration-resistant prostate cancer	NCT01322490	Although safe and well tolerated, PROSTVAC did not improve overall survival	[60]
DNA vaccines								
pTVG-AR	AR	GMCSF	I	40	A phase I study of a DNA vaccine encoding Androgen Receptor Ligand-Binding Domain (AR LBD) +/-GMCSF	NCT02411786		[61]

pTVG-HP	PAP	Recombinant human GM-CSF	I	22	Prostatic Acid Phosphatase (PAP) vaccine in patients with prostate cancer	NCT00582140		[62]
pTVG-HP	PAP	rhGM-CSF	II	17	Two-arm study of a DNA vaccine encoding prostatic acid phosphatase (PAP) in patients with non-metastatic castrate-resistant prostate cancer	NCT00849121		[63]
pVAX/PSA	PSA	GM-CSF and IL-2	I	9	A phase I trial of DNA vaccination with a plasmid expressing prostate-specific antigen in patients with hormone-refractory prostate cancer			[64]
pPJV7611 (NY-ESO-1 Plasmid DNA)	NY-ESO-1		I	18	NY-ESO-1 Plasmid DNA (pPJV7611) Cancer Vaccine	NCT00199849		
Neoantigen DNA vaccine		Nivolumab, Ipilimumab, and PROSTVAC	I	19	Neoantigen DNA Vaccine in Combination With Nivolumab/Ipilimumab and PROSTVAC in Metastatic Hormone-Sensitive Prostate Cancer	NCT03532217		
ZYC300 (plasmid DNA encoding CYP1B1, encapsulate in poly-DL-lactide microparicles)	CYP1B1	Cyclophosphamide	I	22	A study of ZYC300 administered with cyclophosphamide pre-dosing	NCT00381173		
pVAXrcPSAv53l (DNA encoding rhesus PSA)	PSA		I/II	15	dose finding study of a DNA vaccine delivered with intradermal electroporation in patients with prostate cancer	NCT00859729		[65]
pTVG-AR	AR	Nivolumab and/or androgen deprivation (Degarelix)	I/II	39	Androgen deprivation, with or without pTVG-AR, and with or without nivolumab, in patients with newly diagnosed, high-risk prostate cancer	NCT04989946		
pTVG-HP	PAP	Pembrolizumab	I/II	66	Vaccine therapy and pembrolizumab in treating patients with hormone-resistant, metastatic prostate cancer	NCT02499835		[66, 67]
DOM PSMA (Plasmid encoding immunogenic helper domain of PSMA)	PSMA		I/II	32	DNA fusion-gene vaccination in patients with prostate cancer induces high-frequency CD8+ T-cell responses and increases PSA doubling time			[68]

MKC1106-PP (recombinant plasmid pPRA-PSM)	Preferentially expressed antigen in melanoma (PRAME) and PSMA		I/II	24	A phase 1 study of a vaccine targeting preferentially expressed antigen in melanoma and prostate-specific membrane antigen in patients with advanced solid tumors	NCT00423254		[69]
pTVG-HP	PAP	Recombinant human GM-CSF	II	99	Phase II PAP plus GM-CSF versus GM-CSF alone for non-metastatic prostate cancer	NCT01341652		[70]
pTVG-HP and/or pTVG-AR	PAP and AR	Pembrolizumab	II	60	pTVG-HP DNA vaccine with or without pTVG-AR DNA vaccine and pembrolizumab in patients with castration-resistant, metastatic prostate cancer	NCT04090528		
pTVG-HP	PAP	Nivolumab (anti-PD-1 Ab) and GM-CSF	II	19	pTVG-HP and nivolumab in patients with non-metastatic PSA-recurrent prostate cancer	NCT03600350		
RNA vaccines								
hTERT mRNA DC			I/II	0	Human telomerase reverse transcriptase messenger RNA (hTERT mRNA) transfected dendritic cell vaccines	NCT01153113	Withdrawn/ Terminated	
CV9103	PSA, PSMA, PSCA and STEAP		I/II	6	RNActive®-derived therapeutic vaccine	NCT00906243		[71]
CV9103	PSA, PSMA, PSCA and STEAP		I/II	48	Safety and efficacy trial of a RNActive®-derived prostate cancer vaccine in hormone refractory disease	NCT00831467		[72]
CV9104	PSA, PSMA, PAP, and MUC-1		I/II	197	Trial of RNActive®-derived prostate cancer vaccine in metastatic castrate-refractory prostate cancer	NCT01817738		

W_pro1 (serum-stable RNA lipoplexes)	Five antigens	Cemiplimab	I/II	130	PRO-MERIT (Prostate cancer messenger RNA immunotherapy)	NCT04382898		
CV9104	PSA, PSMA, PAP, and MUC-1		II	35	An open label randomised trial of RNActive® cancer vaccine in high risk and intermediate risk patients with prostate cancer	NCT02140138		

References:

1. Berger, M., Kreutz, F. T., Horst, J. L., Baldi, A. C. and Koff, W. J. (2007). "Phase I study with an autologous tumor cell vaccine for locally advanced or metastatic prostate cancer." *J Pharm Pharm Sci* **10**: 144-52.
2. Simons, J. W., Mikhak, B., Chang, J. F., DeMarzo, A. M., Carducci, M. A., Lim, M., Weber, C. E., Baccala, A. A., Goemann, M. A., Clift, S. M., Ando, D. G., Levitsky, H. I., Cohen, L. K., Sanda, M. G., Mulligan, R. C., Partin, A. W., Carter, H. B., Piantadosi, S., Marshall, F. F. and Nelson, W. G. (1999). "Induction of immunity to prostate cancer antigens: results of a clinical trial of vaccination with irradiated autologous prostate tumor cells engineered to secrete granulocyte-macrophage colony-stimulating factor using ex vivo gene transfer." *Cancer Res.* **59**: 5160-8.
3. Higano, C. S., Corman, J. M., Smith, D. C., Centeno, A. S., Steidle, C. P., Gittleman, M., Simons, J. W., Sacks, N., Aimi, J. and Small, E. J. (2008). "Phase 1/2 dose-escalation study of a GM-CSF-secreting, allogeneic, cellular immunotherapy for metastatic hormone-refractory prostate cancer." *Cancer* **113**: 975-84.
4. Small, E. J., Sacks, N., Nemunaitis, J., Urba, W. J., Dula, E., Centeno, A. S., Nelson, W. G., Ando, D., Howard, C., Borellini, F., Nguyen, M., Hege, K. and Simons, J. W. (2007). "Granulocyte macrophage colony-stimulating factor--secreting allogeneic cellular immunotherapy for hormone-refractory prostate cancer." *Clin Cancer Res* **13**: 3883-91.
5. van den Eertwegh, A. J., Versluis, J., van den Berg, H. P., Santegoets, S. J., van Moorselaar, R. J., van der Sluis, T. M., Gall, H. E., Harding, T. C., Jooss, K., Lowy, I., Pinedo, H. M., Scheper, R. J., Stam, A. G., von Blomberg, B. M., de Gruijl, T. D., Hege, K., Sacks, N. and Gerritsen, W. R. (2012). "Combined immunotherapy with granulocyte-macrophage colony-stimulating factor-transduced allogeneic prostate cancer cells and ipilimumab in patients with metastatic castration-resistant prostate cancer: a phase 1 dose-escalation trial." *Lancet Oncol* **13**: 509-17.
6. Obradovic, A. Z., Dallos, M., Zahurak, M. L., Partin, A. W., Schaeffer, E. M., Ross, A. E., Allaf, M. E., Nirschl, T. R., Chapman, C. G., O'Neal, T., Cao, H., Durham, J. N., Guner, G., Baena-Del Valle, J. A., Ertunc, O., De Marzo, A. M., Antonarakis, E. S. and Drake, C. G. (2020). "T-Cell Infiltration and Adaptive Treg Resistance in Response to Androgen Deprivation With or Without Vaccination in Localized Prostate Cancer." *Clin Cancer Res*.
7. Michael, A., Ball, G., Quatan, N., Wushishi, F., Russell, N., Whelan, J., Chakraborty, P., Leader, D., Whelan, M. and Pandha, H. (2005). "Delayed Disease Progression after Allogeneic Cell Vaccination in Hormone-Resistant Prostate Cancer and Correlation with Immunologic Variables." *Clin Cancer Res* **11**: 4469-78.
8. Frank, M. O., Kaufman, J., Tian, S., Suarez-Farinas, M., Parveen, S., Blachere, N. E., Morris, M. J., Slovin, S., Scher, H. I., Albert, M. L. and Darnell, R. B. (2010). "Harnessing naturally occurring tumor immunity: a clinical vaccine trial in prostate cancer." *PLoS One* **5**.
9. Podrazil, M., Horvath, R., Becht, E., Rozkova, D., Bilkova, P., Sochorova, K., Hromadkova, H., Kayserova, J., Vavrova, K., Lastovicka, J., Vrabcova, P., Kubackova, K., Gasova, Z., Jarolim, L., Babjuk, M., Spisek, R., Bartunkova, J. and Fucikova, J. (2015). "Phase I/II clinical trial of dendritic-cell based immunotherapy (DCVAC/PCa) combined with chemotherapy in patients with metastatic, castration-resistant prostate cancer." *Oncotarget* **6**: 18192-205.
10. Frank, M. O., Kaufman, J., Parveen, S., Blachère, N. E., Orange, D. E. and Darnell, R. B. (2014). "Dendritic cell vaccines containing lymphocytes produce improved immunogenicity in patients with cancer." *J Transl Med* **12**: 338.
11. Vogelzang, N. J., Beer, T. M., Gerritsen, W., Oudard, S., Wiechno, P., Kukielka-Budny, B., Samal, V., Hajek, J., Feyerabend, S., Khoo, V., Stenzl, A., Csöszi, T., Filipovic, Z., Goncalves, F., Prokhorov, A., Cheung, E., Hussain, A., Sousa, N., Bahl, A., Hussain, S., Fricke, H., Kadlecova, P., Scheiner, T., Korolkiewicz, R. P., Bartunkova, J. and Spisek, R. (2022). "Efficacy and Safety of Autologous Dendritic Cell-Based Immunotherapy, Docetaxel, and Prednisone vs Placebo in Patients With Metastatic Castration-Resistant Prostate Cancer: The VIABLE Phase 3 Randomized Clinical Trial." *JAMA Oncol* **8**: 546-52.
12. Slovin, S. F., Ragupathi, G., Adluri, S., Ungers, G., Terry, K., Kim, S., Spassova, M., Bornmann, W. G., Fazzari, M., Dantis, L., Olkiewicz, K., Lloyd, K. O., Livingston, P. O., Danishefsky, S. J. and Scher, H. I. (1999). "Carbohydrate vaccines in cancer: immunogenicity of a fully synthetic globo H hexasaccharide conjugate in man." *Proc. Natl. Acad. Sci. U. S. A.* **96**: 5710-5.

13. Slovin, S. F., Ragupathi, G., Musselli, C., Fernandez, C., Diani, M., Verbel, D., Danishefsky, S., Livingston, P. and Scher, H. I. (2005). "Thomsen-Friedenreich (TF) antigen as a target for prostate cancer vaccine: clinical trial results with TF cluster (c)-KLH plus QS21 conjugate vaccine in patients with biochemically relapsed prostate cancer." *Cancer Immunol Immunother* **54**: 694-702.
14. Slovin, S. F., Ragupathi, G., Fernandez, C., Diani, M., Jefferson, M. P., Wilton, A., Kelly, W. K., Morris, M., Solit, D., Clausen, H., Livingston, P. and Scher, H. I. (2007). "A polyvalent vaccine for high-risk prostate patients: "are more antigens better?"." *Cancer Immunol Immunother* **56**: 1921-30.
15. Meidenbauer, N., Harris, D. T., Spitler, L. E. and Whiteside, T. L. (2000). "Generation of PSA-reactive effector cells after vaccination with a PSA-based vaccine in patients with prostate cancer." *Prostate* **43**: 88-100.
16. Perambakam, S., Hallmeyer, S., Reddy, S., Mahmud, N., Bressler, L., DeChristopher, P., Mahmud, D., Nunez, R., Sosman, J. A. and Peace, D. J. (2006). "Induction of specific T cell immunity in patients with prostate cancer by vaccination with PSA146-154 peptide." *Cancer Immunol Immunother* **55**: 1033-42.
17. McNeel, D. G., Knutson, K. L., Schiffman, K., Davis, D. R., Caron, D. and Disis, M. L. (2003). "Pilot study of an HLA-A2 peptide vaccine using flt3 ligand as a systemic vaccine adjuvant." *J Clin Immunol* **23**: 62-72.
18. Berinstein, N. L., Karkada, M., Morse, M. A., Nemunaitis, J. J., Chatta, G., Kaufman, H., Odunsi, K., Nigam, R., Sammatur, L., MacDonald, L. D., Weir, G. M., Stanford, M. M. and Mansour, M. (2012). "First-in-man application of a novel therapeutic cancer vaccine formulation with the capacity to induce multi-functional T cell responses in ovarian, breast and prostate cancer patients." *J Transl Med* **10**: 156.
19. Wood, L. V., Fojo, A., Roberson, B. D., Hughes, M. S., Dahut, W., Gulley, J. L., Madan, R. A., Arlen, P. M., Sabatino, M., Stroncek, D. F., Castiello, L., Trepel, J. B., Lee, M. J., Parnes, H. L., Steinberg, S. M., Terabe, M., Wilkerson, J., Pastan, I. and Berzofsky, J. A. (2016). "TARP vaccination is associated with slowing in PSA velocity and decreasing tumor growth rates in patients with Stage D0 prostate cancer." *Oncoimmunology* **5**: e1197459.
20. Feyerabend, S., Stevanovic, S., Gouttefangeas, C., Wernet, D., Hennenlotter, J., Bedke, J., Dietz, K., Pascolo, S., Kuczyk, M., Rammensee, H. G. and Stenzl, A. (2009). "Novel multi-peptide vaccination in Hla-A2+ hormone sensitive patients with biochemical relapse of prostate cancer." *Prostate* **69**: 917-27.
21. Obara, W., Sato, F., Takeda, K., Kato, R., Kato, Y., Kanehira, M., Takata, R., Mimata, H., Sugai, T., Nakamura, Y. and Fujioka, T. (2017). "Phase I clinical trial of cell division associated 1 (CDCA1) peptide vaccination for castration resistant prostate cancer." *Cancer Sci* **108**: 1452-7.
22. Schuhmacher, J., Heidu, S., Balchen, T., Richardson, J. R., Schmeltz, C., Sonne, J., Schweiker, J., Rammensee, H. G., Thor Straten, P., Røder, M. A., Brasso, K. and Gouttefangeas, C. (2020). "Vaccination against RhoC induces long-lasting immune responses in patients with prostate cancer: results from a phase I/II clinical trial." *J ImmunoTher Cancer* **8**.
23. Kouiavskaia, D. V., Berard, C. A., Datena, E., Hussain, A., Dawson, N., Klyushnenkova, E. N. and Alexander, R. B. (2009). "Vaccination with agonist peptide PSA: 154-163 (155L) derived from prostate specific antigen induced CD8 T-cell response to the native peptide PSA: 154-163 but failed to induce the reactivity against tumor targets expressing PSA: a phase 2 study in patients with recurrent prostate cancer." *J Immunother* **32**: 655-66.
24. Noguchi, M., Kakuma, T., Uemura, H., Nasu, Y., Kumon, H., Hirao, Y., Moriya, F., Suekane, S., Matsuoka, K., Komatsu, N., Shichijo, S., Yamada, A. and Itoh, K. (2010). "A randomized phase II trial of personalized peptide vaccine plus low dose estramustine phosphate (EMP) versus standard dose EMP in patients with castration resistant prostate cancer." *Cancer Immunol Immunother* **59**: 1001-9.
25. Filaci, G., Fenoglio, D., Nolè, F., Zanardi, E., Tomasello, L., Aglietta, M., Del Conte, G., Carles, J., Morales-Barrera, R., Guglielmini, P., Scagliotti, G., Signori, A., Parodi, A., Kalli, F., Astone, G., Ferrera, F., Altosole, T., Lamperti, G., Criscuolo, D., Gianese, F. and Boccardo, F. (2021). "Telomerase-based GX301 cancer vaccine in patients with metastatic castration-resistant prostate cancer: a randomized phase II trial." *Cancer Immunol Immunother* **70**: 3679-92.
26. Noguchi, M., Fujimoto, K., Arai, G., Uemura, H., Hashine, K., Matsumoto, H., Fukasawa, S., Kohjimoto, Y., Nakatsu, H., Takenaka, A., Fujisawa, M., Uemura, H., Naito, S., Egawa, S., Fujimoto, H., Hinotsu, S. and Itoh, K. (2021). "A randomized phase III trial of personalized peptide vaccination for castrationresistant prostate cancer progressing after docetaxel." *Oncol Rep* **45**: 159-68.
27. Fong, L., Brockstedt, D., Benike, C., Breen, J. K., Strang, G., Ruegg, C. L. and Engleman, E. G. (2001). "Dendritic Cell-Based Xenoantigen Vaccination for Prostate Cancer Immunotherapy." *J Immunol* **167**: 7150-6.

28. Sonpavde, G., McMannis, J. D., Bai, Y., Seethammagari, M. R., Bull, J. M. C., Hawkins, V., Dancsak, T. K., Lapteva, N., Levitt, J. M., Moseley, A., Spencer, D. M. and Slawin, K. M. (2017). "Phase I trial of antigen-targeted autologous dendritic cell-based vaccine with in vivo activation of inducible CD40 for advanced prostate cancer." *Cancer Immunol Immunother* **66**: 1345-57.
29. Scholz, M., Yep, S., Chancey, M., Kelly, C., Chau, K., Turner, J., Lam, R. and Drake, C. G. (2017). "Phase I clinical trial of sipuleucel-T combined with escalating doses of ipilimumab in progressive metastatic castrate-resistant prostate cancer." *Immunotargets Ther* **6**: 11-6.
30. Zanetti, M. (2003). "Protocol #0207-545: a phase I/II, escalating dose, open-label evaluation of safety, feasibility, and tolerability of transgenic lymphocyte immunization (TLI) vaccine subjects with histologically proven prostate adenocarcinoma." *Hum Gene Ther* **14**: 301-2.
31. Murphy, G. P., Tjoa, B. A., Simmons, S. J., Ragde, H., Rogers, M., Elgamal, A., Kenny, G. M., Troychak, M. J., Salgaller, M. L. and Boynton, A. L. (1999). "Phase II prostate cancer vaccine trial: report of a study involving 37 patients with disease recurrence following primary treatment." *Prostate* **39**: 54-9.
32. Westdorp, H., Creemers, J. H. A., van Oort, I. M., Schreibelt, G., Gorris, M. A. J., Mehra, N., Simons, M., de Goede, A. L., van Rossum, M. M., Croockewit, A. J., Figdor, C. G., Witjes, J. A., Aarntzen, E., Mus, R. D. M., Brüning, M., Petry, K., Gotthardt, M., Barentsz, J. O., de Vries, I. J. M. and Gerritsen, W. R. (2019). "Blood-derived dendritic cell vaccinations induce immune responses that correlate with clinical outcome in patients with chemo-naive castration-resistant prostate cancer." *J ImmunoTher Cancer* **7**: 302.
33. Small, E. J., Lance, R. S., Gardner, T. A., Karsh, L. I., Fong, L., McCoy, C., DeVries, T., Sheikh, N. A., GuhaThakurta, D., Chang, N., Redfern, C. H. and Shore, N. D. (2015). "A Randomized Phase II Trial of Sipuleucel-T with Concurrent versus Sequential Abiraterone Acetate plus Prednisone in Metastatic Castration-Resistant Prostate Cancer." *Clin Cancer Res* **21**: 3862-9.
34. Antonarakis, E. S., Kibel, A. S., Yu, E. Y., Karsh, L. I., Elfiky, A., Shore, N. D., Vogelzang, N. J., Corman, J. M., Millard, F. E., Maher, J. C., Chang, N. N., DeVries, T., Sheikh, N. A. and Drake, C. G. (2017). "Sequencing of Sipuleucel-T and Androgen Deprivation Therapy in Men with Hormone-Sensitive Biochemically Recurrent Prostate Cancer: A Phase II Randomized Trial." *Clin Cancer Res* **23**: 2451-9.
35. Burch, P. A., Croghan, G. A., Gastineau, D. A., Jones, L. A., Kaur, J. S., Kylstra, J. W., Richardson, R. L., Valone, F. H. and Vuk-Pavlovic, S. (2004). "Immunotherapy (APC8015, Provenge) targeting prostatic acid phosphatase can induce durable remission of metastatic androgen-independent prostate cancer: a Phase 2 trial." *Prostate* **60**: 197-204.
36. Twardowski, P., Wong, J. Y. C., Pal, S. K., Maughan, B. L., Frankel, P. H., Franklin, K., Junqueira, M., Prajapati, M. R., Nachaegari, G., Harwood, D. and Agarwal, N. (2019). "Randomized phase II trial of sipuleucel-T immunotherapy preceded by sensitizing radiation therapy and sipuleucel-T alone in patients with metastatic castrate resistant prostate cancer." *Cancer Treat Res Commun* **19**: 100116.
37. Marshall, C. H., Fu, W., Wang, H., Park, J. C., DeWeese, T. L., Tran, P. T., Song, D. Y., King, S., Afful, M., Hurrelbrink, J., Manogue, C., Cotogno, P., Moldawer, N. P., Barata, P. C., Drake, C. G., Posadas, E. M., Armstrong, A. J., Sartor, O. and Antonarakis, E. S. (2021). "Randomized Phase II Trial of Sipuleucel-T with or without Radium-223 in Men with Bone-metastatic Castration-resistant Prostate Cancer." *Clin Cancer Res* **27**: 1623-30.
38. Pachynski, R. K., Morishima, C., Szmulewitz, R., Harshman, L., Appleman, L., Monk, P., Bitting, R. L., Kucuk, O., Millard, F., Seigne, J. D., Fling, S. P., Maecker, H. T., Duault, C., Ramchurren, N., Hess, B., D'Amico, L., Lacroix, A., Kaiser, J. C., Morre, M., Gregoire, A., Cheever, M., Yu, E. Y. and Fong, L. (2021). "IL-7 expands lymphocyte populations and enhances immune responses to sipuleucel-T in patients with metastatic castration-resistant prostate cancer (mCRPC)." *J ImmunoTher Cancer* **9**.
39. Wargowski, E., Johnson, L. E., Eickhoff, J. C., Delmastro, L., Staab, M. J., Liu, G. and McNeel, D. G. (2018). "Prime-boost vaccination targeting prostatic acid phosphatase (PAP) in patients with metastatic castration-resistant prostate cancer (mCRPC) using Sipuleucel-T and a DNA vaccine." *J ImmunoTher Cancer* **6**: 21.
40. Jha, G. G., Gupta, S., Tagawa, S. T., Koopmeiners, J. S., Vivek, S., Dukdek, A. Z., Cooley, S. A., Blazar, B. R. and Miller, J. S. (2017). A phase II randomized, double-blind study of sipuleucel-T followed by IDO pathway inhibitor, indoximod, or placebo in the treatment of patients with metastatic castration resistant prostate cancer (mCRPC). 2017 ASCO Annual Meeting**:** Abstract #3066.

41. Dorff, T., Hirasawa, Y., Acoba, J., Pagano, I., Tamura, D., Pal, S., Zhang, M., Waitz, R., Dhal, A., Haynes, W., Shon, J., Scholz, M., Furuya, H., Chan, O. T. M., Huang, J. and Rosser, C. (2021). "Phase Ib study of patients with metastatic castrate-resistant prostate cancer treated with different sequencing regimens of atezolizumab and sipuleucel-T." *J ImmunoTher Cancer* **9**.
42. Kantoff, P. W., Higano, C. S., Shore, N. D., Berger, E. R., Small, E. J., Penson, D. F., Redfern, C. H., Ferrari, A. C., Dreicer, R., Sims, R. B., Xu, Y., Frohlich, M. W. and Schellhammer, P. F. (2010). "Sipuleucel-T immunotherapy for castration-resistant prostate cancer." *N Engl J Med* **363**: 411-22.
43. Bilusic, M., McMahon, S., Madan, R. A., Karzai, F., Tsai, Y. T., Donahue, R. N., Palena, C., Jochems, C., Marté, J. L., Floudas, C., Strauss, J., Redman, J., Abdul Sater, H., Rabizadeh, S., Soon-Shiong, P., Schlom, J. and Gulley, J. L. (2021). "Phase I study of a multitargeted recombinant Ad5 PSA/MUC-1/brachyury-based immunotherapy vaccine in patients with metastatic castration-resistant prostate cancer (mCRPC)." *J ImmunoTher Cancer* **9**.
44. Theoret, M. R., Arlen, P. M., Pazdur, M., Dahut, W. L., Schlom, J. and Gulley, J. L. (2007). "Phase I trial of an enhanced prostate-specific antigen-based vaccine and anti-CTLA-4 antibody in patients with metastatic androgen-independent prostate cancer." *Clin Genitourin Cancer* **5**: 347-50.
45. Gatti-Mays, M. E., Redman, J. M., Donahue, R. N., Palena, C., Madan, R. A., Karzai, F., Bilusic, M., Sater, H. A., Marté, J. L., Cordes, L. M., McMahon, S., Steinberg, S. M., Orpia, A., Burmeister, A., Schlom, J., Gulley, J. L. and Strauss, J. (2020). "A Phase I Trial Using a Multitargeted Recombinant Adenovirus 5 (CEA/MUC1/Brachyury)-Based Immunotherapy Vaccine Regimen in Patients with Advanced Cancer." *Oncologist* **25**: 479-e899.
46. Eder, J. P., Kantoff, P. W., Roper, K., Xu, G. X., Bubley, G. J., Boyden, J., Gritz, L., Mazzara, G., Oh, W. K., Arlen, P., Tsang, K. Y., Panicali, D., Schlom, J. and Kufe, D. W. (2000). "A phase I trial of a recombinant vaccinia virus expressing prostate-specific antigen in advanced prostate cancer." *Clin Cancer Res* **6**: 1632-8.
47. Aurisicchio, L., Fridman, A., Mauro, D., Sheloditna, R., Chiappori, A., Bagchi, A. and Ciliberto, G. (2020). "Safety, tolerability and immunogenicity of V934/V935 hTERT vaccination in cancer patients with selected solid tumors: a phase I study." *J Transl Med* **18**: 39.
48. Autio, K. A., Higano, C. S., Nordquist, L. T., Appleman, L. J., Zhang, T., Zhu, X., Babiker, H. M., Vogelzang, N. J., Prasad, S., Schweizer, M. T., Billotte, S., Binder, J., Cavazos, N., Li, R., Chan, K., Cho, H., Dermyer, M., Hollingsworth, R., Kern, K. A. and Petrylak, D. P. (2021). "First-in-human, phase I study of PF-06753512, a vaccine-based immunotherapy regimen (PrCa VBIR), in biochemical relapse (BCR) and metastatic castration-resistant prostate cancer (mCRPC)." *Journal of Clinical Oncology* **39**: 2612-.
49. Cappuccini, F., Bryant, R., Pollock, E., Carter, L., Verrill, C., Hollidge, J., Poulton, I., Baker, M., Mitton, C., Baines, A., Meier, A., Schmidt, G., Harrop, R., Protheroe, A., MacPherson, R., Kennish, S., Morgan, S., Vigano, S., Romero, P. J., Evans, T., Catto, J., Hamdy, F., Hill, A. V. S. and Redchenko, I. (2020). "Safety and immunogenicity of novel 5T4 viral vectored vaccination regimens in early stage prostate cancer: a phase I clinical trial." *J ImmunoTher Cancer* **8**.
50. Heery, C. R., Palena, C., McMahon, S., Donahue, R. N., Lepone, L. M., Grenga, I., Dirmeier, U., Cordes, L., Marté, J., Dahut, W., Singh, H., Madan, R. A., Fernando, R. I., Hamilton, D. H., Schlom, J. and Gulley, J. L. (2017). "Phase I Study of a Poxviral TRICOM-Based Vaccine Directed Against the Transcription Factor Brachyury." *Clin Cancer Res* **23**: 6833-45.
51. Drake, C. G., Pachynski, R. K., Subudhi, S. K., McNeel, D. G., Antonarakis, E. S., Bauer, T. M., Lauer, P., Brockstedt, D., Patricia, D., Wade, M., Zudaire, E., Bandyopadhyay, N., Parasrampuria, D. A., Girgis, S., Mason, G. E., Knoblauch, R. E., Stone, N., Infante, J. R., Gottardis, M. M. and Fong, L. (2022). "Safety and preliminary immunogenicity of JNJ-64041809, a live-attenuated, double-deleted Listeria monocytogenes-based immunotherapy, in metastatic castration-resistant prostate cancer." *Prostate Cancer Prostatic Dis* **25**: 219-28.
52. Redman, J. M., Steinberg, S. M. and Gulley, J. L. (2018). "Quick efficacy seeking trial (QuEST1): a novel combination immunotherapy study designed for rapid clinical signal assessment metastatic castration-resistant prostate cancer." *J ImmunoTher Cancer* **6**: 91.
53. Heery, C. R., Madan, R. A., Stein, M. N., Stadler, W. M., Di Paola, R. S., Rauckhorst, M., Steinberg, S. M., Marté, J. L., Chen, C. C., Grenga, I., Donahue, R. N., Jochems, C., Dahut, W. L., Schlom, J. and Gulley, J. L. (2016). "Samarium-153-EDTMP (Quadramet®) with or without vaccine in metastatic castration-resistant prostate cancer: A randomized Phase 2 trial." *Oncotarget* **7**: 69014-23.
54. Madan, R. A., Karzai, F., Donahue, R. N., Al-Harthy, M., Bilusic, M., Rosner, II, Singh, H., Arlen, P. M., Theoret, M. R., Marté, J. L., Cordes, L., Couvillon, A., Hankin, A., Williams, M., Owens, H., Lochrin, S. E., Chau, C. H., Steinberg, S., Figg, W. D., Dahut, W., Schlom, J. and Gulley, J. L. (2021). "Clinical and

immunologic impact of short-course enzalutamide alone and with immunotherapy in non-metastatic castration sensitive prostate cancer." *J ImmunoTher Cancer* **9**.

55. McNeel, D. G., Chen, Y. H., Gulley, J. L., Dwyer, A. J., Madan, R. A., Carducci, M. A. and DiPaola, R. S. (2015). "Randomized phase II trial of docetaxel with or without PSA-TRICOM vaccine in patients with castrate-resistant metastatic prostate cancer: A trial of the ECOG-ACRIN cancer research group (E1809)." *Hum Vaccin Immunother* **11**: 2469-74.
56. Abdul Sater, H., Marte, J. L., Donahue, R. N., Walter-Rodriguez, B., Heery, C. R., Steinberg, S. M., Cordes, L. M., Chun, G., Karzai, F., Bilusic, M., Harmon, S. A., Turkbey, I. B., Choyke, P. L., Schlom, J., Dahut, W. L., Madan, R. A., Pinto, P. A. and Gulley, J. L. (2020). "Neoadjuvant PROSTVAC prior to radical prostatectomy enhances T-cell infiltration into the tumor immune microenvironment in men with prostate cancer." *J ImmunoTher Cancer* **8**.
57. Kantoff, P. W., Schuetz, T. J., Blumenstein, B. A., Glode, L. M., Bilhartz, D. L., Wyand, M., Manson, K., Panicali, D. L., Laus, R., Schlom, J., Dahut, W. L., Arlen, P. M., Gulley, J. L. and Godfrey, W. R. (2010). "Overall survival analysis of a phase II randomized controlled trial of a Poxviral-based PSA-targeted immunotherapy in metastatic castration-resistant prostate cancer." *J Clin Oncol* **28**: 1099-105.
58. Parsons, J. K., Pinto, P. A., Pavlovich, C. P., Uchio, E., Kim, H. L., Nguyen, M. N., Gulley, J. L., Jamieson, C., Hsu, P., Wojtowicz, M., Parnes, H., Schlom, J., Dahut, W. L., Madan, R. A., Donahue, R. N. and Chow, H. S. (2018). "A Randomized, Double-blind, Phase II Trial of PSA-TRICOM (PROSTVAC) in Patients with Localized Prostate Cancer: The Immunotherapy to Prevent Progression on Active Surveillance Study." *Eur Urol Focus* **4**: 636-8.
59. DiPaola, R. S., Chen, Y. H., Bubley, G. J., Stein, M. N., Hahn, N. M., Carducci, M. A., Lattime, E. C., Gulley, J. L., Arlen, P. M., Butterfield, L. H. and Wilding, G. (2015). "A national multicenter phase 2 study of prostate-specific antigen (PSA) pox virus vaccine with sequential androgen ablation therapy in patients with PSA progression: ECOG 9802." *Eur Urol* **68**: 365-71.
60. Gulley, J. L., Borre, M., Vogelzang, N. J., Ng, S., Agarwal, N., Parker, C. C., Pook, D. W., Rathenborg, P., Flaig, T. W., Carles, J., Saad, F., Shore, N. D., Chen, L., Heery, C. R., Gerritsen, W. R., Priou, F., Langkilde, N. C., Novikov, A. and Kantoff, P. W. (2019). "Phase III Trial of PROSTVAC in Asymptomatic or Minimally Symptomatic Metastatic Castration-Resistant Prostate Cancer." *J Clin Oncol* **37**: 1051-61.
61. Kyriakopoulos, C. E., Eickhoff, J. C., Ferrari, A. C., Schweizer, M. T., Wargowski, E., Olson, B. M. and McNeel, D. G. (2020). "Multicenter Phase I Trial of a DNA Vaccine Encoding the Androgen Receptor Ligand-binding Domain (pTVG-AR, MVI-118) in Patients with Metastatic Prostate Cancer." *Clin Cancer Res* **26**: 5162-71.
62. McNeel, D. G., Dunphy, E. J., Davies, J. G., Frye, T. P., Johnson, L. E., Staab, M. J., Horvath, D. L., Straus, J., Alberti, D., Marnocha, R., Liu, G., Eickhoff, J. C. and Wilding, G. (2009). "Safety and immunological efficacy of a DNA vaccine encoding prostatic acid phosphatase in patients with stage D0 prostate cancer." *J Clin Oncol* **27**: 4047-54.
63. McNeel, D. G., Becker, J. T., Eickhoff, J. C., Johnson, L. E., Bradley, E., Pohlkamp, I., Staab, M. J., Liu, G., Wilding, G. and Olson, B. M. (2014). "Real-time immune monitoring to guide plasmid DNA vaccination schedule targeting prostatic acid phosphatase in patients with castration-resistant prostate cancer." *Clin Cancer Res* **20**: 3692-704.
64. Pavlenko, M., Roos, A. K., Lundqvist, A., Palmborg, A., Miller, A. M., Ozenci, V., Bergman, B., Egevad, L., Hellstrom, M., Kiessling, R., Masucci, G., Wersall, P., Nilsson, S. and Pisa, P. (2004). "A phase I trial of DNA vaccination with a plasmid expressing prostate-specific antigen in patients with hormone-refractory prostate cancer." *Br J Cancer* **91**: 688-94.
65. Eriksson, F., Totterman, T., Maltais, A. K., Pisa, P. and Yachnin, J. (2013). "DNA vaccine coding for the rhesus prostate specific antigen delivered by intradermal electroporation in patients with relapsed prostate cancer." *Vaccine* **31**: 3843-8.
66. McNeel, D. G., Eickhoff, J. C., Wargowski, E., Zahm, C., Staab, M. J., Straus, J. and Liu, G. (2018). "Concurrent, but not sequential, PD-1 blockade with a DNA vaccine elicits anti-tumor responses in patients with metastatic, castration-resistant prostate cancer." *Oncotarget* **P9**: 25586-96.
67. McNeel, D. G., Eickhoff, J. C., Wargowski, E., Johnson, L. E., Kyriakopoulos, C. E., Emamekhoo, H., Lang, J. M., Brennan, M. J. and Liu, G. (2022). "Phase 2 trial of T-cell activation using MVI-816 and pembrolizumab in patients with metastatic, castration-resistant prostate cancer (mCRPC)." *J ImmunoTher Cancer* **10**.

68. Chudley, L., McCann, K., Mander, A., Tjelle, T., Campos-Perez, J., Godeseth, R., Creak, A., Dobbyn, J., Johnson, B., Bass, P., Heath, C., Kerr, P., Mathiesen, I., Dearnaley, D., Stevenson, F. and Ottensmeier, C. (2012). "DNA fusion-gene vaccination in patients with prostate cancer induces high-frequency CD8(+) T-cell responses and increases PSA doubling time." *Cancer Immunol Immunother* **61**: 2161-70.
69. Weber, J. S., Vogelzang, N. J., Ernstoff, M. S., Goodman, O. B., Cranmer, L. D., Marshall, J. L., Miles, S., Rosario, D., Diamond, D. C., Qiu, Z., Obrocea, M. and Bot, A. (2011). "A phase 1 study of a vaccine targeting preferentially expressed antigen in melanoma and prostate-specific membrane antigen in patients with advanced solid tumors." *J Immunother* **34**: 556-67.
70. McNeel, D. G., Eickhoff, J. C., Johnson, L. E., Roth, A. R., Perk, T. G., Fong, L., Antonarakis, E. S., Wargowski, E., Jeraj, R. and Liu, G. (2019). "Phase II Trial of a DNA Vaccine Encoding Prostatic Acid Phosphatase (pTVG-HP [MVI-816]) in Patients With Progressive, Nonmetastatic, Castration-Sensitive Prostate Cancer." *J Clin Oncol* **37**: 3507-17.
71. Kubler, H., Scheel, B., Gnad-Vogt, U., Miller, K., Schultze-Seemann, W., Vom Dorp, F., Parmiani, G., Hampel, C., Wedel, S., Trojan, L., Jocham, D., Maurer, T., Rippin, G., Fotin-Mleczek, M., von der Mulbe, F., Probst, J., Hoerr, I., Kallen, K. J., Lander, T. and Stenzl, A. (2015). "Self-adjuvanted mRNA vaccination in advanced prostate cancer patients: a first-in-man phase I/IIa study." *J ImmunoTher Cancer* **3**: 26.
72. Fotin-Mleczek, M., Duchardt, K. M., Lorenz, C., Pfeiffer, R., Ojkić-Zrna, S., Probst, J. and Kallen, K. J. (2011). "Messenger RNA-based vaccines with dual activity induce balanced TLR-7 dependent adaptive immune responses and provide antitumor activity." *J Immunother* **34**: 1-15.