

の観点から、適切な実験動物種は存在しないこと等に留意が必要。

・毒性試験については、合成ペプチドの場合には化学合成由来の不純物や意図しない化合物の混在による安全性リスクが懸念されることから、これを確認する上で動物試験も有用性への言及。

(臨床)

・投与方法

皮下、皮内、腫瘍内、リンパ節内など様々な投与方法が試みられている→投与部位/投与方法の説明(非臨床試験から)とその妥当性

・至適用量等

DLT や用量相関性など従来の抗がん剤開発に必要なとされる概念について、評価対象が合成ペプチドであることを踏まえた対応の考え方の整理が必要。合成ペプチドとアジュバントとの配合やリポソーム化では、ペプチド単独とは異なると考えられる(アジュバントの項)。また、臨床試験全般を通じて用量の適切性をどのように評価するべきかの整理が必要。ペプチドやタンパク質のみでは、最高耐用投与量(MTX)に到達することは余り想定されない。アジュバントについて別途考慮をする必要がある。

・投与スケジュール

長期にわたるワクチン投与(追加免疫の実施)も想定される。投与スケジュールの妥当性の説明。追加免疫では、異なるがんワクチンが投与されることもありうる。

・併用薬の記載

後述する免疫活性化薬、免疫抑制解除のための抗体/低分子薬; GM-CSF やインターロイキン2などの免疫活性化剤。抗 CTLA4 抗体、抗 PD-1 抗体、抗腫瘍抗原抗体などの抗体医薬品の併用。シクロホスファミドや他の Treg 抑制抗がん剤。TGF- β 等に対するアンチセンスや siRNA などの核酸医薬。

・遅発性の効果発現・患者選択

ペプチドワクチンは遅発性の効果発現が見られることが想定されることを踏まえ、観察期間に重みを付けた統計手法(Harrington-Fleming法 等)によって評価する必要性に言及する必要がある。

このことから、免疫系を介した遅発性の効果発現を評価できる対象(癌腫、治療ライン等)を選択する必要性に言及が必要。コホートが複雑になる可能性について記載する(ワクチンの有無、アジュバント、Treg 抑制処理などの組み合わせ)。

進行期の被験者を対象とした場合、薬剤の投与開始から病状進行までの期間が比較的短いため、免疫反応による抗腫瘍活性が現れるまでの時間を確保できない可能性がある。また、複数の治療をすでに受けていることが多く、評価が困難な可能性が高い。

一方で早期の被験者を対象とした場合、結論が得られるまでに時間がかかる可能性が高い。

・免疫応答性の評価

抗原特異的免疫応答性(MIATA-P; テトラマーアッセイ、エリスポットアッセイ、フローサイトメトリー) 抗原非特異的免疫応答性(抗体産生)

・免疫抑制状態の評価

免疫抑制状態からの解除が抗腫瘍効果に寄与している可能性(Ipilimumab、抗 PD-1 抗体のデータ)に加え mogamulizumab、低分子医薬品(サイクロヘキシミド)、siRNA(抗 TGF- β)の言及
評価方法、DTH、末梢血 Treg 細胞数(フローサイトメトリーアッセイ)、がん組織へ infusion している Treg 細胞数。(非常の多くの NIH Clinical Trial でサイクロホスファミド等の Treg 抑制作用を持つ薬剤が使用されている)

・HLA

適合する HLA 型を有する被験者を対象とするのが一般的である。

同じ標的抗原であっても、被験者の HLA 型により選択すべきペプチドが異なる。治験を実施する際は、ペプチド1つ1つではなく血清 HLA グループ型毎(例 A19 (A29、A30、A31、A32、A33、A74))で計画するなど工夫が必要。

・その他

PD マーカー(サロゲートマーカー)の検討
アジュバントの検討(低分子化学薬品、TLR を介した核酸、GM-CSF 等も含めるべきか)

免疫活性化薬: GM-CSF、IL-12、IL-2

早期探索試験

腫瘍縮小効果が得られない症例においても生命予後延長が得られる可能性があることから、生命予後の指標を主目的とした臨床試験デザインが重要。

シングルアーム試験とランダム化比較試験

シングルアーム試験: 早期に結果、解析困難。

ランダム化比較試験: 信頼性の高い試験結果が得られる。終末期では受入困難。

患者集団選択についての言及が必要と考えられる。NIH Clinical Trial では患者選定基準の記載(転位性がん、進行性がん)

個々の患者のがん組織における標的抗原の測定法開発

がんペプチドワクチンと同時開発が必要。

αFPやPSAなどの末梢血中のがん関連抗原の測定についての言及。

検証的試験

腫瘍縮小にとらわれない生命予後を主目的とした研究デザインを検討すべき。

主要評価項目として、全生存期間 (OS)、無増悪生存期間 (PFS)、無病生存期間 (DFS) 等。

以上の要件を取り入れて現時点でのがんワクチンの臨床評価のためのガイドライン素案を次のように提示する (資料 2)。

E. 結論

1) がんワクチンはこれまでの抗がん剤や腫瘍抗体医薬品とは異なり生体の免疫防御システムを活性化することにより抗腫瘍効果を発揮しようとする新たなコンセプトに基づく製品である。NIH Clinical Protocol 等の情報より、がんワクチンによって惹起される抗腫瘍免疫反応を評価するために種々の免疫評価指標が用いられていることを明らかにしたが、がんワクチン開発においてはこれらの免疫指標とがん治療における有効性指標との相関を明らかにすることにより効率的ながんワクチン開発に寄与することが期待される。

2) わが国でも多くのがんワクチンの臨床研究が実施されており、また医薬品としての開発を目指した動きも活発である。本研究の成果によりがんワクチンの開発において目指すべき指標について情報提供ができ、より合理的ながんワクチンの開発が可能になると期待される。

F. 健康危険情報

なし

G. 研究発表

1. 論文発表

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- 1) Yamaguchi, T.: Current Situation of Japanese Biologics. CMC Forum Japan, Tokyo (2012)
 - 2) Yamaguchi, T.: Japanese Perspective on Regulation of Biosimilar Products. APEC Biosimilar Symposium. Seoul/Korea (2012)
 - 3) 山口照英: 10年後に再生医療はどのようなになっているのか? 日本再生医療学会. ワークショップ、横浜 (2012)
 - 4) 山口照英: バイオ医薬品のウイルス安全性. 日本ウイルス学会. シンポジウム (2012)

H. 知的財産権の出願・登録状況

1. 特許取得

2. 実用新案登録

3. その他

資料 1 NIH Clinical Protocol に登録されているがんワクチンの臨床プロトコール

1	Completed	NY-ESO-1 Plasmid DNA (pPJV7611) Cancer Vaccine	
		Conditions:	Prostate Cancer; Bladder Cancer; Non-Small Cell Lung Cancer; Esophageal Cancer; Sarcoma
		Intervention:	Biological: NY-ESO-1 plasmid DNA Cancer Vaccine
2	Completed	Trastuzumab, Cyclophosphamide, and an Allogeneic GM-CSF-secreting Breast Tumor Vaccine for the Treatment of HER-2/Neu-Overexpressing Metastatic Breast Cancer	
		Condition:	Breast Neoplasms
		Interventions:	Biological: Allogeneic GM-CSF-secreting breast cancer vaccine; Drug: Trastuzumab; Drug: Cyclophosphamide
3	Terminated	Vaccine Maintenance Treatment for Non-Small Cell Lung Cancer	
		Condition:	Carcinoma, Non-Small-Cell Lung
		Intervention:	Biological: HyperAcute-Lung Cancer Vaccine
4	Completed	A Cancer Vaccine (CG8123) Given With and Without Cyclophosphamide for Advanced Stage Non-Small Cell Lung Cancer (NSCLC)	
		Conditions:	Lung Cancer; Carcinoma, Non-Small-Cell Lung
		Interventions:	Biological: CG8123; Drug: Cyclophosphamide
5	Recruiting	RBL001/RBL002 Phase I Clinical Trial	
		Condition:	Melanoma
		Intervention:	Biological: RBL001/RBL002
6	Completed	Dose Escalation and Efficacy Trial of GVAX® Prostate Cancer Vaccine	
		Condition:	Prostate Cancer
		Intervention:	Biological: Immunotherapy allogeneic GM-CSF secreting cellular vaccine
7	Active, not recruiting	Vaccine Study for Surgically Resected Pancreatic Cancer	
		Condition:	Pancreatic Cancer
		Intervention:	Biological: HyperAcute(R)-Pancreatic Cancer Vaccine
8	Terminated	Low Dose Vaccine Study for Surgically Resected Pancreatic Cancer	
		Condition:	Pancreatic Cancer
		Intervention:	Biological: HyperAcute(R)-Pancreatic Cancer Vaccine
9	Active, not recruiting	Phase 1/2a Study of Cancer Vaccine to Treat Smoldering Multiple Myeloma	
		Condition:	Smoldering Multiple Myeloma
		Intervention:	Drug: PVX-410

10	Recruiting	CRS-207 Cancer Vaccine in Combination With Chemotherapy as Front-line Treatment for Malignant Pleural Mesothelioma	
		Condition:	Malignant Pleural Mesothelioma
		Intervention:	Biological: Vaccine plus chemotherapy
11	Active, not recruiting	Cancer Vaccine Study for Unresectable Stage III Non-small Cell Lung Cancer	
		Condition:	Non-small Cell Lung Cancer
		Interventions:	Biological: Stimuvax (L-BLP25); Biological: Placebo
12	Recruiting	Trial of RNAActive®-Derived Prostate Cancer Vaccine in Metastatic Castrate-refractory Prostate Cancer	
		Condition:	Prostate Cancer
		Interventions:	Biological: CV9104; Biological: Placebo
13	Withdrawn	Experimental Therapeutic Cancer Vaccine Created In-situ in Patients With Stage II-Stage IV Cancer	
		Conditions:	Solid Tumors Stage II, Stage III and Stage IV; Breast Cancer; Colorectal Cancer; Prostate Cancer; Melanoma; Ovarian Cancer; Sarcoma; Non-small Cell Lung Cancer
		Interventions:	Biological: AlloStim; Procedure: Cryoablation
14	Recruiting	Cancer Vaccine Study for Stage III, Unresectable, Non-small Cell Lung Cancer (NSCLC) in the Asian Population	
		Condition:	Non-Small Cell Lung Cancer
		Interventions:	Biological: L-BLP25 or BLP25 liposome vaccine (Stimuvax); Biological: Placebo
15	Completed	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	
		Condition:	Prostate Cancer
		Intervention:	Biological: Immunotherapy allogeneic GM-CSF secreting cellular vaccine
16	Recruiting	Vaccine Therapy With or Without Cyclophosphamide in Treating Patients Undergoing Chemotherapy and Radiation Therapy for Stage I or Stage II Pancreatic Cancer That Can Be Removed by Surgery	
		Condition:	Pancreatic Cancer
		Interventions:	Biological: GVAX pancreatic cancer vaccine; Drug: cyclophosphamide
17	Completed	Phase I/II Study To Test The Safety and Efficacy of TVI-Brain-1 As A Treatment For Recurrent Grade IV Glioma	
		Conditions:	Glioma; High Grade Astrocytoma; Glioblastoma Multiforme
		Intervention:	Biological: Cancer vaccine plus immune adjuvant, plus activated white blood cells
18	Terminated	S0310: Vaccine Therapy in Treating Patients With Stage IIIB or Stage IV Bronchoalveolar Lung Cancer	

		Condition:	Lung Cancer
		Intervention:	Biological: GVAX lung cancer vaccine
19	Active, not recruiting	A Clinical Study to Assess Safety and Efficacy of a Tumor Vaccine in Patients With Advanced Renal Cell Carcinoma (ASET)	
		Condition:	Stage IV Renal Cell Cancer
		Intervention:	Biological: MGN1601
20	Recruiting	To Identify HLA-A1101-restricted Peptide Epitopes Derived From Novel Oncoantigens (URLC10, KIF20A, and CDCA1) Applicable for Cancer Vaccine in Singapore	
		Condition:	Anonymous Donors at Blood Donation Center (NUH)
		Intervention:	
21	Not yet recruiting	Derivation of Tumor Specific Hybridomas	
		Condition:	Glioblastoma
		Intervention:	Biological: Tumor Vaccine
22	Active, not recruiting	Cancer Vaccines CRS-207 and GVAX Pancreas for Metastatic Pancreatic Adenocarcinoma	
		Condition:	Pancreatic Cancer
		Interventions:	Drug: GVAX Pancreas, Cyclophosphamide and CRS-207; Drug: GVAX Pancreas and Cyclophosphamide
23	Active, not recruiting	A Randomized Trial to Study the Safety and Efficacy of EGF Cancer Vaccination in Late-stage (III/IV) Non-small Cell Lung Cancer Patients	
		Condition:	Carcinoma, Non-Small-Cell Lung
		Intervention:	Biological: Therapeutic EGF Vaccine (Cyclophosphamide and the recombinant human rEGF-P64K/Montanide ISA 51 vaccine)
24	Active, not recruiting	Safety and Efficacy Trial of a RnActive®-Derived Prostate Cancer Vaccine in Hormone Refractory Disease	
		Condition:	Hormonal Refractory Prostate Cancer
		Intervention:	Biological: CV9103
25	Recruiting	Pilot Study of a Breast Cancer Vaccine Plus Poly-ICLC for Breast Cancer	
		Condition:	Breast Cancer
		Intervention:	Biological: 9 Peptides from Her-2/neu, CEA, & CTA + poly-ICLC
26	Active, not recruiting	Trastuzumab, Cyclophosphamide, and Vaccine Therapy in Treating Patients With High-Risk or Metastatic Breast Cancer	
		Condition:	Breast Cancer
		Interventions:	Biological: allogeneic GM-CSF-secreting breast cancer vaccine; Biological: trastuzumab; Drug:
27	Terminated	Trial of Melaxin Cancer Vaccine Plus Bacillus Calmette-Guerin (BCG) to Treat Malignant Melanoma	
		Condition:	Melanoma
		Intervention:	Biological: Melaxin (autologous dendritoma vaccine) and BCG
28	Recruiting	Cyclophosphamide and Vaccine Therapy With or Without Trastuzumab in Treating Patients With Metastatic Breast Cancer	
		Condition:	Breast Cancer
		Interventions:	Biological: allogeneic GM-CSF-secreting breast cancer vaccine; Biological: trastuzumab; Drug:

29	Unknown †	Trial of an RNA^{Active}®-Derived Cancer Vaccine in Stage III/IV Non Small Cell Lung Cancer (NSCLC)
		Condition: Non Small Cell Lung Cancer Intervention: Biological: CV9201
30	Recruiting	Safety Study of Peptide Cancer Vaccine To Treat HLA-A*24-positive Advanced Small Cell Lung Cancer
		Condition: Small Cell Lung Cancer Intervention: Biological: HLA-A*2402-restricted CDCA1 and KIF20A peptides
31	Recruiting	Safety Study of Peptide Cancer Vaccine To Treat HLA-A*02-positive Advanced Non-small Cell Lung Cancer
		Condition: Non-small Cell Lung Cancer Intervention: Biological: HLA-A*0201 or HLA-A*0206-restricted URLC10 peptides
32	Recruiting	Safety Study of Peptide Cancer Vaccine To Treat HLA-A*24-positive Advanced Non-small Cell Lung Cancer
		Condition: Non-Small Cell Lung Cancer Intervention: Biological: HLA-A*2402restricted URLC10, CDCA1, and KIF20A peptides
33	Completed	The Use of Dendritic Cell/Tumor Fusions as a Novel Tumor Vaccine in Patients With Multiple Myeloma
		Condition: Multiple Myeloma Intervention: Biological: Dendritic Cell Tumor Fusion Vaccine
34	Active, not recruiting	Study To Test the Safety and Efficacy of TVI-Brain-1 As A Treatment for Recurrent Grade IV Glioma
		Conditions: Grade IV Glioma; Grade IV Astrocytoma; Glioblastoma Multiforme Intervention: Biological: TVI-Brain-1
35	Completed	Vaccine Therapy With or Without Cyclophosphamide and Doxorubicin in Women With Stage IV Breast Cancer
		Condition: Breast Cancer Interventions: Biological: allogeneic GM-CSF-secreting breast cancer vaccine; Drug: cyclophosphamide; Drug: doxorubicin
36	Unknown †	Dendritic Cell Cancer Vaccine for High-grade Glioma
		Condition: Glioblastoma Multiforme Interventions: Drug: Trivax, Temozolomide, Surgery, Radiotherapy; Drug: Temozolomide, Surgery, Radiotherapy
37	Recruiting	Vaccine Therapy and Aldesleukin in Treating Women With Metastatic Breast Cancer
		Condition: Breast Cancer Interventions: Biological: allogeneic large multivalent immunogen breast cancer vaccine; Biological: aldesleukin
38	Recruiting	Phase II Study of S-488410 to Treat Non-small Cell Lung Cancer
		Condition: Carcinoma, Non-Small-Cell Lung Intervention: Drug: S-488410
39	Unknown †	Comparison of the Human Papillomavirus (HPV) Type 16 E7-Specific Immune Response Between a Normal Population and Patients With
		Condition: Cervical Cancer Intervention:
40	Completed	In-Situ Therapeutic Cancer Vaccine for Metastatic Cancer Combining AlloStim With Tumor Cryoablation
		Condition: Metastatic Cancer Interventions: Biological: AlloStim-7; Procedure: percutaneous tumor cryoablation; Biological: AlloStim8 or AlloStim-9
41	Unknown †	GVAX in Advanced Prostate Cancer Patients Made Lymphopenic
		Condition: Prostate Cancer Intervention: Biological: GM-CSF gene transduced allogeneic vaccine GVAX

42	Recruiting	Ad/HER2/Neu Dendritic Cell Cancer Vaccine Testing
		Conditions: Breast Neoplasms; Breast Cancer; Adenocarcinomas; Metastatic Solid Tumors Characterized by HER2/Neu Intervention: Biological: Autologous Ad HER2 dendritic cell vaccine
43	Not yet recruiting	Study of AlloStim In-Situ Vaccine in Pre-Treated Metastatic Breast Cancer
		Condition: Metastatic Breast Cancer Interventions: Biological: AlloStim; Procedure: cryoablation
44	Recruiting	VXM01 Phase I Dose Escalation Study in Patients With Locally Advanced, Inoperable and Stage IV Pancreatic Cancer
		Condition: Stage IV Pancreatic Cancer Interventions: Biological: VXM01; Biological: Placebo
45	Recruiting	A Neoadjuvant Study of Androgen Ablation Combined With Cyclophosphamide and GVAX Vaccine for Localized Prostate Cancer
		Condition: Prostate Cancer Adenocarcinoma in Situ Interventions: Drug: degarelix acetate; Drug: Cyclophosphamide, GAVX (GM-CSF-secreting cell-based (PC3/LNCaP) prostate
46	Terminated	Vaccine Treatment for Advanced Breast Cancer
		Condition: Breast Cancer Intervention: Biological: HyperAcute - Breast cancer vaccine
47	Completed	Vaccine Treatment for Surgically Resected Pancreatic Cancer
		Condition: Pancreatic Cancer Intervention: Biological: HyperAcute-Pancreatic Cancer Vaccine
48	Completed	Vaccine Treatment for Hormone Refractory Prostate Cancer
		Condition: Prostate Cancer Intervention: Biological: HyperAcute-Prostate Cancer Vaccine
49	Active, not recruiting	Phase 1-2 Study of a Cancer Vaccine to Treat Patients With Advanced Stage Ovarian, Fallopian or Peritoneal Cancer
		Conditions: Ovarian Cancer; Fallopian Tube Cancer; Peritoneal Cancer Interventions: Biological: DPX-Survivac; Drug: low dose cyclophosphamide (oral)
50	Terminated	Tumor-Pulsed Dendritic Cells Used as a Tumor Vaccine
		Condition: Metastatic Colorectal Cancer Intervention: Drug: Interleukin-2 (IL-2)
51	Completed	Biological Therapy in Treating Patients With Metastatic Cancer
		Conditions: Breast Cancer; Colorectal Cancer; Extrahepatic Bile Duct Cancer; Gallbladder Cancer; Gastric Cancer; Head and Neck Cancer; Liver Cancer; Lung Cancer; Metastatic Cancer; Ovarian Cancer; Pancreatic Cancer; Testicular Germ Cell Tumor Intervention: Biological: CEA RNA-pulsed DC cancer vaccine
52	Completed	Tumor Vaccine and Interferon Gamma in Treating Patients With Refractory Epithelial Ovarian Cancer
		Condition: Recurrent Ovarian Epithelial Cancer Interventions: Biological: ALVAC-hB7.1; Biological: recombinant interferon gamma; Other: laboratory biomarker analysis
53	Completed	Treating High Risk Leukemia With CD40 Ligand & IL-2 Gene Modified Tumor Vaccine
		Condition: Leukemia Intervention: Biological: Tumor Vaccine: CD40 LIGAND AND IL-2 GENE MODIFIED AUTOLOGOUS SKIN FIBROBLASTS AND TUMOR CELLS
54	Unknown †	The Use of Dendritic Cell/Tumor Hybridomas as a Novel Tumor Vaccine in Patients With Advance Melanoma

		Condition:	Metastatic Melanoma
		Intervention:	Biological: DC/tumor fusion vaccine
55	Recruiting	Randomized Phase II Adjuvant Chemotherapy ± FANG™ in Colorectal Carcinoma With Liver Metastases	
		Condition:	Colon Cancer
		Interventions:	Biological: FANG Vaccine; Drug: Placebo
56	Unknown †	Androgen Ablation Therapy With or Without Vaccine Therapy in Treating Patients With Prostate Cancer	
		Condition:	Prostate Cancer
		Interventions:	Biological: GVAX prostate cancer vaccine; Drug: bicalutamide; Drug: goserelin; Drug: leuprolide acetate
57	Recruiting	Trial of Adjuvant FANG™ Vaccine for High Risk Stage III/IV Ovarian Cancer	
		Condition:	Ovarian Cancer
		Interventions:	Biological: FANG; Drug: standard of care observational follow-up
58	Completed Has	Universal Granulocyte-Macrophage Colony-Stimulating Factor (GM-CSF)-Producing and CD40L Expressing Bystander Cell Line for Tumor	
		Condition:	Melanoma (Skin)
		Intervention:	Biological: Bystander-Based Autologous Tumor Cell Vaccine
59	Completed	A Pilot Study of NY-ESO-1b Peptide Plus CpG 7909 and Montanide ISA-51 in Patients With Cancer.	
		Conditions:	Cancer; Neoplasm
		Intervention:	Biological: NY-ESO-1b peptide plus CpG 7909 and Montanide ISA-51
60	Completed Has	Allogeneic Cellular Vaccine 1650-G for Non-Small Cell Lung Cancer	
		Condition:	Non-Small Cell Lung Cancer
		Intervention:	Drug: 1650-G Vaccine
61	Recruiting	Study of OTSGC-A24 Vaccine in Advanced Gastric Cancer	
		Condition:	Gastric Cancer
		Intervention:	Biological: OTSGC-A24
62	Completed	Safety and Immune Response to a Multi-component Immune Based Therapy (MKC1106-MT) for Patients With Melanoma.	
		Conditions:	Advanced Melanoma; Stage III and IV Melanoma
		Interventions:	Biological: Biological: MKC1106-MT; Biological: Biological: MKCC1106-MT
63	Completed	Safety Study of a Liposomal Vaccine to Treat Malignant Melanoma	
		Condition:	Melanoma
		Intervention:	Biological: Lipovaxin-MM
64	Completed	RNA-Loaded Dendritic Cell Cancer Vaccine	
		Condition:	Renal Cell Carcinoma
		Intervention:	Biological: MB-002
65	Recruiting	Autologous T-Cells Combined With Autologous OC-DC Vaccine in Ovarian Cancer	
		Conditions:	Ovarian Carcinoma; Fallopian Tube Cancer; Primary Peritoneal Cancer
		Interventions:	Biological: OC-DC vaccine; Drug: Bevacizumab; Drug: cyclophosphamide 300 mg/m2/d for 3 days; Drug:
66	Completed	Lung Cancer Vaccine Plus Oral Dietary Supplement	
		Condition:	Lung Cancer
		Intervention:	Biological: vaccine 1650-G
67	Active, not recruiting	Ovarian Cancer Vaccine for Patients in Remission	
		Condition:	Epithelial Ovarian Cancer
		Intervention:	Biological: MUC1 Dendritic Cell Vaccine (Cvac)

68	Unknown †	Four Doses of MAGE Vaccine for Patients With Squamous Cell Carcinoma of the Head and Neck	
		Conditions:	Squamous Cell Carcinoma; Head and Neck Cancer
		Intervention:	Biological: MAGE-A3 HPV-16 vaccine
69	Terminated	Safety, Immune and Tumor Response to a Multi-component Immune Based Therapy (MKC1106-MT) for Patients With Melanoma	
		Conditions:	Stage III Melanoma; Stage IV Melanoma
		Intervention:	Biological: MKC1106-MT
70	Unknown †	Allogeneic Whole Cell Cancer Vaccine for Metastatic Epithelial Tumors	
		Conditions:	Colorectal Cancer; Ovarian Cancer; Gastric Cancer; Breast Cancer; Lung Cancer
		Intervention:	Biological: Allogeneic whole epithelial tumor cells, DNP-conjugated and irradiated
71	Recruiting	A Phase I Cancer Vaccine Study for Patients With Metastatic Breast Cancer	
		Condition:	Metastatic Breast Cancer
		Intervention:	Biological: Dendritic Cell Vaccination
72	Active, not recruiting	Ovarian Cancer Vaccine for Patients Who Have Progressed During the CAN-003 Study	
		Condition:	Epithelial Ovarian Cancer
		Intervention:	Biological: MUC1 Dendritic Cell Vaccine (Cvac)
73	Terminated	Clinical Trial Studying a Personalized Cancer Vaccine in Patients With Non-metastatic Kidney Cancer	
		Conditions:	Kidney Cancer; Renal Cell Carcinoma
		Intervention:	Biological: HSPPC-96
74	Completed	NY-ESO-1 Protein With Montanide and CpG 7909 as Cancer Vaccine in Several Tumors	
		Condition:	Tumors
		Intervention:	Biological: NY-ESO-1 protein with CpG 7909 and Montanide
75	Completed	Study to Assess dHER2+AS15 Cancer Vaccine Given in Combination With Lapatinib to Patients With Metastatic Breast Cancer	
		Condition:	Metastatic Breast Cancer
		Interventions:	Biological: dHER2 + AS15 ASCI; Drug: Lapatinib
76	Unknown †	A Phase I Safety Study of a Cancer Vaccine to Treat HLA-A2 Positive Advanced Stage Ovarian, Breast and Prostate Cancer	
		Conditions:	Ovarian Neoplasms; Breast Neoplasms; Prostatic Neoplasms
		Intervention:	Biological: DPX-0907 consists of 7 tumor-specific HLA-A2-restricted peptides, a universal T Helper peptide, a polynucleotide adjuvant, a liposome and Montanide ISA51 VG
77	Active, not recruiting	Evaluation of a New Anti-cancer Vaccine for Patients With Non-small Cell Lung Cancer, After Tumor Removal by Surgery	
		Conditions:	Non-Small Cell Lung Cancer; Lung Cancer, Non-Small Cell
		Intervention:	Biological: Immunotherapeutic GSK2302032A, different formulations
78	Terminated	Trial to Compare the Routes of Administration of an Investigational, Personalized, Therapeutic Cancer Vaccine Oncophage (HSPPC-96) in	
		Condition:	Renal Cell Carcinoma
		Intervention:	Biological: autologous human tumor-derived HSPPC-96
79	Unknown †	Study of Repeat Intranodal Injection of Memgen's Cancer Vaccine, Ad-ISF35, in Subjects With Chronic Lymphocytic Leukemia/Small	
		Conditions:	Chronic Lymphocytic Leukemia; Small Lymphocytic Lymphoma
		Intervention:	Biological: ISF35
80	Completed	Vaccine Therapy and Biological Therapy in Treating Patients With Advanced Cancer	

		Conditions:	Breast Cancer; Cervical Cancer; Colorectal Cancer; Lung Cancer; Ovarian Cancer; Pancreatic Cancer
		Interventions:	Biological: aldesleukin; Biological: mutant p53 peptide pulsed dendritic cell vaccine; Biological: ras peptide cancer
81	Completed	Vaccine Therapy Plus Biological Therapy in Treating Adults With Metastatic Solid Tumors	
		Conditions:	Colorectal Cancer; Endometrial Cancer; Head and Neck Cancer; Liver Cancer; Lung Cancer; Melanoma (Skin); Pancreatic Cancer; Testicular Germ Cell Tumor; Unspecified Adult Solid Tumor, Protocol Specific
		Interventions:	Biological: aldesleukin; Biological: ras peptide cancer vaccine; Biological: sargramostim; Drug: DetoxPC
82	Completed	Vaccine Therapy Combined With Adjuvant Chemoradiotherapy in Treating Patients With Resected Stage I or Stage II Adenocarcinoma	
		Condition:	Pancreatic Cancer
		Interventions:	Biological: GVAX pancreatic cancer vaccine; Procedure: Adjuvant therapy (5-FU and radiation)
83	Completed	Vaccine Therapy in Treating Patients With Colon, Pancreatic, or Lung Cancer	
		Conditions:	Recurrent Colon Cancer; Extensive Stage Small Cell Lung Cancer; Stage III Pancreatic Cancer; Stage III Rectal Cancer; Limited Stage Small Cell Lung Cancer; Recurrent Pancreatic Cancer; Recurrent Rectal Cancer; Stage III Non-Small Cell Lung Cancer; Stage I Pancreatic Cancer; Stage II Non-Small Cell Lung Cancer; Stage IVB Pancreatic Cancer; Stage II Pancreatic Cancer; Stage III Colon Cancer; Stage IVA Pancreatic Cancer
		Interventions:	Drug: Detox-B adjuvant; Drug: ras peptide cancer vaccine
84	Completed	Vaccine Therapy Plus Interleukin-12 in Treating Patients With Metastatic Prostate Cancer That Has Not Responded to Hormone Therapy	
		Condition:	Prostate Cancer
		Interventions:	Biological: PSA prostate cancer vaccine; Biological: recombinant interleukin-12
85	Completed	Vaccine Therapy Plus QS21 in Treating Patients With Advanced Pancreatic or Colorectal Cancer	
		Conditions:	Colorectal Cancer; Pancreatic Cancer
		Interventions:	Biological: QS21; Biological: ras peptide cancer vaccine
86	Completed	Vaccine Therapy With or Without Interleukin-2 in Treating Patients With Locally Advanced or Metastatic Colorectal Cancer	
		Condition:	Colorectal Cancer
		Interventions:	Biological: aldesleukin; Biological: ras peptide cancer vaccine; Procedure: adjuvant therapy
87	Unknown †	Vaccine Therapy in Treating Patients With Recurrent Prostate Cancer	
		Condition:	Prostate Cancer
		Interventions:	Biological: PSA prostate cancer vaccine; Biological: incomplete Freund's adjuvant
88	Completed	Vaccine Therapy and Sargramostim in Treating Patients With Non-Small Cell Lung Cancer	
		Condition:	Lung Cancer
		Interventions:	Biological: ras peptide cancer vaccine; Biological: sargramostim
89	Unknown †	Vaccine Therapy in Treating Patients With Metastatic Prostate Cancer That Has Not Responded to Hormone Therapy	
		Condition:	Prostate Cancer
		Interventions:	Biological: PSA prostate cancer vaccine; Biological: therapeutic autologous dendritic cells
90	Completed	Vaccine Therapy in Treating Patients With Myelodysplastic Syndrome	
		Conditions:	Leukemia; Myelodysplastic Syndromes
		Interventions:	Biological: ras peptide cancer vaccine; Biological: sargramostim
91	Completed	Vaccine Therapy in Treating Women With Metastatic Breast Cancer	
		Condition:	Breast Cancer