

Completed	Synthetic Vaccine in Patients With Chronic Myeloid Leukemia and Minimal Residual Disease		Synthetic Tumor-Specific Breakpoint Peptide Vaccine in Patients With CML and Minimal Residual Disease
	Conditions:	Chronic Myeloid Leukemia; Minimal Residual Disease	
	Intervention:	Biological: Synthetic Tumor-Specific Breakpoint Peptide Vaccine	
	Primary Outcome Measures: To evaluate the anti-leukemic effects of vaccination with CML breakpoint peptides as measured by a one-log decrease in circulating BCR-ABL transcripts using reverse transcription polymerase chain reaction (RT-PCR). [Time Frame: September 2007]		
Terminated	Docetaxel in Combination With GVAX® Immunotherapy Versus Docetaxel and Prednisone in Prostate Cancer Patients		Docetaxel in Combination With CG1940 and CG8711 Versus Docetaxel and Prednisone
	Condition:	Prostate Cancer	
	Interventions:	Biological: Immunotherapy allogeneic GM-CSF secreting cellular vaccine; Drug: Chemotherapy (docetaxel and prednisone) 2005	
	Primary Outcome Measures: Survival [Time Frame: 0] [Designated as safety issue: No]		
	Secondary Outcome Measures: Time to disease progression. Time to pain progression. [Time Frame: 0] [Designated as safety issue: No]		
Not yet recruiting	An Intervention Study To Improve HPV Immunization in Haitian and African American Girls		
	Condition:	Cervical Cancer	
	Intervention:	Behavioral: BNI-brief Negotiated Interview	
Recruiting	Phase III Lucanix™ Vaccine Therapy in Advanced Non-small Cell Lung Cancer (NSCLC) Following Front-line Chemotherapy		Lucanix™ (Belagenpumatucel-L) in Advanced Non-small Cell Lung Cancer:
	Conditions:	Lung Neoplasm; Carcinoma, Non-Small-Cell Lung: Stage IIIA (T3,N2 Only); Carcinoma, Non-Small-Cell Lung:	
	Interventions:	Biological: Lucanix™; Other: Placebo Comparator 2008	
	<p>Primary Outcome: Compare the overall survival of subjects with stage III or IV non-small cell lung cancer treated with belagenpumatucel-L (Lucanix™) vs placebo. [7 years]</p> <p>Secondary Outcome: Evaluate the progression free survival (PFS) of subjects treated with Lucanix™ compared to treatment within the Best Support Care control group. [3 years] . /Evaluate the quality of life (QOL) as determined by the Lung Cancer Symptom Scale (LCSS) compared to treatment within the Best Supportive Care control group. [3 years] . /Evaluate the time-to-progression of subjects treated with Lucanix™ compared to treatment within the Best Supportive Care control group. [3 years] . /Evaluate the best overall tumor response in subjects treated with Lucanix™ compared to treatment in the Best Supportive Care control group. [3 years] . /Evaluate the response duration in subjects treated with Lucanix™ compared to the Best Supportive Care control group. [3 years] /Evaluate the rate of CNS metastases development in subjects treated with Lucanix™ as compared to the Best Supportive Care control group. [7 years] /Adverse events of subjects treated with Lucanix™ will be compared to subjects in the Best Supportive Care control group. [7 years]</p> <p>Blood samples are collected and analyzed for routine chemistry, cytokines, chemokines, and some instances circulating tumor cells, including response to multiple lung cancer-associated antigens by IFN-γ ELISPOT CD8+ assay; CEA by CD4 class II assay; lung tumor-associated antigens by in vitro proliferation assays; regulatory T-cell (Treg) phenotype by flow cytometry; and Treg function.</p> <p>Subjects complete the Lung Cancer Symptom Scale quality of life questionnaire at baseline, on the days of treatment, 30 days after completion of study treatment, and then every 3 months for 1 year.</p> <p>After completion of study treatment, subjects are followed every 3 months for 1 year and then annually for 4 years</p>		
Active, not recruiting	A Phase I/II Study With CEA(6D) VRP Vaccine in Patients With Advanced or Metastatic CEA-Expressing Malignancies		Active Immunotherapy With CEA(6D)VRP Vaccine(AVX701) Advanced or Metastatic Malignancies Expressing CEA or Stage III Colon Cancer
	Conditions:	Colorectal Cancer; Breast Cancer; Lung Cancer; Pancreatic Cancer; Colon Cancer	
	Intervention:	Biological: AVX701	

	<p>CEA represents an attractive target antigen for immunotherapy since it is over expressed in nearly all colorectal cancers and pancreatic cancers, and is also expressed by some lung and breast cancers, and uncommon tumors such as medullary thyroid cancer, but is not expressed in other cells of the body except for low-level expression in gastrointestinal epithelium [1]. That CEA is a potential target for T cell mediated immune responses in humans is demonstrated by the observation that CEA contains epitopes that may be recognized in an MHC restricted fashion by T cells [2-11]. Specifically, there is support for the existence of human cytolytic T cells (CTLs) that recognize CEA epitopes that bind to MHC molecules HLA- A2, A3, and A24. For the most part, these T cells have been generated by in vitro cultures using antigen-presenting cells pulsed with the epitope of interest to stimulate peripheral blood mononuclear cells. In addition, T cell lines have been generated after stimulation with CEA latex beads, CEA protein-pulsed plastic adherent peripheral blood mononuclear cells, or DCs sensitized with CEA RNA. T cells have also been generated from patients immunized with a vaccinia vector encoding CEA immunogen (discussed below). Using high-performance liquid chromatography mass-spectrometry-based approaches, HLA A2-presented peptides from CEA have been identified in primary gastrointestinal tumors [12]. Of the HLA A2 restricted epitopes of CEA, CAP-1, a nine amino acid sequence, has been shown to stimulate CTLs from cancer patients immunized with vaccinia-CEA. Cap-1(6D) is a peptide analog of CAP-1. Its sequence includes a heteroclitic (nonanchor position) mutation, resulting in an amino acid change from Asn to Asp, to enhance recognition by the T-cell receptor without any change in binding to HLA A2. Compared with the non mutated CAP-1 epitope, Cap-1(6D) has been shown to enhance the sensitization of CTLs by 100 to 1,000 times [3, 5, 13]. CTL lines could be elicited from peripheral blood mononuclear cells of healthy volunteers by in vitro sensitization to the Cap-1(6D) peptide but not to the CAP-1 peptide. These cell lines can lyse human tumor cells expressing endogenous CEA. /evaluate CEA-specific immune response to immunizations [Time Frame: 3 years]</p>	
Recruiting	<p>Dendritic Cell Vaccine for Patients With Brain Tumors</p> <p>Conditions: Glioma; Anaplastic Astrocytoma; Anaplastic Astro-oligodendroglioma; Glioblastoma</p> <p>Intervention: Biological: autologous tumor lysate-pulsed DC vaccination 2010</p>	<p>Autologous Dendritic Cells Pulsed With Tumor Lysate Antigen +/- Toll-like Receptor Agonists for the Treatment of Malignant Glioma</p>
	<p>Tumor Lysate Antigen +/- Toll-like Receptor Agonists: Experimental</p> <p>Cohort #1 will receive autologous tumor lysate-pulsed DC vaccination alone. Cohort #2 will receive autologous tumor lysate-pulsed DC vaccination together with adjuvant 5% imiquimod (TLR7 agonist). Cohort #3 will receive autologous tumor lysate-pulsed DC vaccination together with adjuvant poly ICLC (TLR3 agonist).</p> <p>Intervention: Biological: autologous tumor lysate-pulsed DC vaccination</p> <p>目的: Dendritic cells (DC) (cells which "present" or "show" cell identifiers to the immune system) isolated from the subject's own blood will be treated with tumor-cell lysate isolated from tumor tissue taken from the same subject during surgery. This pulsing (combining) of antigen-presenting and tumor lysate will be done to try to stimulate the immune system to recognize and destroy the patient's intracranial brain tumor. These pulsed DCs will then be injected back into the patient intradermally as a vaccine. The investigators will also utilize adjuvant imiquimod or poly ICLC in some treatment cohorts. It is thought that the host immune system might be taught to "recognize" the malignant brain tumor cells as "foreign" to the body by effectively presenting unique tumor antigens to the host immune cells (T-</p>	
Recruiting	<p>Vaccine Therapy in Treating Patients Undergoing Surgery for Recurrent Glioblastoma Multiforme</p> <p>Condition: Brain and Central Nervous System Tumors</p> <p>Interventions: Biological: autologous CD133-positive BTSC mRNA-pulsed autologous dendritic cell vaccine; Procedure: adjuvant therapy; Procedure: therapeutic conventional surgery 2009</p>	<p>Recurrent GBM Stem Cell Tumor Amplified RNA Immunotherapy Trial</p>

	<p>Biological: autologous CD133-positive BTSC mRNA-pulsed autologous dendritic cell vaccine An escalating total dose of mRNA-loaded DCs (2×10^6, 5×10^6, and 2×10^7 per vaccination) will be evaluated for purpose of establishing a MTD and a DLT Primary Outcome: Feasibility and safety [12 months] Secondary Outcome: Humoral and cellular immune responses [12 months] Primary: To evaluate the feasibility and safety of an autologous brain tumor stem cell mRNA-loaded dendritic cell vaccine for recurrent glioblastoma multiforme. Secondary: To assess humoral and cellular immune responses to vaccination. /To compare the proportion of vaccinated patients alive at 6 months from the time of surgery for recurrent tumor with matched historical cohorts. Patients undergo surgical resection of tumor. Tumor tissue samples are collected to isolate brain tumor stem cells (BTSCs) and for extraction and amplification of BTSC-specific mRNA. Within 4 weeks after surgical resection, patients undergo leukapheresis over 4 hours to generate dendritic cells (DCs). Patients also undergo leukapheresis at 1 week after the third vaccination and then at least every 3 months as needed for generation of additional DCs.</p>	
Active, not recruiting	<p>Vaccine Therapy in Treating Patients With Malignant Glioma</p> <p>Condition: Brain and Central Nervous System Tumors</p> <p>Intervention: Biological: glioma-associated antigen peptide-pulsed autologous dendritic cell vaccine 2008</p>	<p>Glioma-Associated Antigen (GAA) Peptide-pulsed Dendritic Cell Vaccination in Malignant Glioma Patients</p>
	<p>Primary Outcome: Dose-limiting toxicity and maximum tolerated dose of autologous dendritic cells pulsed with synthetic glioma-associated antigen (GAA) peptides /Survival. /Tumor progression. /Cellular immune response. Patients are followed every 2 months for 1 year.</p>	
Recruiting	<p>Vaccine Therapy and Monoclonal Antibody Therapy in Treating Patients With Stage III or Stage IV Melanoma That Cannot Be</p> <p>Condition: Melanoma (Skin)</p> <p>Interventions: Biological: MART-1:26-35(27L) peptide vaccine; Biological: NY-ESO-1 peptide vaccine; Biological: anti-PD-1 human monoclonal antibody MDX-1106; Biological: gp100:209-217(210M) peptide vaccine; Biological: gp100:280-288(288V) peptide vaccine; Drug: Montanide ISA 51 VG; Other: laboratory biomarker analysis; Other: pharmacological study 2010</p>	<p>Vaccine Combining Multiple Class I Peptides and Montanide ISA 51 VG With Escalating Doses of Anti-PD-1 Antibody BMS-936558 for Patients With Unresectable Stages III/IV Melanoma</p>
	<p>Primary Outcome: Best overall response (complete or partial response, stable disease, or progressive disease). Adverse events Secondary Outcome: Time to response. Duration of response. Primary: To assess the safety and tolerability of multiple class I peptide vaccine comprising gp100:209-217(210M), MART-1:26-35(27L), gp100:280-288(288V), and NY-ESO-1 emulsified in Montanide ISA 51 VG and anti-PD-1 human monoclonal antibody MDX-1106 (BMS-936558) in HLA-A*0201-positive patients with unresectable stage III or IV malignant melanoma. Secondary: To evaluate the immune response at week 12 in patients treated with these regimens compared to the immune response to peptide vaccine alone. /To assess the host immune response (immunogenicity) to BMS-936558. /To assess, preliminarily, the efficacy of these regimens in these patients. OUTLINE: This is a dose-escalation study of anti-PD-1 human monoclonal antibody MDX-1106. Blood samples are collected for pharmacokinetic and immunologic analysis. After completion of study therapy, patients are followed up periodically for 2 years.</p>	
Recruiting	<p>Tumor Lysate Pulsed Dendritic Cell Immunotherapy for Patients With Brain Tumors</p> <p>Condition: Glioblastoma</p> <p>Interventions: Biological: Dendritic Cell Immunotherapy; Biological: Dendritic Cell Vaccine 2007</p>	<p>Tumor Lysate-Pulsed Dendritic Cell Immunotherapy for Patients With Atypical or Malignant, Primary or Metastatic Brain Tumors of the Central Nervous System</p>

	<p>Detailed Description: To become eligible for therapy the following criteria must be fulfilled: No age or gender limit. /Patients with atypical malignant brain tumors. /Must have a Karnofsky performance of at least 60%. /Hematologic studies and chemistry profiles will be within the parameters of the protocol. /Tumor specimen of adequate size to yield protein concentration, tumor lysate peptide must be generated in sufficient quantity and patient must have no prior sensitivity to the components of the dendritic cell vaccine. /Patients are excluded if they have systemic disease, presence of acute infection, known history of autoimmune disorder and pregnancy.</p>	
Recruiting	<p>DC Vaccine Therapy Combined With Cytokine-Induced Killer Cell in Treating Patients With Renal Cell Carcinoma</p> <p>Condition: Renal Cell Carcinoma/ in Patients With Renal Cell Cancer</p> <p>Interventions: Biological: DC-CIK; Drug: IL-2/IFN-α Autologous Tumor Lysate (DC-Vaccine) 2009</p>	<p>Autologous Dendritic Cells Loaded With Autologous Tumor Lysate in Combination With Cytokine-Induced Killer Cell (CIK)</p>
	<p>Primary Outcome: Objective tumor response (complete and partial response), Time to recurrence (TTR), Progression-free(PFS) and overall survival(OS) as measured by RECIST criteria. [every 3 months] Secondary Outcome: Immunity as measured by T-cell functionality (immuknow assay)to the tumor. Safety as measured by NCI common toxicity table (CTC) at completion of study. [Time Frame: at screening, baseline, weeks 4 , 12 and years 1 after first vaccination, and at completion of study treatment] Primary: Determine the clinical responses(objective response, progression-free survival, and overall survival) in patients with renal cell carcinoma treated with autologous dendritic cells (DC) loaded with autologous tumor lysate (DC vaccine) in combination with Cytokine-Induced Killer Cell (CIK). Secondary: Determine cellular immune response response in terms of immuknow assay, and correlate immune response with objective clinical response in patients treated with this regimen. Determine safety of multiple administrations of this regimens in these patients.</p>	
Recruiting	<p>One Dose of Cyclophosphamide or Denileukin Diftitox Followed By Expanding a Patient's Own T Cells in the Laboratory in Treating Patients With HER-2/Neu Overexpressing Metastatic Breast Cancer, Ovarian Cancer, or Non-Small Cell Lung Cancer Previously Treated With HER-2/Neu Vaccine</p> <p>Conditions: HER2-positive Breast Cancer; Recurrent Breast Cancer; Recurrent Non-small Cell Lung Cancer; Recurrent Ovarian Epithelial Cancer; Recurrent Ovarian Germ Cell Tumor; Stage IV Breast Cancer; Stage IV Non-small Cell Lung Cancer; Stage IV Ovarian Epithelial Cancer; Stage IV Ovarian Germ Cell Tumor</p> <p>Interventions: Drug: ex vivo-expanded HER2-specific T cells; Drug: cyclophosphamide; Biological: denileukin diftitox; Other: flow cytometry; Other: immunoenzyme technique 2005</p>	<p>Infusion of HER-2/Neu Specific T-cells in Patients With Advanced Stage HER-2/Neu Expressing Cancers Who Have Received a HER-2/Neu Vaccine</p>

	<p>Primary Outcome: Feasibility of expanding HER2 specific T cells ex vivo [Time Frame: From baseline] /Safety [Time Frame: From baseline]</p> <p>Secondary Outcome: Extent to which to HER2 specific T cell immunity can be boosted. /Anti-tumor effects of HER2 specific T cells, as assessed by RECIST criteria. /Persistence of T cell immune augmentation[One month following last infusion and then every 2 months for 1 year] /Progression.</p> <p>PRIMARY OBJECTIVES: I. To assess the feasibility of expanding HER2 specific T cells ex vivo for infusion into subjects who have advanced HER2 overexpressing cancer. II. To assess the toxicity associated with infusing autologous HER2 specific T cells into patients using either a single dose of cyclophosphamide or ONTAK (denileukin diftitox) prior to T cell infusion. SECONDARY OBJECTIVES: I. To investigate to what extent HER2 specific T cell immunity can be boosted in individuals treated with a single dose of cyclophosphamide or ONTAK (denileukin diftitox) followed by infusion of autologous HER2 specific T cells. II. To investigate the potential anti-tumor effects of HER2 specific T cells in patients with HER2 overexpressing advanced-stage cancers. III. To evaluate how long tumor antigen specific T cell immune augmentation persists in vivo after a single dose of cyclophosphamide or ONTAK (denileukin diftitox) followed by infusion of autologous HER2 specific T cells. OUTLINE: This is a dose-escalation study of ex vivo-expanded HER2-specific T cells. Patients are assigned to 1 of 2 treatment groups. GROUP A: Patients receive low-dose cyclophosphamide IV on day -1 and 3 escalating doses of autologous ex vivo-expanded HER2-specific T cells IV over 30 minutes on days 1, 10, and 20. GROUP B: Patients receive denileukin diftitox IV over 1 hour on day -1 and 3 escalating doses of autologous ex vivo-expanded HER2-specific T cells IV over 30 minutes on days 1, 10, and 20. After completion of study treatment, patients are followed periodically.</p>	
Not yet recruiting	Human Papillomavirus (HPV) Vaccine Pilot Project Condition: Cervical Cancer Intervention: Biological: Gardasil® HPV vaccine	
Recruiting	Vaccine Therapy and Autologous Lymphocyte Infusion With or Without Fludarabine in Treating Patients With Metastatic Conditions: Intraocular Melanoma; Melanoma (Skin) Interventions: Biological: dendritic cell vaccine therapy; Biological: therapeutic autologous lymphocytes; Drug: fludarabine	MART-1/gp100/Tyrosinase/NY-ESO-1 Peptide-Pulsed Dendritic Cells Matured Using Cytokines With Autologous

	<p>Primary Outcome: Overall survival. /Progression-free survival. Time to progression Secondary Outcome: Immunological response in patients receiving MART-1/gp100/tyrosinase/NY-ESO-1 with fludarabine. /Toxicity of MART-1/gp100/tyrosinase/NY-ESO-1 with fludarabine. Primary: Assess the toxicity and immune responses in HLA-A*0201-positive patients with chemotherapy-naïve metastatic melanoma treated with either escalating doses of fludarabine or no fludarabine followed by autologous lymphocyte infusion and vaccination with dendritic cells matured ex vivo with a cytokine cocktail and pulsed with MART-1/gp100/tyrosinase/NY-ESO-1/MAGE-3 class I and II peptides. Secondary: Compare clinical responses in patients receiving these regimens. All patients undergo two apheresis procedures, one to collect lymphocytes for the autologous lymphocyte infusion and one to collect dendritic cells (DC) for the production of the autologous vaccine. Autologous DC are pulsed with tumor antigen class I and II peptides derived from MART-1, gp100, tyrosinase, NY-ESO-1, and MAGE-3 and matured with a cytokine cocktail comprising tumor necrosis factor-α, interleukin (IL)-6, IL-1β, and prostaglandin E2. Arm I: Patients receive fludarabine IV over 30 minutes on days -7 to -3 (beginning 3 days after the second apheresis procedure). Patients receive autologous lymphocyte infusion IV over 1 hour on day 0 followed by vaccination with autologous peptide-pulsed DC intranodally over 24 hours on days 1, 8, 22, and 36. Patients who have stable disease or who achieve a response to treatment may receive re-treatment with fludarabine, autologous lymphocyte infusion, and autologous peptide-pulsed DC vaccine (as above) approximately 4 weeks to 6 months after the last DC vaccine. Cohorts of 3-12 patients receive escalating doses of fludarabine until the maximum tolerated dose (MTD) is determined. The MTD is defined as the dose preceding that at which 2 of 6 or 3 of 12 patients experience dose-limiting toxicity. Arm II: Patients receive autologous lymphocyte infusion and vaccination with autologous peptide-pulsed DC as in arm I. Patients who have stable disease or who achieve a response to treatment may receive re-treatment with autologous lymphocyte infusion and autologous peptide-pulsed DC vaccine (as in arm I) approximately 4 weeks to 6 months after the last DC vaccine. After completion of study therapy, patients are followed every 3 months for 2 years, every 6 months for 3 years, and then annually thereafter.</p>						
Active, not recruiting	<p>Vaccine Therapy in Treating Patients With Liver or Lung Metastases From Colorectal Cancer</p> <table border="1" data-bbox="264 899 2134 1017"> <tr> <td data-bbox="264 899 439 960">Conditions:</td> <td data-bbox="439 899 1630 960">Colorectal Cancer; Metastatic Cancer</td> <td data-bbox="1630 899 2134 1017" rowspan="2">Active Immunotherapy With PANVAC or Autologous, Cultured Dendritic Cells Infected With PANVAC After Complete Resection of Hepatic or Pulmonary Metastases of Colorectal Carcinoma</td> </tr> <tr> <td data-bbox="264 960 439 1017">Interventions:</td> <td data-bbox="439 960 1630 1017">Biological: falimarev; Biological: inalimarev; Biological: sargramostim; Biological: therapeutic autologous dendritic cells 2005</td> </tr> </table>		Conditions:	Colorectal Cancer; Metastatic Cancer	Active Immunotherapy With PANVAC or Autologous, Cultured Dendritic Cells Infected With PANVAC After Complete Resection of Hepatic or Pulmonary Metastases of Colorectal Carcinoma	Interventions:	Biological: falimarev; Biological: inalimarev; Biological: sargramostim; Biological: therapeutic autologous dendritic cells 2005
Conditions:	Colorectal Cancer; Metastatic Cancer	Active Immunotherapy With PANVAC or Autologous, Cultured Dendritic Cells Infected With PANVAC After Complete Resection of Hepatic or Pulmonary Metastases of Colorectal Carcinoma					
Interventions:	Biological: falimarev; Biological: inalimarev; Biological: sargramostim; Biological: therapeutic autologous dendritic cells 2005						
	<p>Primary Outcome: •Disease-free survival at 2 years Secondary Outcome: •Rate of immune response as measured by ELISpot assay at 16 weeks Primary: •Compare 2-year disease-free survival of patients with completely resected hepatic or pulmonary metastases secondary to colorectal cancer treated with adjuvant vaccine therapy comprising vaccinia-CEA-MUC-1-TRICOM vaccine (PANVAC-V) and fowlpox-CEA-MUC-1-TRICOM vaccine (PANVAC-F) administered with autologous dendritic cells or with sargramostim (GM-CSF). Secondary: •Compare the rate and magnitude of immune response, as determined by ELISpot, in patients treated with these regimens. OUTLINE: This is a randomized study. Patients are randomized to 1 of 2 treatment arms. •Arm I: Patients undergo leukapheresis to obtain leukocytes for generation of autologous dendritic cells (DC). Patients then receive autologous DC loaded with vaccinia-CEA-MUC-1-TRICOM (PANVAC-V) vaccine subcutaneously (SC) and intradermally (ID) on day 1 and autologous DC loaded with fowlpox-CEA-MUC-1-TRICOM (PANVAC-F) vaccine SC and ID on days 28, 56, and 84. •Arm II: Patients receive PANVAC-V SC on day 1 and PANVAC-F SC on days 28, 56, and 84. Patients also receive sargramostim (GM-CSF) SC into the same injection site once daily on days 0-3, 28-31, 56-59, and 84-87. After completion of study treatment, patients are followed for 2 years.</p>						

Terminated	Histocompatibility Leukocyte Antigen (HLA)-A*0201 Restricted Peptide Vaccine Therapy in Patients With Colorectal Cancer		Multiple-Vaccine Therapy Using Epitope Peptide Restricted to HLA-A*0201 in Combination With Tegafur/Uracil/ Folate in Treating Patients With Refractory Colorectal Cancer
	Conditions:	Colorectal Cancer; Colon Cancer; Rectal Cancer	
	Intervention:	Biological: VEGFR1 and VEGFR2 2008	
	<p>Primary Outcome: •safety(Phase I:toxicities as assessed by NCI CTCAE version3) and efficacy(Phase II:Feasibility as evaluated by RECIST) [2 months]</p> <p>Secondary Outcome: •To evaluate immunological responses [2 months]</p> <p>VEGF receptor 1 and 2 are essential targets to tumor angiogenesis, and we identified that peptides derived from these receptors significantly induce the effective tumor specific CTL response in vitro and vivo. According to these findings, in this trial, we evaluate the safety, clinical and immunological response of those peptides. Patients will be vaccinated twice a week for 8 weeks. On each vaccination day, VEGFR1 peptide (1mg) and VEGFR2 peptide (1mg) mixed with Montanide ISA 51 will be administered by subcutaneous injection. The patients will also receive oral chemotherapy (Tegafur/Uracil/Folate) simultaneously. Repeated cycles of the vaccine and the chemotherapy will be administered until patients develop progressive disease or unacceptable toxicity, whichever occurs first. In the phase I study, we evaluate the safety and tolerability of these peptide vaccine. In the following phase II study, we evaluate the immunological and clinical response of this vaccine therapy.</p>		
Terminated	Histocompatibility Leukocyte Antigen (HLA)-A*2402 Restricted Peptide Vaccine Therapy in Patients With Colorectal Cancer		Multiple-Vaccine Therapy Using Epitope Peptide Restricted to HLA-A*2402 in Combination With Tegafur/Uracil/ Folate in Treating Patients With Refractory Colorectal Cancer
	Conditions:	Colorectal Cancer; Colon Cancer; Rectal Cancer	
	Intervention:	Biological: RNF43, TOMM34, VEGFR1 and VEGFR2 2008	
	<p>Primary Outcome: •safety(Phase I:toxicities as assessed by NCI CTCAE version3) and efficacy(Phase II:Feasibility as evaluated by RECIST) [2 months]</p> <p>Secondary Outcome: •To evaluate immunological responses [2 months]</p> <p>RNF43 and TOMM34 have been identified as cancer specific molecules especially in colorectal cancer using genome-wide expression profile analysis by cDNA microarray technique. VEGF receptor 1 and 2 are essential targets to tumor angiogenesis, and we identified that peptides derived from these receptors significantly induce the effective tumor specific CTL response in vitro and vivo. Patients will be vaccinated twice a week for 8 weeks. On each vaccination day, RNF43 peptide (1mg), TOMM34 peptide (1mg), VEGFR1 peptide (1mg) and VEGFR2 peptide (1mg) mixed with Montanide ISA 51 will be administered by subcutaneous injection. The patients will also receive oral chemotherapy (Tegafur/Uracil/Folate) simultaneously. Repeated cycles of the vaccine and the chemotherapy will be administered until patients develop progressive disease or unacceptable toxicity, whichever occurs first. In the phase I study, we evaluate the safety and tolerability of these peptide vaccine. In the following phase II study, we evaluate the immunological and clinical response of this vaccine therapy.</p>		
Not yet recruiting	Does the HPV Vaccine Cause the Same Response in Adolescent Kidney and Liver Transplant Patients as in Healthy Controls?		Immunogenicity Of A Prophylactic Quadrivalent Human Papillomavirus (Types 6, 11, 16, And 18) L1 Virus-Like Particle Vaccine In Male And Female Adolescent Transplant Recipients.
	Conditions:	Cervical Cancer; HPV; Warts	
	Intervention:	Biological: Quadrivalent HPV for types 6, 11, 16 and 18 2010	
	The purpose of the study is to understand if children with liver and kidney transplants develop the antibodies from the Gardasil vaccine.		
Completed	Peptide-pulsed vs. RNA-transfected Dendritic Cell Vaccines in Melanoma Patients		DC Vaccines Presenting HLA Class I and II Restricted Tumor Epitopes Either by Peptide-pulsing or mRNA Transfection in Melanoma Patients
	Condition:	Melanoma Stage III or IV	
	Intervention:	Biological: autologous dendritic cell vaccine 2005	

	<p>Primary Outcome: •Immune response [first 10 years] Secondary Outcome: •Safety [first 10 years]</p> <p>MHC Class I restricted epitopes: Active Comparator: HLA-A2.1 patients are vaccinated with dendritic cells loaded with MHC Class I restricted epitopes of tumor antigens gp100 and tyrosinase. /Intervention: Biological: autologous dendritic cell vaccine.</p> <p>MHC Class I and II restricted epitopes: Experimental: HLA-A2.1 and HLA-DR4 patients are vaccinated with dendritic cells loaded with MHC Class I and II restricted epitopes of tumor antigens gp100 and tyrosinase. Intervention: Biological: autologous dendritic cell vaccine</p> <p>mRNA transfected DC: Experimental: HLA-A2.1 and/or HLA-DR4 patients are vaccinated with dendritic cells transfected with mRNA encoding tumor antigens gp100 and tyrosinase. Intervention: Biological: autologous dendritic cell vaccine</p>	
Terminated	<p>Vaccine Therapy in Treating Patients With Acute Myeloid Leukemia</p> <p>Condition: Leukemia</p> <p>Interventions: Drug: autologous tumor cell vaccine; Drug: therapeutic autologous dendritic cells; Procedure: tumor cell-derivative vaccine therapy 2005</p>	<p>Dendritic/Leukemic Fusion Cell Vaccine Therapy For AML Patients In First Remission; A Phase I Clinical Trial</p>
	<p>Primary: •Determine the maximum tolerated dose of autologous dendritic and leukemic fusion cell vaccine in patients with acute myeloid leukemia. •Determine the toxicity of this vaccine in these patients.</p> <p>Secondary: •Determine whether cellular immunity can be induced by this vaccine in these patients</p> <p>Cohorts of 3 patients receive escalating doses of autologous dendritic and leukemic fusion cell vaccine until the maximum tolerated dose (MTD) is determined. The MTD is defined as the dose preceding that at which 2 of 3 patients experience dose-limiting toxicity. Patients are followed every 3 months for 5 years.</p>	
Completed	<p>Vaccine Therapy in Treating Patients With Metastatic Melanoma</p> <p>Condition: Melanoma (Skin)</p> <p>Intervention: Biological: recombinant fowlpox-TRICOM vaccine</p>	<p>Intratumoral Injection of rF-TRICOMTM in Patients With Metastatic Melanoma Who Have Detectable Tumor Associated T Cells</p>
	<p>Primary Outcome: •Safety and tolerability. /•Local response rate (complete or partial response, stable or progressive disease). /•Overall clinical response as measured by RECIST criteria.</p> <p>Secondary Outcome: •Change in mRNA expression of B7-1, LFA-3, and/or ICAM-1 in the tumor microenvironment and correlate with response. /•Change in tumor-associated T cells and correlate with response. /•Time to tumor progression.</p> <p>Primary: •Determine the safety and tolerability of intratumoral fowlpox-TRICOM in patients with metastatic melanoma. /•Determine the local response rate in patients treated with this agent. /•Determine systemic clinical response in patients treated with this agent.</p> <p>Secondary: •Determine the increase in transgene expression of B7-1, leukocyte function-associated antigen-3 (LFA-3), and intercellular adhesion molecule-1 (ICAM-1) in patients treated with this agent. /•Determine the effects of this agent on CD8-positive antitumor T-cell frequency as measured by tetramer and ELISpot in patients who are HLA-A2 positive. /•Correlate transgene expression of B7-1, LFA-3, and ICAM-1 by tumor cells with changes in function or number of melanoma antigen-specific CD8-positive T lymphocytes in patients treated with this agent.</p> <p>Patients are followed every 3 months until disease progression and then approximately every 6 months for 5-15 years</p>	
Terminated	<p>Study of a Multi-Antigen Therapeutic Vaccine in Patients With Metastatic Melanoma</p>	
Has Results	<p>Conditions: Melanoma; Cancer 2008</p> <p>Interventions: Biological: ALVAC(2) Melanoma multi-antigen therapeutic vaccine; Biological: Intron A, Interferon alpha -2b</p>	<p>Multi-Antigen Therapeutic Vaccine in Patients With Metastatic Melanoma</p>

	<p>Primary Outcome: •Summary of Disease Progression in Study Participants, Intent-to-treat Population [up to 35 weeks]. /Number of evaluable study participants who had died or experienced objective disease progression (no clinical objective response to treatment as evaluated by computed tomography [CT] scans or physical examination). /•Progression-Free Survival Time by Response Evaluation Criteria in Solid Tumor (RECIST) Criteria in the Intent-to-treat Population [up to 35 weeks]. /Progression-Free Survival was assessed by the Response Evaluation Criteria in Solid Tumor criteria from the computed tomography (CT) scans, as per-protocol</p> <p>Secondary Outcome: •Best Overall Objective Response as Number of Participants Responding in the Intent-to-treat Population [up to 35 weeks]. /Objective response rate (ORR) is the sum of complete response (CR) and partial response (PR) Complete response = Disappearance of all target lesions. Partial response = At least a 30% decrease in the sum of longest diameter of target lesions, taking as reference the baseline sum longest diameter. /•Best Overall Objective Response in the Intent-to-treat Population [up to 35 weeks]. /Objective response rate (ORR) is the sum of complete response (CR) and partial response (PR) Complete response = Disappearance of all target lesions. Partial response = At least a 30% decrease in the sum of longest diameter of target lesions, taking as reference the baseline sum longest diameter. /•Best Overall Objective Response as Mean Duration of Response (Weeks) in the Intent-to-treat Population [up to 35 weeks]. /Objective response rate (ORR) is the sum of complete response (CR) and partial response (PR) Complete response = Disappearance of all target lesions. Partial response = At least a 30% decrease in the sum of longest diameter of target lesions, taking as reference the baseline sum longest diameter.</p> <p>•Number of Participants Reporting a Grade 3 or Grade 4 Adverse Events by Preferred Term [up to 35 weeks]. /Common Terminology Criteria for Adverse Events (CTCAE) definitions: Grade 3 is a severe adverse event; Grade 4 is a life-threatening or disabling adverse event.</p>	
Terminated	<p>Histocompatibility Leukocyte Antigen (HLA)-A*0201 Restricted Peptide Vaccine Therapy in Patients With Breast Cancer</p> <p>Condition: Breast Cancer</p> <p>Intervention: Biological: VEGFR1 and VEGFR2 2008</p>	<p>Multiple-Vaccine Therapy Using Epitope Peptide Restricted to HLA-A*0201for Refractory Breast Cancer</p>
	<p>Primary Outcome: •safety(Phase I:toxicities as assessed by NCI CTCAE version3) and efficacy(Phase II:Feasibility as evaluated by RECIST) [2 months]</p> <p>Secondary Outcome: •To evaluate immunological responses [2 months]</p> <p>VEGF receptor 1 and 2 are essential targets to tumor angiogenesis, and we identified that peptides derived from these receptors significantly induce the effective tumor specific CTL response in vitro and vivo. According to these findings, in this trial, we evaluate the safety, immunological and clinical response of those peptides. Patients will be vaccinated twice a week for 8 weeks. On each vaccination day, VEGFR1 peptide (1mg) and VEGFR2 peptide (1mg) mixed with Montanide ISA 51 will be administered by subcutaneous injection. Repeated cycles of the vaccine will be administered until patients develop progressive disease or unacceptable toxicity, whichever occurs first. In the phase I study, we evaluate the safety and tolerability of these peptide vaccine. In the following phase II study, we evaluate the immunological and clinical response of this vaccine therapy.</p>	
Recruiting	<p>Radiation, Chemotherapy, Vaccine and Anti-MART-1 and Anti-gp100 Cells for Patients With Metastatic Melanoma</p> <p>Conditions: Melanoma; Skin Cancer</p> <p>Interventions: Drug: MART-1: 26-35(27L) Peptide; Drug: Montanide ISA 51 VG; Drug: gp100:154-162 Peptide; Drug: PG 13/Faf2aB C 162D1 (anti- MART-1 F5 TCR); Drug: PG13-154-Ecll AIB (anti-gp100:154-162 TCR); Procedure: Radiation; Drug: Aldesleukin; Drug: Fludarabine; Drug: Cyclophosphamide; Genetic: Anti-gp 100:154 TCR PBL; Genetic: Anti-MART-1 F5 TCR PBL 2009</p>	<p>Metastatic Melanoma Using a Chemoradiation Lymphodepleting Conditioning Regimen Followed by Infusion of Anti-Mart-1 and Anti-gp100 TCR-Gene Engineered Lymphocytes and Peptide Vaccines</p>
	<p>•The procedure also uses one of two vaccines-the anti-MART-1 peptide or the anti-gp100 peptide-to stimulate cells in the immune system that may increase the effectiveness of the anti-MART-1 and anti-gp100 cells. Both vaccines are made from a virus that is modified to carry a copy of the MART-1 gene or gp100 gene. The virus cannot cause disease in humans.</p> <p>Primary Outcome: •Patients with melanoma, determine if the anti-gp100:154-162 TCR and anti-MART-1:27-25 TCR PBLs, IL-2 and the gp100:154-162 or the MART-1:26-35(27L) peptides after chemoradiation will lead to complete tumor regression and increased cell persisten...</p> <p>Secondary Outcome: •Determine the toxicity profile of these treatment regimen</p>	

Completed	Broad Spectrum HPV Vaccine Dose Escalation Study		Dose-Escalation Study of Octavalent Human Papillomavirus (HPV) L1 Virus-Like Particle (VLP) Vaccine Adjuvanted With Amorphous Aluminum Hydroxyphosphate Sulfate (AAHS) and ISCOMATRIX™ (IMX)
	Conditions:	Human Papilloma Virus; Cervical Cancer; Vulvar Cancer; Vaginal Cancer; Genital Warts	
	Interventions:	Biological: V502; Biological: Comparator: V502 Dose formulation 2; Biological: Comparator: V502 Dose formulation 3; Biological: Comparator: V502 Dose formulation 4; Biological: Comparator: Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant Vaccine (GARDASIL™) 2009	
Active, not recruiting	Vaccine Therapy in Treating Patients With Unresected Stage III or Stage IV Melanoma		Vaccines from white blood cells and a donor's tumor cells may help the body build an effective immune response to kill tumor
	Condition:	Melanoma (Skin) Matured Dendritic Cells Pulsed Ex Vivo With 3 Melanoma Cell Line Lysates (IDD-3)	
	Intervention:	Biological: autologous dendritic cell-allogeneic melanoma tumor cell lysate vaccine 2005	
<p>Primary Outcome: •Tumor control rate (complete response, partial response, or stable disease) for 4-8 weeks</p> <p>Secondary Outcome: •Safety and •Immune response</p> <p>Primary: •Determine the clinical activity of vaccine therapy comprising autologous dendritic cells pulsed with allogeneic melanoma tumor cell lysates (IDD-3), as measured by tumor control, in patients with unresected stage IIIB or IIIC or stage IV melanoma.</p> <p>Secondary: •Determine the immunologic activity of this vaccine, as measured by T-cell and antibody responses to lysate or to melanoma antigens or peptides, in these patients. •Determine the safety of this vaccine, as measured by the incidence and severity of adverse events, in these patients.</p> <p>patients are followed at 2, 10, 18, and 26 weeks</p>			
Active, not recruiting	Aldesleukin With or Without Vaccine Therapy in Treating Patients With Stage IV Melanoma		IL-2 With or Without an Allogeneic Large Multivalent Immunogen (LMI) Vaccine for the Treatment of Stage IV Melanoma
	Condition:	Stage IV Melanoma	
	Interventions:	Biological: aldesleukin; Biological: allogeneic large multivalent immunogen vaccine 2008	
<p>Aldesleukin may stimulate the white blood cells to kill tumor cells. Vaccines may help the body build an effective immune response to kill tumor cells. Giving aldesleukin together with vaccine therapy may kill more tumor cells. It is not yet known whether aldesleukin is more effective with or without vaccine therapy in treating melanoma.</p> <p>Primary Outcome: •Progression-free survival [at 2 months]. /To determine progression free survival (PFS) of LMI vaccination plus IL-2, IL-2 alone, and crossover . Progression free survival will be measured in months from time of response to time of disease progression as defined by Solid Tumor Response Criteria (RECIST).</p> <p>Secondary Outcome: •Clinical response [2 months]. /To determine clinical response of each treatment group - Clinical response will be determined using Solid Tumor Response Criteria (RECIST). /•Survival [1 Year, 2 Years]. /To determine one and two year survival rates of each treatment group. /•Immune response [48 hours]. /Immune responses will be assessed by Delayed Type Hypersensitive (DTH) responses to LMI, IFN-γ production by CD8 T cells using the ELISPOT assay, and CD8 T cell binding to HLA-A2 multimers complexed with melanoma-derived peptides (pentamer analysis). DTH reactions are determined at 48 hours by measuring the largest diameter and right angle diameter of the area of induration and calculating the mean. DTH responses are recorded as present or absent but cannot be used as a quantitative measure of immune activation.</p> <p>Patients undergo blood sample collection periodically for correlative laboratory studies. Samples are analyzed for immune responses to keyhole limpet hemocyanin and tetanus toxoid (control antigens) by ELISA assay; IFN-γ production by CD8 T cells in response to melanoma-derived peptides by ELISpot assay; delayed-type hypersensitivity response to vaccination; and frequency of peripheral blood lymphocytes, including T cells, B cells, NK cells, and monocytes, by flow cytometry.</p>			
Completed	Active Specific Immunotherapy for Follicular Lymphomas With Tumor-Derived Immunoglobulin Idiotype Antigen Vaccines		Immunotherapy for Follicular Lymphomas With Tumor-Derived Immunoglobulin Idiotype Antigen Vaccines
	Conditions:	B Cell Lymphoma; Follicular Lymphoma; Lymphoma	
	Interventions:	Drug: Id-KLH Vaccine; Drug: GM-CSF 1999	