	The idiotype of the immunoglobulin on a given B cell malignancy (Id) can serve as a clonal marker, and a previous pilot study in lymphoma patients has demonstrated that autologous Id protein can be formulated into an immunogenic, tumor specific antigen by conjugation to a carrier protein (KLH) and administration with an emulsion-based adjuvant. The goals of vaccine development in the current study are to develop vaccines: 1) with improved potency and 2) which are more effective at inducing cell-mediated immune responses. The selection of GM-CSF as the immunological "adjuvant" is a direct extension of our laboratory studies in small animal models demonstrating that GM-CSF can enhance the potency of the prototype Id-KLH vaccine by augmenting almost exclusively the cellular arm of the immune response.		
Recruiting	Monoclonal Antibody Therapy and Vaccine Therapy in Treating Patients With Stage IV Melanoma That Has Been Removed By		This phase I trial is studying the side effects and best dose of anti-PD-1 human monoclonal antibody MDX-1106 when given together with and vaccine therapy in treating patients with stage IV melanoma that has been removed by surgery
	Condition:	Melanoma (Skin)	
	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	
	Primary: •To assess the safety and tolerability of treatment with anti-PD-1 human monoclonal antibody MDX-1106 in combination with a peptide vaccine comprising gp100:209-217(210M) peptide, MART-1:26-35(27L) peptide, gp100:280-288(288V) peptide, NY-ESO-1 peptide, and Montanide ISA 51 VG in patients with HLA-A*0201-positive, resected stage IV melanoma. Secondary: •To evaluate the immune response to this treatment at week 12 compared to the immune response to treatment with the peptide vaccine alone that was determined in previous studies. /To assess the host immune response (immunogenicity) to anti-PD-1 human monoclonal antibody MDX-1106. /•To assess, preliminarily, the efficacy of this treatment as measured as time to relapse. Patients are followed up for up to 2 years. RATIONALE: Monoclonal antibodies, such as anti-PD-1 human monoclonal antibody MDX-1106, can block tumor growth in different ways. Some block the ability of tumor cells to grow and spread. Others find tumor cells and help kill them or carry tumor-killing substances to them. Vaccines made from peptides may help the body build an effective immune response to kill tumor cells. Giving monoclonal antibody therapy together with vaccine therapy may be an effective treatment for		
Completed	Vaccine Treatment for Advanced Malignant Melanoma		Antitumor Vaccination Using Alpha(1,3)Galactosyltransferase Expressing Allogeneic Tumor Cells for Refractory or Recurrent Malignant Melanoma
	Condition:	Malignant Melanoma	
	Intervention:	Biological: HyperAcute-Melanoma Vaccine 2006	

	Primary Outcome: •Number of Subjects Who Seroconverted for Anti-human Papilloma Virus 16 (Anti-HPV-16) and Anti-human Papilloma Virus 18 (Anti-HPV-18) Antibodies [Month 7]. /Seroconversion is defined as the appearance of antibodies with titers greater than or equal to the predefined cut-off value in the serum of subjects seronegative before vaccination. Cut-off values assessed include 8 enzyme-linked immunosorbent assay units per milliliter (EL.U/mL) for anti-HPV-16 antibodies and 7 EL.U/mL for anti-HPV-18 antibodies. **Secondary Outcome**: •Titers of Anti-human Papilloma Virus 16 (Anti-HPV-16) and Anti-human Papilloma Virus 18 (Anti-HPV-18) Antibodies [Month 7]. /Titers are given as Geometric Mean Titers (GMTs) expressed as Enzyme-linked Immunosorbent Assay Units Per Milliliter (EL.U/mL). •Number of Subjects Reporting Solicited Symptoms [7 days]. /Solicited local symptoms assessed include pain, redness and swelling. Solicited general symptoms assessed include arthralgia, fatigue, fever, gastro-intestinal symptoms, headache, myalgia, rash and urticaria. •Number of Subjects Reporting Unsolicited Adverse Events (AEs) [Within 30 days]. /Unsolicited adverse event = Any adverse event (AE) reported in addition to those solicited during the clinical study. Also any "solicited" symptom with onset outside the specified period of follow-up for solicited symptoms was reported as an unsolicited adverse event. •Number of Subjects Reporting Unsolicited Adverse Events as New Onset Chronic Diseases (NOCDs) and Other Medically Significant Adverse Events (AEs) [(up to Month 7)]. /NOCDs assessed include e.g. autoimmune disorders, asthma, type I diabetes, allergies,... Medically significant AEs assessed include AEs prompting emergency room or physician visits that are not related to common diseases or routine visits for physical examination or vaccination, or SAEs that are not related to common diseases. •Number of Subjects Reporting Serious Adverse Events [(up to Month 7)]. /Serious adverse events assessed include medical occurrences that results in death, is life threatening, require hospitalization or prolongation of hospitalization, result in disability/incapacity or are a congenital anomaly/birth defect in the offspring of a study subject	
Completed Has Results	Study to Evaluate the Immune Response and Safety of GSK Biologicals' HPV Vaccine in Healthy Women Aged 18–35 Years Conditions: Human Papillomavirus (HPV) Infection; Associated Cervical Neoplasia Interventions: Biological: Placebo; Biological: HPV-16/18 L1 VLP AS04 (Cervarix TM)	to Evaluate the Immunogenicity & Safety of GSK Biologicals' HPV-16/18 L1 VLP AS04 Vaccine
Completed	Vaccine Therapy in Treating Patients With Advanced Melanoma Conditions: Intraocular Melanoma; Malignant Conjunctival Neoplasm; Melanoma (Skin) Interventions: Biological: incomplete Freund's adjuvant; Biological: multi-epitope melanoma peptide vaccine; Biological: tetanus toxoid helper peptide; Procedure: biopsy 2008	Multipeptide Vaccine in Melanoma Patients With Evaluation of the Injection Site Microenvironment
	Primary Outcome: •Features of lymphoid neogenesis at the replicate immunization site. **Secondary Outcome**: •Proliferating T cells in the replicate immunization site. /•Toll-like receptor signaling in the replicate immunization site. / •Regulatory processes in the replicate immunization sites. /•CD8+ and CD4+ peptide-reactive T-cell responses among lymphocytes infiltrating skin at the replicate immunization sites and in the peripheral blood. /•CCR and integrin expression on vaccine-induced T cells in the peripheral blood and at the replicate immunization site.	
Recruiting	Dendritic Cell Based Therapy for Breast Cancer Patients Condition: Breast Cancer Interventions: Biological: DC vaccine; Drug: Exemestane 2009	p53peptide-pulsed Dendritic Cells in Combination With Second Line Endocrine Therapy (Exemestane, Aromasin®) as Treatment for Breast Cancer
	Primary Outcome: •To determine time to progression [after 8 and 16 weeks] **Secondary Outcome**: •To evaluate safety of DC vaccination in combination with Exemestane, to evaluate clinical tumor response, to evaluate treatment induced immune response to p53 end to evaluate duration of tumor and immune responses [Weekly the first 4 weeks, thereafter biweekly for five months, thereafter monthly] Detailed Description: Only patients who have tumors > 5 % positive for p53 by IHC can be referred to this treatment. All patients will receive standard dosage of Exemestane +/- p53-DC vaccination. Patients who express HLA-A2 will also receive DC vaccination. Patients that do not express HLA-A2 will receive only Exemestane and be regarded as controls.	

Completed	Evaluation of the Immune and Safety Response of GlaxoSmithKline (GSK) Biologicals' HPV Vaccine in Healthy Indian Women	
Has Results	Conditions: Cervical Cancer; Papillomavirus Infection	
	Interventions: Biological: HPV-16/18 VLP/AS04 Vaccine (Cervarix TM); Biological: Placebo 2009	
Active, not recruiting	Chemotherapy, Radiation Therapy, and Vaccine Therapy With Basiliximab in Treating Patients With Glioblastoma Multiforme That Has Been Removed by Surgery	Primary: ·Functional suppressive capacity of CD4+CD25+CD127- T-regulatory cells. /·Comparison of proliferative T-cell response to PHA among treatment groups
	Condition: Brain and Central Nervous System Tumors	
	Interventions: Biological: PEP-3-KLH conjugate vaccine; Biological: daclizumab; Drug: temozolomide; Other: placebo; Biological: PEP-3-KLH (with versus without daclizumab/basiliximab) [26 months] 2008	
	Primary: •To determine if basiliximab inhibits the functional and numeric recovery of T-regulatory cells (Tregs) after therapeutic temozolomide (TMZ)-induced lymphopenia in the context of vaccinating adult patients with newly diagnosed glioblastoma multiforme (GBM) using PEPvIII-keyhole limpet hemocyanin (KLH). **Secondary:** •To evaluate the safety of basiliximab in the context of vaccinating adult patients with newly diagnosed GBM using PEP-3-KLH conjugate vaccine during recovery from therapeutic TMZ-induced lymphopenia. /•To determine if basiliximab enhances the magnitude or character of PEPvIII-KLH-induced cellular or humoral immune responses, inhibits or enhances activation-induced cell death, or induces immunologic or clinical evidence of autoimmunity. /•To determine if basiliximab enhances the magnitude or character of PEPvIII-KLH-induced cellular or humoral immune responses, inhibits or enhances activation-induced cell death, or induces immunologic or clinical evidence of autoimmunity. /•To determine if basiliximab alters the phenotype (CD56-expression), cytokine secretion profile, or cytotoxicity of CD3-negative CD56-positive natural killer cells. /•To determine if basiliximab, in addition to vaccination, extend progression-free survival compared to historical cohorts. /•To characterize immunologic cell infiltrate in recurrent tumors and seek evidence of antigen escape outgrowth. RATIONALE: Drugs used in chemotherapy, such as temozolomide, work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. Radiation therapy uses high-energy x-rays to kill tumor cells. Vaccines may help the body build an effective immune response to kill tumor cells. Monoclonal antibodies, such as basiliximab, can block tumor growth in different ways. Some block the ability of tumor cells to grow and spread. Others find tumor cells and help kill them or carry tumor-killing substances to them. It is not yet known whether giving chemotherapy, radiation therapy, and vaccine therapy together with basiliximab is a more effective treatment for glioblastoma multiforme than chemotherapy, radiation therapy, and vaccine therapy alone.	
Active, not recruiting	Rituximab, Autologous Vaccine Therapy, and Sargramostim in Treating Patients With Recurrent or Refractory Follicular B-Cell	Rituxan Plus FavId (Tumor-Specific Idiotype-KLH) and GM-CSF Immunotherapy in Patients With Grade 1 or 2 Follicular B-Cell Lymphoma
	Condition: Lymphoma	
	Interventions: Biological: autologous immunoglobulin idiotype-KLH conjugate vaccine; Biological: rituximab; Biological: sargramostim 2003	
	OBJECTIVES: •*Compare the 9-month objective response rate of patients with recurrent or refractory grade I or II follicular B-cell lymphoma treated with rituximab,* autologous immunoglobulin idiotype-KLH conjugate vaccine, and sargramostim (GM-CSF) vs historical control patients who received rituximab alone./•Compare the median duration of response and median time to progression in patients treated with this regimen vs historical controls. /•Determine the immune response (humoral and/or cellular) of patients treated with this regimen. /•Determine the safety of this regimen in these patients. Patients are followed every 6 months for at least 2 years. RATIONALE: Monoclonal antibodies such as rituximab can locate cancer cells and either kill them or deliver cancer-killing substances to them without harming normal cells. Vaccines made from a person's cancer cells may make the body build an immune response to kill cancer cells. Colony-stimulating factors such as sargramostim increase the number of immune cells found in bone marrow or peripheral blood. Combining rituximab with autologous vaccine therapy and sargramostim may cause a stronger immune response and kill more cancer cells.	
Active, not	Vaccine Therapy in Treating Patients With Acute Lymphoblastic Leukemia	Vaccination With Autologous CD40-

recruiting	Condition:	Leukemia	Activated Acute Lymphoblastic Leukemia Cells
	Intervention:	Biological: autologous tumor cell vaccine 2001	
	OBJECTIVES: •Determine the feasibility of generating a vaccine comprising CD40-activated autologous leukemic cells for patients with B-cell acute lymphoblastic leukemia (ALL). /•Determine the feasibility of this regimen in patients with B-cell ALL./ •Determine the toxicity of this regimen in these patients. /•Assess the ALL-specific immunity in patients treated with this regimen. /•Assess the generation of immunity to control antigens in patients treated with this regimen. /•Determine, in a preliminary manner, the effect of this regimen on tumor response in these patients. Patients are followed at approximately 2 months after last vaccination.		
Active, not recruiting	Vaccine Therapy Followed by Biological Therapy in Treating Patients With Stage III or Stage IV Melanoma		a MART-1/gp100/Tyrosinase Peptide-Pulsed Dendritic Cell Vaccine Treated With CD40 Ligand/Gamma Interferon With Subcutaneous IL-2 for Metastatic Melanoma
	Condition:	Melanoma (Skin)	
	Interventions:	Biological: MART-1 antigen; Biological: aldesleukin; Biological: gp100 antigen; Biological: recombinant CD40-ligand; Biological: recombinant interferon gamma; Biological: recombinant interleukin-4; Biological: sargramostim; Biological: therapeutic autologous dendritic cells; Biological: therapeutic tumor infiltrating lymphocytes; Biological: tyrosinase peptide; Radiation: Candida albicans skin test reagent	
	OBJECTIVES: •Determine the clinical response rate and immune response in HLA-A2 positive patients with stage III or IV melanoma after receiving autologous dendritic cells pulsed with melanoma antigen peptides (MART-1:26-35, gp100:209-217, and tyrosinase:368-376) and treated ex vivo with CD40-ligand and interferon gamma, followed by interleukin-2 in vivo. /•Determine the toxicities of this regimen in these patients. Patients are followed at 4 weeks, then every 3 months for 2 years, then every 6 months for 3 years, and then annually thereafter. **RATIONALE:** Vaccines made from melanoma cells may make the body build an immune response to kill tumor cells. Biological therapies such as interferon gamma and interleukin-2 use different ways to stimulate the immune system and stop cancer cells from growing. Combining vaccine therapy with biological therapy may kill more tumor cells		
Completed	A Study to Evaluate Tolerability and Immunogenicity of V504 Administered Concomitantly With GARDASIL		
	Conditions:	Cervical Cancer; Vulvar Cancer; Vaginal Cancer; Genital Warts; Human Papillomavirus Infection	
	Interventions:	Biological: V504; Biological: Comparator: Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant Vaccine; Biological: Comparator: Placebo (unspecified)	
Completed	Vaccine Therapy Plus Interleukin-2 in Treating Patients With Stage III, Stage IV, or Recurrent Follicular Lymphoma		Immunotherapy for Follicular Lymphomas With Liposomes Containing Tumor-Derived Antigen and IL-2
	Condition:	Lymphoma	
	Interventions:	Biological: aldesleukin; Biological: autologous tumor cell vaccine 2001	
	OBJECTIVES: •Assess the safety of immunotherapy with autologous tumor cell vaccine and interleukin-2 in patients with stage III, IV, or recurrent follicular lymphoma. /•Determine the clinical response of patients treated with this regimen. /•Assess the immune response of patients treated with this vaccine. OUTLINE: This is a multicenter study. Patients are stratified according to prior therapy (no prior biologic therapy or chemotherapy for lymphoma vs prior prednisone, doxorubicin, cyclophosphamide, and etoposide (PACE) chemotherapy). Patients without prior therapy are further stratified according to accessibility of lymph nodes (easily accessible (stratum Ia) vs not easily accessible (stratum Ib)). Patients are followed at 1 and 4 months, every 3 months for 1 year, and every 6 months thereafter until relapse or progression of disease.		
Active, not recruiting	Vaccine Therapy in Treating Patients With Newly Diagnosed Glioblastoma Multiforme		Anti-Tumor Immunotherapy Targeted Against Cytomegalovirus in Patients With Newly-Diagnosed Glioblastoma Multiforme During Recovery From Therapeutic
	Condition:	Brain and Central Nervous System Tumors	
	Interventions:	Biological: tetanus toxoid; Biological: therapeutic autologous dendritic cells; Biological: therapeutic autologous lymphocytes 2008	

	Primary Outcome: •Feasibility and safety of vaccination with cytomegalovirus pp65-LAMP mRNA-loaded dendritic cells (DCs) with or without autologous lymphocyte transfer [26 months] **Secondary Outcome**: •Humoral and cellular immune responses [26 months]. /•Time to progression /•Differential ability of indium In-111-labeled DCs to track to the inguinal lymph nodes under different skin preparative conditions. /•Differential ability of indium In-111-labeled DCs to track to lymph nodes on the tumor bearing and non-tumor bearing side of the cervical lymph nodes. /•Immunologic cell infiltrate in recurrent tumors. /•Evidence of antigen-escape outgrowth in recurrent or progressive tumors. RATIONALE: Vaccines may help the body build an effective immune response to kill cancer cells. Radiation therapy uses high-energy x-rays to kill cancer cells. Drugs used in chemotherapy, such as temozolomide, work in different ways to stop the growth of cancer cells, either by killing the cells or by stopping them from dividing. Giving vaccine therapy together with radiation therapy and chemotherapy may kill more cancer cells.	
Completed	Tumor RNA Transfected Dendritic Cell Vaccines Condition: Prostate Cancer Intervention: Biological: Tumor RNA transfected dendritic cells 2005	
	Purpose: The purpose of this study is to use dendritic cells transfected with amplified RNA from autologous tumor cells to develop a vaccine strategy for the treatment of prostate cancer in patients with disseminated disease. **Detailed Description:** The specific aims are: 1) to evaluate, in a phase I clinical trial, the safety of vaccinating patients with dendritic cells transfected with RNA from autologous cancer cells; 2) to analyze the T cell responses induced by the treatment; and 3) to improve the efficacy of the treatment by developing methods to increase the induction of CD4+T cell responses.	
Active, not recruiting	Antiangiogenic Peptide Vaccine Therapy With Gemcitabine in Treating Patient With Pancreatic Cancer (Phase1/2) Condition: Pancreatic Cancer Interventions: Biological: VEGFR1-1084, VEGFR2-169; Drug: Gemcitabine 2008	Antiangiogenic Vaccine Therapy Using Epitope Peptide Derived From VEGFR1 and VEGFR2 With Gemcitabine in Treating
	Purpose : The purpose of this study is to evaluate the safety, and tolerability of HLA-A*2402 restricted epitope peptide VEGFR1 and VEGFR2 emulsified with Montanide ISA 51 in combination with gemcitabine. **Primary Outcome**: •toxicities as assessed by NCI-CACAE ver3) [3 months] **Secondary Outcome**: •Differences of peptide specific CTL response in vitro among sequence of gemcitabine and peptide vaccine administration [3months]. /•CD8 population [3months]. /•Change in level of regulatory T cells [3months]. /•Objective response rate [1year] . /•feasibility [1year]. / •Survival [1year] **Detailed Description:** Vascular endothelial growth factor receptor 1 and 2 (VEGFR1 andVEGFR2) 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 in vivo. According to these findings, in this trial, we evaluate the safety, tolerability and immune response of these peptide emulsified with Montanide ISA 51 in combination with gemcitabine	
Completed	Histocompatibility Leukocyte Antigen (HLA)-A*0201 Restricted Peptide Vaccine Therapy in Patients With Esophageal Cancer Condition: Esophageal Cancer 東大 Intervention: Biological: URLC10, VEGFR1 and VEGFR2 2008	Multiple-Vaccine Therapy Using Epitope Peptide Restricted to HLA-A*0201 for Refractory Esophageal Cancer

	Primary Outcome: •Safety(Phase I:toxicities as assessed by NCI CTCAE version3) and efficacy(Phase II:Feasibility as evaluated by RECIST) [Time Frame: two months] **Secondary Outcome**: •*To evaluate immunological responses [two months]* **Detailed Description:** URLC10 has been identified as cancer specific molecules especially in non small cell lung cancer using genome-wide expression profile analysis by cDNA microarray technique. In a prior study, it has been shown that URLC10 is upregulated in human esophageal tumors. 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, the URLC10-117 peptide(1mg), VEGFR1 peptide(1mg) and VEGFR2 peptide(1mg) mixed with Montanide ISA 51 will be administered by subcutaneous injection. Repeated cycles of 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 vaccines. In the following phase II study, we evaluate the immunological and clinical response of this vaccine therapy.	
Completed	Histocompatibility Leukocyte Antigen (HLA)-A*2402 Restricted Peptide Vaccine Therapy in Patients With Esophageal Cancer Condition: Esophageal Cancer 東大 Intervention: Biological: URC10, TTK, KOC1 2008	Multiple-Vaccine Therapy Using Epitope Peptide Restricted to HLA-A*2402 for Refractory Esophageal Cancer
	Primary Outcome: Safety(Phase I:toxicities as assessed by NCI CTCAE version3) and efficacy(Phase II:Feasibility as evaluated by RECIST) [2 months] Secondary Outcome: •To evaluate immunological responses [2 months]. **Detailed Description:** URLC10, KOC1 and TTK have been identified as cancer specific molecules especially in non small cell lung cancer using genome-wide expression profile analysis by cDNA microarray technique. In a prior study, it has been shown that URLC10, KOC1 and TTK are upregulated in human esophageal tumors. We identified that peptides derived from these proteins 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, the URLC10 peptide (1mg), KOC1 peptide (1mg), and TTK peptide (1mg) mixed with Montanide ISA 51 will be administered by subcutaneous injection. Repeated cycles of 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 vaccines. In the following phase II study, we evaluate the immunological and clinical response of this vaccine therapy.	
Completed	Histocompatibility Leukocyte Antigen (HLA)-A*0201 Restricted Peptide Vaccine Therapy in Patients With Gastric Cancer Condition: Gastric Cancer Intervention: Biological: URLC10, VEGFR1 and VEGFR2 2008	Multiple-Vaccine Therapy Using Epitope Peptide Restricted to HLA-A*0201 for Refractory Gastric Cancer

	Primary Outcome: safety (Phase I: toxicities as assessed by NCI CTCAE version 3) and efficacy (Phase II: evaluated by RECIST) [2 mo] **Secondary Outcome**: •To evaluate immunological responses [two months] **Detailed Description:** URLC10 has been identified as cancer specific molecules especially in non small cell lung cancer using genome-wide expression profile analysis by cDNA microarray technique. In a prior study, it has been shown that URLC10 is upregulated in human gastric tumors. 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, the URLC10-117 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 (S-1) simultaneously. Repeated cycles of 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 vaccines. In the following phase II study, we evaluate the immunological and clinical response of this vaccine therapy.	
Completed	Histocompatibility Leukocyte Antigen (HLA)-A*2402 Restricted Peptide Vaccine Therapy in Patients With Gastric Cancer		Multiple-Vaccine Therapy Using Epitope Peptide Restricted to HLA-A*2402 for Refractory Gastric Cancer
	Condition:	Gastric Cancer	
	Intervention:	Biological: URLC10, KOC1, VEGFR1 and VEGFR2 2008	
	Primary Outcome: •safety (Phase I: toxicities as assessed by NCI CTCAE version 3) and efficacy (Phase II: Feasibility as evaluated by RECIST) [2 months]. /**Secondary Outcom**: •To evaluate immunological responses [Time Frame: two months] Detailed Description: URLC10 and KOC1 have been identified as cancer specific molecules especially in non small cell lung cancer using genome-wide expression profile analysis by cDNA microarray technique. In a prior study, it has been shown that URLC10 and KOC1 are upregulated in human gastric tumors. 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, the URLC10 peptide (1mg), KOC1 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 (S-1) simultaneously. Repeated cycles of 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 vaccines. In the following phase II study, we evaluate the immunological and clinical response of this vaccine therapy.	
Recruiting	Reduced Intensity Stem Cell Transplantation for Chronic Lymphocytic Leukemia Followed by Vaccination		Stem Cell Transplantation for Advanced CLL Followed by Vaccination With Lethally Irradiated Autologous Tumor Cells Admixed With GM-CSF Secreting K562 Cells
	Condition:	Chronic Lymphocytic Leukemia	
	Interventions:	Biological: GM-K562 vaccine; Procedure: stem cell transplantation 2007	

	Primary Outcome:•To assess the safety and toxicity of vaccination with lethally irradiated autologous CLL cells admixed with GM-562 cells following reduced intensity allogeneic stem cell transplant for CLL patients with advanced disease. [: 2 years] **Secondary Outcome**: •To characterize the biologic activity in response to vaccination with lethally irradiated autologous CLL cells admixed with GM-562 cells, following reduced intensity allogeneic stem cell transplant [2 years]. •to estimate duration of disease response, disease free and overall survival. [2 years] Detailed Description: •This study can be divided into four phases: 1) Screening; 2) Reduced intensity transplant phase; 3) Vaccinations (cycle 1 and cycle 2:each cycle lasts 7 weeks) and 4) Vaccine completion. •Screening Phase: After signing the consent form, participants will be asked to undergo some screening tests and procedures to find out if they are eligible to participate in the study. These tests and procedures are likely to be part of regular cancer care and may be done even if the patient does not take part in the research study. It is important to note that if insufficient numbers of the participants leukemia cells to generate vaccine were collected on the CLL collection and banking study (DFHCC study #06-200), then they will not be eligible to participate in this study. •Allogeneic reduced intensity stem cell transplant phase: The transplant phase of the study will begin when the participant is admitted to the hospital to receive chemotherapy and stem cell transplant. The minimum duration of hospitalization for the procedure is approximately 8 days. Undergoing transplant involves the following procedures and treatments: Central intravenous catheter; chemotherapy; medications to prevent graft versus host disease (GVHD); medication to prevent infections; physical exams; blood tests and bone marrow biopsy and aspirate. •Vaccination Phase: Vaccinations will be given in two cycles, of seven weeks each, that are identical with the exception of when they are administered. Cycle 1 vaccination will begin approximately one month after the stem cells have been infused, provided there is no significant evidence of GVHD. Cycle 2 vaccination will be being approximately one month after discontinuing tacrolimus, provided there is no evidence of severe acute or chronic GVHD. The vaccine will be given 6 times over a period of two months. The participant will receive vaccination shots once weekly for 3 vaccines and then every other week for 3 vaccines. •Skin biopsies will be done after the first and after the fifth vaccinations. Current status of the participants CLL will be assessed to determine how the disease has responded to transplant and vaccination. These tests include analysis of bone marrow and blood tests. •Vaccine completion phase: After one cycle of vaccination is completed, the participant will return to the outpatient clinic monthly for check-ups for 6 visits, to monitor the effects of the vaccine. •Since this trial involves the use of genetically modified cells, it is recommended that participants on this trial undergo annual checkups for at least 20 years, in order to monitor for long term effects of the vaccination treatment.	
Recruiting	Autologous OC-DC Vaccine in Ovarian Cancer Conditions: Chemotherapy; Tumor; Ovarian Cancer Intervention: Biological: OCDC 2010	Dendritic Cell Vaccine Loaded With Autologous Tumor for Recurrent Ovarian, Primary Peritoneal or Fallopian Tube Cancer

	Primary Outcome: •Safety [30 days]. /Safety will be established by grading the observed toxicities using the NCI Common Toxicity Criteria (CTC Version3.0). All toxicities observed within 30 days of last vaccination will be included. **Secondary Outcome**: •Clinical Response. /Clinical Response will be determined by RECIST criteria. Response rate is the proportion of patients that achieve CR or PR. /•Dose limiting toxicity. /Dose-limiting toxicity is defined as: any Grade 3 or higher allergic, autoimmune or injection site reaction or any Grade 4 hematologic or non-hematologic toxicity (except fever). /•Immune Response Immune Response. /Immune response will be evaluated by IFN-g ELISPOT analysis of tumor-reactive T cells, and in HLAA2+ subjects, by tetramer analyis of Her-2 specific T cells in peripheral blood. Response is defined by a 3 fold increase relative to pre-vaccination. **Detailed Description**: The primary objective is to compare the feasibility and safety of administering OC-DC intranodally alone or and in combination with either intravenous Daclizumab alone or intravenous Bevacizumab and Daclizumab in subjects with recurrent ovarian, fallopian tube, primary peritoneal or papillary serous endometrial cancer. The secondary objective is to assess the immunogenicity of OC-DC administered alone or combined with either intravenous Daclizumab alone or intravenous Bevacizumab and Daclizumab and to assess the effect of OC-DC alone or combined with either intravenous Daclizumab alone or intravenous Bevacizumab and Daclizumab on peripheral blood T cell subsets including regulatory T cells and finally to asses the clinical response rates.	
Completed	Vaccination of Follicular Lymphomas With Tumor-Derived Immunoglobulin Idiotype Conditions: B Cell Lymphoma; Follicular Lymphoma; Neoplasm Interventions: Drug: Id-KLH Vaccine; Drug: QS-21 (Stimulation-QS-21) Drug 1999	Vaccination of Follicular Lymphomas With Tumor-Derived Immunoglobulin Idiotype
	Detailed Description: The idiotype of the immunoglobulin on a given B cell malignancy (Id) can serve as a clonal marker, and a previous pilot study in lymphoma patients has demonstrated that autologous Id protein can be formulated into an immunogenic, tumor specific antigen by conjugation to a carrier protein (KLH) and administration with an emulsion-based adjuvant. The objectives of this study are: 1) to evaluate feasibility and toxicity of new vaccine formulations, and 2) to evaluate cellular and humoral immune responses against the unique idiotype of the patient's lymphoma. The goal of this study is to treat patients with follicular lymphomas to complete remission or minimal residual disease with chemotherapy. Six to twelve months after completion of chemotherapy, in an effort to reduce the relapse rate (by eradicating microscopic disease resistant to chemotherapy), patients will receive one of two new formulations of an autologous Id vaccine	
Terminated	Histocompatibility Leukocyte Antigen (HLA)-A*2402 Restricted Peptide Vaccine Therapy in Patients With Breast Cancer Condition: Breast Cancer Intervention: Biological: TTK peptide mixed with Montanide ISA 51 2008	Multiple-Vaccine Therapy Using Epitope Peptide Restricted to HLA-A*2402 for Refractory Breast Cancer
	Primary Outcome: •safety (Phase I: toxicities as assessed by NCI CTCAE version3) and efficacy (Phase II: feasibility as evaluated by RECIST) [2 months] **Secondary Outcome**: •to evaluate immunological responses [Time Frame: 2 months] **Detailed Description**: TTK has been identified as cancer specific molecules especially in breast cancer using genome-wide expression profile analysis by cDNA microarray technique. We have determined the HLA-A*2402 restricted epitope peptide derived from this molecule and identified that this peptide significantly induces 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 that peptide. Patients will be vaccinated twice a week for 8 weeks. On each vaccination day, TTK-A24-567 peptide (1mg) mixed with Montanide ISA 51 will be administered by subcutaneous injection. Repeated cycles of 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 this peptide vaccine. In the following phase II study, we evaluate the immunological and clinical response of this vaccine therapy.	
Active, not recruiting	Vaccine Therapy and Sargramostim in Treating Patients With Soft Tissue Sarcoma Condition: Sarcoma Interventions: Biological: NY-ESO-1 peptide vaccine; Biological: sargramostim 2001	NY-ESO-1 Immunization in Patients With NY-ESO-1/LAGE Antigen Expressing Cancer

	OBJECTIVES: •Determine the safety and tolerability of NY-ESO-1 peptide vaccine and sargramostim (GM-CSF) in patients with stage II, III, or IV soft tissue sarcoma expressing NY-ESO-1 or LAGE antigen. /•Determine the immunologic profile (NY-ESO-1 antibody, CD8+ cells, and delayed-type hypersensitivity) in patients treated with this regimen. /•Determine tumor responses in patients treated with this regimen.15 patients will be accrued for this study within 12 months	
Recruiting	Histocompatibility Leukocyte Antigen (HLA)-A*2402 Restricted Peptide Vaccine Therapy in Patients With Non-Small Cell Lung Condition: Non Small Cell Lung Cancer Intervention: Biological: URLC10, TTK and KOC1 2008	Multiple-Vaccine Therapy Using Epitope Peptide Restricted to HLA-A*0201for Refractory Non-Small Cell Lung Cancer
	Primary Outcome: •safety(Phase I:toxicities as assessed by NCI CTCAE version3) and efficacy(Phase II:Feasibility as evaluated by RECIST) [two months] **Secondary Outcome**: •To evaluate immunological responses [Time Frame: two months] Detailed Description: URLC10,TTK and KOC1 has been identified as cancer specific molecules especially in non small cell lung cancer using genome-wide expression profile analysis by cDNA microarray technique. We have determined the HLA-A*2402 restricted epitope peptides derived from these molecules and identified that these peptides 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, the URLC10-177 peptide(1mg), TTK-567 peptide(1mg) and KOC1-508 peptide(1mg) mixed with Montanide ISA 51 will be administered by subcutaneous injection. Repeated cycles of 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.	
Recruiting	Histocompatibility Leukocyte Antigen (HLA)-A*0201 Restricted Peptide Vaccine Therapy in Patients With Non-Small Cell Lung Condition: Non Small Cell Lung Cancer Intervention: Biological: URLC10, VEGFR1 and VEGFR2 2008	Multiple-Vaccine Therapy Using Epitope Peptide Restricted to HLA-A*0201 for Refractory Non-Small Cell Lung Cancer
	Primary Outcome:•safety(Phase I:toxicities as assessed by NCI CTCAE version3) and efficacy(Phase II:Feasibility as evaluated by RECIST) [two months] **Secondary Outcome**: •To evaluate immunological responses [two months] •Time to progression [one years] **Detailed Description**: URLC10 has been identified as cancer specific molecules especially in non small cell lung cancer using genome-wide expression profile analysis by cDNA microarray technique. We have determined the HLA-A*0201 restricted epitope peptides derived from these molecules. We also tend to use the peptides targeting to tumor angiogenesis. 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, the URLC10-117 peptide(1mg), VEGFR1 peptide(1mg) and VEGFR2 peptide(1mg) mixed with Montanide ISA 51 will be administered by subcutaneous injection. Repeated cycles of 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.	
Suspended	Vaccine Therapy in Treating Patients With Stage III or Stage IV Melanoma Condition: Melanoma (Skin) 2006 Interventions: Biological: PADRE 965.10; Biological: alpha-type-1 polarized dendritic cells; Biological: keyhole limpet hemocyanin; Biological: therapeutic autologous dendritic cells; Other: immunoenzyme technique	Alpha-Type-1 DC-Based and cDC-Based Intralymphatic Vaccines in Patients With Metastatic Melanoma