	An Evaluation of the Immunological Parameters Associated With a Skin-Test and Immunization of Lung and Mesothelioma Cancer Patients With Autologous Lung Tumor Associated Antigen: Characterization of the Patients' Cytolytic and Helper T Cell Reactivity for Identification of the Specific Antigen(s): A Pilot Study OBJECTIVES: I. Define the immunological parameters of **cytolytic T cell and T helper cell activity** associated with **skin testing** and vaccination with **autologous lung tumor associated antigen and detoxPC** in patients with curatively resected stage I, II, or IIIA non-small cell lung cancer (NSCLC) or stage I or II mesothelioma. II. Evaluate any responses associated with an enhanced antitumor immune status in this patient population with this treatment regimen. OUTLINE: Patients undergo **delayed type hypersensitivity** skin testing with **autologous tumor associated antigen (TAA)** and **memory antigens** (i.e., **Monilia, PPD, and Trichophyton**) intradermally at 1-4 weeks following surgical tumor resection. At week 4-9, patients receive low dose cyclophosphamide IV once. At 3 days following chemotherapy, patients receive autologous TAA with DetoxPC intradermally for up to 3 doses over 4 weeks. At 2-3 weeks following vaccination, patients undergo repeat skin testing. At week 6-12, patients with a positive skin test undergo biopsy of the skin test/vaccination site followed by leukapheresis at week 12-20 if T cells exhibit active antitumor reactivity. Patients with stable or regressive disease receive additional vaccination courses at week 20 and thereafter. Patients are followed for 5 years. PROJECTED ACCRUAL: A total of 20 patients will be accrued for this study within 2 years.
Completed	Monoclonal Antibody Vaccine Therapy in Treating Patients With Ovarian Epithelial, Fallopian Tube, or Peritoneal Cancer Conditions: Fallopian Tube Cancer; Ovarian Cancer; Peritoneal Cavity Cancer 2003–2011 Intervention: Biological: abagovomab
	Phase I Trial of the **Monoclonal Anti-Idiotype Antibody ACA125** in Patients With Epithelial Ovarian, Fallopian Tube, or Peritoneal Cancer **OBJECTIVES: 1)** Determine the safety of varying routes and doses of monoclonal antibody ACA125 anti-idiotype vaccine in patients with ovarian epithelial, fallopian tube, or peritoneal cancer. 2) Determine an optimal dose and route of this vaccine for a phase II study. 3) Determine the immune response induced by this vaccination in these patients. 4) Determine the time to development of objective tumor response in patients treated with this regimen. **OUTLINE:** This is a multicenter study. Patients are randomized to 1 of 4 treatment arms. Arm I: Patients receive lower-dose monoclonal antibody ACA125 anti-idiotype vaccine (MOAB ACA125) intramuscularly (IM) on weeks 0, 2, 4, 6, 10, and 14 in the absence of disease progression or unacceptable toxicity. Arm II: Patients receive higher-dose MOAB ACA125 IM as in arm I. Arm III: Patients receive lower-dose MOAB ACA125 subcutaneously (SC) on weeks 0, 2, 4, 6, 10, and 14 in the absence of disease progression or unacceptable toxicity. Arm IV: Patients receive higher-dose MOAB ACA125 SC as in arm III. Patients are followed every 6-12 weeks for 2 years. PROJECTED ACCRUAL: A total of 40 patients (10 patients per cohort) will be accrued for this study
Active, not recruiting	Vaccine Therapy in Treating Patients With Stage IIB, Stage IIC, Stage III, or Stage IV Melanoma Condition: Melanoma (Skin) 2005–2009 Interventions: Biological: human gp100 plasmid DNA vaccine; Biological: mouse gp100 plasmid DNA vaccine

	Injection of AJCC Stage IIB, IIC, III, and IV Melanoma Patients With **Human and Mouse gp100 DNA**: A Phase I Trial to Assess Safety and Immune Response **Primary** 1) Determine the safety and feasibility of vaccination with human and mouse gp100 DNA in patients with stage IIB, IIC, III, or IV melanoma. 2) Determine the maximum tolerated dose of this regimen in these patients. 3) Compare the antibody and T-cell response in patients treated with two different vaccination schedules. **Secondary: 1)** Assess antitumor response in patients treated with this regimen. 2) OUTLINE: This is a randomized, crossover, dose-escalation study. Patients are randomized to 1 of 2 treatment arms. 3) Arm I: Patients receive human gp100 DNA vaccine intramuscularly (IM) once in weeks 1, 4, and 7. Patients then receive mouse gp100 DNA vaccine IM once in weeks 10, 13, and 16. 4) Arm II: Patients receive mouse gp100 DNA vaccine IM once in weeks 1, 4, and 7. Patients then receive human gp100 DNA vaccine IM once in weeks 10, 13, and 16. 5) In both arms, treatment continues in the absence of disease progression or unacceptable toxicity. Cohorts of 6-9 patients (at least 3 per treatment arm) receive escalating doses of human and mouse gp100 DNA vaccines until the maximum tolerated dose (MTD) is determined. The MTD is defined as the dose preceding that at which 2 of 9 patients experience dose-limiting toxicity. After completion of study treatment, patients are followed at 3 weeks and then annually for 15 years. PROJECTED ACCRUAL: Approximately 18-27 patients will be accrued for this study within 6-9 months.	
Recruiting	MAGE-A3/HPV 16 Vaccine for Squamous Cell Carcinoma of the Head and Neck Condition: Squamous Cell Carcinoma of the Head and Neck 2005-2009 Interventions: Biological: MAGE-A3; Biological: HPV-16 vaccine	

	A Phase 1 Open Label, Dose Escalation Study to Evaluate the Effect of Four Doses of MAGE-A3/HPV 16 Trojan Peptides 0001 and 0002 Administered Subcutaneously in Combination With Montanide and GM-CSF on Immunological Response, Safety, Tolerability, and Preliminary Efficacy in Patients With Squamous Cell Carcinoma of the Head and Neck. Three dose levels of MAGE-A3 vaccine and HPV 16will be tested : 500ug, 1000 ug and 1500 ug Squamous Cell Carcinoma of the Head and Neck affects 43,000 individuals in the United States annually with an estimated overall survival rate of 50%. In order to improve both the survival rate and quality of life for patients who develop unresectable disease recurrence, new therapeutic alternatives are mandated. One potential treatment alternative for this patient population is the use of peptide-based immunotherapy. Despite the success fo preclinical studies using peptide vaccines, therapeutic responses in patients have been sporadic. The reasons for failure are multifactorial and include problems with patient selection, a limited number of antigenic targets, and an inability to correlate immunologic response with therapeutic efficacy. Specifically, patients with disseminated SCCHN have defects in antigen processing, presentation and effector mechanisms that limit their ability to respond to T cell based immunotherapy. Additionally, a paucity of antigenic peptide epitopes are defined for SCCHN, and immunologic monitoring does not correlate well with clinical response. Recently several investigators, including our research team, have identified a high prevalence of MAGE-A3 and HPV 16 on SCCHN, and characterized several putative cytolytic and helper epitopes. Additionally, we have defined a novel method to enhance the immune response to therapeutic peptide vaccines using Trojan complexes composed of CD4 and CD8 T-cell epitopes, connected by furin cleavable linkers. In order to define the feasibility and safety of these agents in combination with GM-CSF and montanide ISA 51 for the immunotherapy of SCCHN, in this proposed trial, we will screen patients for immunologic competence based on specific eligibility criteria including both antigen and HLA-A2 expression on tumors. In registered patients, we will test the ability of two novel Trojan peptide complexes, composed of MAGE-A3 and human papilloma virus 16 (HPV 16) epitopes, to stimulate antigen-specific CD 4 and CD 8 T-cell responses. Finally, we will correlate immunologic response with cell dose and the generation of both HPV 16 and MAGE-A3 antigen loss and HLA-A2 loss variants on tumors by evaluating patients for: 1) Changes in tumor size by both physical measurement and CT plus PET measurement; 2) Determining what proportions of individuals who achieve a complete response (CR), partial response (PR), or have stable disease (SD); 3) Progression-free survival; 4) Survival. Successful completion of this clinical trial will result in the development of a strong foundation for a Phase II/III clinical trial using HPV 16 and MAGE-A3 Trojan peptides for the immunotherapy of SCCHN.
Recruiting	Safety Study of Multiple-Vaccine to Treat Metastatic Breast Cancer Condition: Metastatic Breast Cancer 2010-2012 Intervention: Biological: CDCA1, URLC10, KIF20A, DEPDC1 and MPHOSPH1

	Phase I Study of Multiple-Vaccine Therapy Using Epitope Peptides Restricted to HLA-A*2402 in Treating Patients With Refractory Breast Cancer Primary: safety (Phase I: toxicities as assessed by NCI CTCAE version3) [Time Frame: 1 month] Secondary: 1) •to evaluate efficacy (feasibility as evaluated by RECIST) [Time Frame: 2 months]. 2) to evaluate overall survival to evaluate progression free survivial to evaluate efficacy (feasibility as evaluated by RECIST) to evaluate immunological responses to evaluate quality of life Biological: CDCA1, URLC10, KIF20A, DEPDC1 and MPHOSPH1 CDCA1, URLC10, KIF20A, DEPDC1 and MPHOSPH1 peptides mixed with Montanide ISA 51 Patients will be vaccinated once a week until patients develop progressive disease or unacceptable toxicity. On each vaccination day, CDCA1 URLC10, KIF20A, DEPDC1 and MPHOSPH1 peptides (0.5, 1 or 2mg of each peptide) mixed with Montanide ISA 51 will be administered by subcutaneous injection. CDCA1, URLC10, KIF20A, DEPDC1 and MPHOSPH1 have 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 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 these peptides. Patients will be vaccinated once a week until patients develop progressive disease or unacceptable toxicity. On each vaccination day, CDCA1, URLC10, KIF20A, DEPDC1 and MPHOSPH1 peptides (0.5, 1 or 2mg of each peptide) 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 peptides vaccine. Also we evaluate the immunological and clinical response of this vaccine therapy.
Completed	flt3L With or Without Vaccine Therapy in Treating Patients With Metastatic Melanoma or Renal Cell Cancer Conditions: Stage IV Melanoma; Stage IV Renal Cell Cancer; Recurrent Renal Cell Cancer; Recurrent Melanoma 2007- Interventions: Drug: flt3 ligand; Drug: gp100 antigen; Drug: MART-1 antigen; Drug: Montanide ISA-51; Drug: tyrosinase
	The drug **flt3L** may stimulate a person's immune system and help to kill tumor cells. Vaccines made from melanoma cells may make the body build an **immune response to and kill their tumor cells**. PURPOSE: Phase II trial to study the effectiveness of flt3L with or without vaccine therapy in treating patients with metastatic melanoma or renal cell cancer. OBJECTIVES: I. Evaluate the immunologic and biologic activity of flt3 ligand (Flt3L) alone in patients with metastatic renal cell cancer or HLA-A2.1 negative melanoma. II. Evaluate the immunologic and biologic activity of Flt3L alone or in combination with melanoma peptide immunization (MART-1, gp100:209-217, gp100:280-288, and tyrosinase) in patients with metastatic, HLA-A2.1 positive melanoma. PROTOCOL OUTLINE: Patients are assigned to 1 of 3 treatment groups: Group 1 (renal cell cancer): Patients receive Flt3 ligand (Flt3L) subcutaneously (SQ) alone on days 1-14. Group 2 (HLA-A2.1 negative melanoma): Patients receive Flt3L SQ alone on days 1-14. Group 3 (HLA-A2.1 positive melanoma): Patients may receive either Flt3L SQ alone on days 1-14 or in combination with melanoma peptide immunization. Patients may receive melanoma peptide immunization comprised of MART-1 immunodominant peptide, gp100:209-217, gp100:280-288, and tyrosinase peptide emulsified in Montanide ISA-51 SQ on day 12 of Flt3L administration. Treatment repeats every 4 weeks for 2 courses. Patients with no response or minor response may receive 2 additional courses. Patients with disease progression after 1 course are removed from study. PROJECTED ACCRUAL: Approximately 54-96 patients (18-32 per treatment group) will be accrued for this study within 16 months
Active, not recruiting	Antiangiogenic Peptide Vaccine Therapy With Gemcitabine in Treating Patient With Pancreatic Cancer Condition: Pancreatic Cancer 2008 Intervention: Biological: VEGFR1-1084, VEGFR2-169, and gemcitabine

	Phase I Sturdy on **Antiangiogenic Vaccine** Therapy Using Epitope Peptide Derived From VEGFR1 and VEGFR2 With Gemcitabine in Treating Patients With Unresectable, Recurrent, or Metastatic Pancreatic Cancer Primary: •Adverse effect, toxicities as assessed by NCI CTCAE version3.0 [Time Frame: 3 months] [Designated as safety issue: Yes] Secondary: •feasibility [Time Frame: 2 years] [Designated as safety issue: No] **VEGFR1-1084, VEGFR2-169**, and gemcitabine. One mg of each peptide will be administered by subcutaneous injection on days 1, 8, 15, and 22 of each 28-day treatment cycles. Gemcitabine will be administered intravenously at a fixed dose of 1000mg/m2 on day 1, 8 and 15. 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	Gemcitabine With Antiangiogenic Peptide Vaccine Therapy in Patients With Pancreatic Cancer Condition: Pancreatic Cancer 2008–2009 Intervention: Biological: VEGFR2–169 and gemcitabine	
	Primary: 1) Safety(toxicities as assessed by NCI CTCAE version 3) [Time Frame: 3 months] **Secondary**: 1) VEGFR2 peptide specific CTL induction in vitro [3 mos], 2) DTH to VEGFR2 peptide [3 mo], 3) Changes in levels of regulatory T cells [3 mo], 4) Objective response rate as assessed by RECIST criteria [1 year], 5) Time to progression [1 yrs], 6) survival [1 yrs], Biological: VEGFR2-169 and gemcitabine Escalating doses of VEGFR2-169 will be administered by subcutaneous injection on days 1,8,15 and 22 of each 28-day treatment cycles(doses of 0.5,1.0,2.0mg/body are planned). Gemcitabine will be administered intravenously at a fixed dose of 1000mg/m2 on days 1,8 and 15. Repeated cycles of VEGFR2-169 and gemcitabine will be administered until patients develop progressive disease or unacceptable toxicity,or for maximum 2 cycles, whichever occurs first. Vascular endothelial growth factor receptor 2(VEGFR2) is essential target for tumor angiogenesis, and VEGFR2-169 induces specific Cytotoxic T lymphocytes (CTL) against VEGFR2 expressed targets. VEGFR2-169 shows strong anti-tumor effects restricted to HLA-A*2402 in vitro, and this peptide induces CTL from cancer patients. 60% in Japanese population have HLA-A*2402. VEGFR2-169 is suitable for clinical trial, and gemcitabine has been approved against pancreatic cancer. Gemcitabine is reported to improve immune-response, therefore synergistic effect between vaccine therapy and chemotherapy will be expected. In this clinical trial, we evaluate the safety, tolerability and immune response of different doses of VEGFR2-169 emulsified with Montanide ISA 51 in combination with gemcitabine and to determine the recommended phase II dose of peptide.	
Active, not recruiting	Peptide Vaccine and S-1/CPT-11 Therapy for Patients With Unresectable Advanced Colorectal Cancer Condition: Colorectal Cancer 2008– Intervention: Biological: RNF43–721	

	The purpose of this study is to evaluate the safety and immune response of different doses of RNF43-721 emulsified with Montanide ISA 51 in combination with S-1/CPT-11 chemotherapy. Primary: •Safety (toxicities as assessed by NCI CTCAE version 3) [Time Frame: 2 months] Secondary: Specific CTL induction in vitro, Objective rate as assessed by RECST criteria [Time Frame: 2 months RNF43 (0.5mg, 1.0mg, 3.0mg/body/week) is a cancer testis antigen which express widely in colorectal cancer tissue but not in normal organs. RNF43-721 induces HLA A24 restricted specific cytotoxic T lymphocytes (CTL) against RNF43 expressed target. S-1/CPT-11 chemotherapy is performed unresectable advanced colorectal cancer in Japan and is reported to be obtained almost the same result compared with FOLFOX or FOLFIRI as first-line chemotherapy for advanced colorectal cancer. Because synergistic effect between vaccine therapy and chemotherapy will be expected, we plan phase I study to evaluate the safety and immune response of different doses of RNF43-721 emulsified with Montanide ISA 51 in combination with S-1/CPT-11 chemotherapy
Recruiting	Evaluate Safety of a Vaccine Against Cervical Cancer (HPV-16/18 L1/AS04) in Healthy Filipino Females Aged 10 Yrs & Above Conditions: HPV-16/18 Infections and Associated Cervical Neoplasia; Papillomavirus Vaccines Intervention: Biological: Cervarix
Recruiting	A Phase I/II Study Of Immunization With Lymphotactin And Interleukin 2 Gene Modified Neuroblastoma Tumor Cells Condition: Neuroblastoma 2008-2012 Intervention: Biological: SJNB-JF-IL2 and SJNB-JF-Lptn cells and SKNLP Unmodified Neuroblastoma Cell Lines

	The investigators intend to test the safety, and immunologic and clinical efficacy of a combination of 2 allogeneic neuroblastoma tumor cell line vaccines, one of which has been genetically modified to secrete the cytokine/chemokine combination of IL-2 and lymphotactin, in patients undergoing chemotherapy for newly diagnosed, high risk neuroblastoma who receive single autologous stem cell rescue as consolidation therapy. This protocol will be carried out as a Phase I/IIa study to evaluate the safety and toxicity of adding a previously unstudied, unmodified, irradiated neuroblastoma cell line (SKNLP) to a studied, safe dose of a gene modified, IL-2/Lptn secreting neuroblastoma cell line SJNB-JF-IL2/Lptn to be given as a vaccine to patients diagnosed with high risk neuroblastoma. **Primary**: 1) Evaluate the safety of repeated immunization with gene-modified, IL-2/lymphotactin secreting SJNB-JF-IL2 and SJNB-JF-Lptn cells co-administered with the unmodified SKNLP neuroblastoma cell line. [1 year], 2) Evaluate the immune response to these immunizations. [1 year], 3) Evaluate changes in minimal residua disease load by polymerase chain reaction pre- and post-vaccination. [1 year] **Secondar**: 1) Estimate 3 year progression free survival (PFS) and overall survival (OS) in vaccinated patients. Biological: SJNB-JF-IL2 and SJNB-JF-Lptn cells and SKNLP Unmodified Neuroblastoma Cell Lines *SJNB-JF-IL2 and SJNB-JF-Lptn cells are each dosed at 1x10e7 cells/m2/vaccination. •Dose Level 1 (3-6 patients) 1x10e6 cells/m2/vaccination dose of SKNLP Unmodified Neuroblastoma Cell Line Vaccine Component. • Dose Level 2 (3-6 patients) 1x10e7 cells/m2/vaccination dose of SKNLP Unmodified Neuroblastoma Cell Line Vaccine Component. TREATMENT PLAN: Standard Chemotherapy for Neuroblastoma: Standard therapy for neuroblastoma is given in 3 phases: induction, consolidation, and maintenance. For enrollment in this vaccine study patients and their physicians must anticipate therapy that will include consolidation with high dose chemotherapy with stem cell rescue. They will be eligible for enrollment in the phase I or phase II trial of vaccination with gene modified and unmodified, allogeneic neuroblastoma cell lines. Patients will receive Induction, Consolidation, and Maintenance therapy per their institutional standards. A general description of the therapy follows: •Induction: Induction consists of multiple cycles of induction chemotherapy with harvest of autologous stem cells immediately following a particular cycle of chemotherapy per institutional standards. Local control of the tumor with radiation therapy and/or surgery occurs following a few cycles of induction chemotherapy or immediately prior to consolidation therapy. •Consolidation: Consolidation must consist of high dose chemotherapy with autologous stem cell rescue (HDT/SCR). •Maintenance: Starting day +90 after HDT/SCR, patients will be treated with Isotretinoin (Cis-Retinoic Acid, CRA).

	VACCINE DOSING: Vaccine components SJNB-JF-IL2 and SJNB-JF-Lptn will each be dosed at 1x10e7 cells/m2. This will be given in conjunction with an escalating dose of SKNLP vaccine in the phase I portion of this study. In the phase II portion of this study, the same dose of SJNB-JF-IL2 and SJNB-JF-Lptn will be given in conjunction with the highest dose of SKNLP determined in the phase I portion. Vaccination will be administered on an inpatient or outpatient basis. Patient will be notified of which dose of vaccine cells they will receive if enrolled in the study. Phase I Dose Escalation Component: While the investigators do not suspect that addition of a second irradiated, unmodified neuroblastoma tumor cell line to the previously tested SJNB-JF gene modified cell line will affect the safety profile of the vaccine, as the SKNLP has not been tested previously in vaccine studies, the investigators will perform an abbreviated dose escalation study of the combined vaccine to assess safety. The investigators know that the vaccine given to patients whose neuroblastoma returned was safe. The vaccine that was given to those patients was treated with the viruses to make cytokines. The investigators have never used the 2nd cell group in patients. Because of this, the investigators plan to treat 3 to 6 patients at a lower dose of cells to see if adding the second cell line is safe to give. •Dose Level 1 (3-6 patients) 1x10e6 cells/m2/vaccination dose of SKNLP Unmodified Neuroblastoma Cell Line Vaccine Component •Dose Level 2 (3-6 patients) 1x10e7 cells/m2/vaccination dose of SKNLP Unmodified Neuroblastoma Cell Line Vaccine Component ◦SJNB-JF-IL2 and SJNB-JF-Lptn cells are each dosed at 1x10e7 cells/m2/vaccination Duration of Therapy: In the absence of treatment delays due to adverse events, treatment may continue with immunizations per the treatment plan up to 12 vaccinations or until one of the following criteria applies: - Disease progression - Intercurrent illness that
Completed	LMB-2 Immunotoxin and Vaccine Therapy in Treating Patients With Metastatic Melanoma That Cannot Be Removed By Conditions: Melanoma (Skin); Non-Melanomatous Skin Cancer 2006-2012 Interventions: Biological: LMB-2 immunotoxin; Biological: MART-1 antigen; Biological: gp100 antigen; Biological: incomplete Freund's adjuvant
	RATIONALE: The **LMB-2 immunotoxin can find tumor cells and kill them without harming normal cells**. Vaccines made from peptides may help the body build an effective immune response to kill tumor cells. Giving LMB-2 immunotoxin together with vaccine therapy may kill more tumor cells. PURPOSE: This phase II trial is studying how well giving LMB-2 immunotoxin together with vaccine therapy works in treating patients with metastatic melanoma that cannot be removed by surgery. **Primary:** •Objective clinical response rate [Designated as safety issue: No] **Secondary** : 1) Changes in levels of **CD4+, CD25+ regulatory T cells** 2) Ability of LMB-2 to augment peptide vaccination. 3) Toxicity **Primary:** Determine objective clinical response in patients with progressive, unresectable metastatic melanoma treated with recombinant LMB-2 immunotoxin and peptide vaccination comprising **gp100:209-217 (210M) antigen, MART-1:27-35 antigen,** and **Montanide ISA-51**. **Secondary:** 1) termine changes in levels of CD4+, CD25+ regulatory T cells in peripheral blood before and after treatment in patients treated with this regimen. 2) determine the ability of recombinant immunotoxin LMB-2 to augment peptide vaccination in these patients. 3) Determine the toxicity profile of this regimen in these patients. OUTLINE: Patients receive LMB-2 immunotoxin IV over 30 minutes twice on days 1-3. Patients then receive peptide vaccinations comprising gp100:209-217 (210M) antigen emulsified in Montanide ISA-51 subcutaneously (SC), and MART-1:27-35 vaccine emulsified in Montanide ISA-51 SC on days 4, 5, 6, and 24-27 (course 1). After week 8, patients achieving tumor response may receive 1 additional course in the absence of disease progression or unacceptable toxicity. After completion of study treatment, patients are followed periodically in the absence of disease progression. PROJECTED ACCRUAL: A total of 26 patients will be accrued for this study.

Completed	Dendritic Cell Vaccine for High Risk Ovarian Cancer Patients Condition: Ovarian Cancer 2007-2011 Intervention: Biological: DC-Ova	
	This is a randomized Phase I/II study designed to assess the induction of an anti-tumor immune response; the effect of **cyclophosphamide** on the vaccine; and to assess safety in subjects with advanced ovarian cancer or primary serous peritoneal cancer given a **multivalent DC vaccine**, with or without a single dose of cyclophosphamide. Potential benefit may range from no direct benefit to the study participants to stimulation of the subject's **own immune system to attack ovarian cancer** to prevent relapse Randomized Phase I/II Pilot Study of the Immunogenicity of Cyclophosphamide With Peptide Pulsed Mature Dendritic Cells for Patients With Previously Treated Ovarian Epithelial or Primary Peritoneal Carcinoma	
Completed	A Phase I Study of gp100 Human Melanoma Peptide Vaccine With Incomplete Freund's Adjuvant Condition: Melanoma 1999-2008 Intervention: Biological: gp100 human melanoma peptide	
	This is a phase I study of melanoma tumor antigen peptide vaccines. The **nine amino acid peptides representing HLA-A2 restricted T cell epitope of the melanoma antigen, gp100** will be administered to patients emulsified in Incomplete Freund's Adjuvant, (IFA). The study is designed to evaluate the toxicity, immunologic effects and potential therapeutic role of repeated doses of gp100 peptide vaccines administered subcutaneously. Immune reactivity to the gp100 epitope peptides will be monitored in all patients by analysis of melanoma-specific T cell precursor frequency prior to and after immunization. This is a phase I study of melanoma tumor antigen peptide vaccines. The nine amino acid peptides representing HLA-A2 restricted T cell epitope of the melanoma antigen, gp100 will be administered to patients emulsified in Incomplete Freund's Adjuvant, (IFA). The study is designed to evaluate the toxicity, immunologic effects and potential therapeutic role of repeated doses of gp100 peptide vaccines administered subcutaneously. Immune reactivity to the gp100 epitope peptides will be monitored in all patients by analysis of melanoma-specific T cell precursor frequency prior to and after immunization.	
Completed Has Results	Evaluation of Immunogenicity and Safety of Human Papillomavirus (HPV) Vaccine Co-administered With Another Vaccine in Conditions: Papillomavirus Vaccines; Human Papillomavirus Infection Interventions: Biological: HPV Vaccine (GSK580299) Cervarix TM; Biological: Engerix B	
Completed	Safety of Peptide Vaccination for Patients With Myelodysplastic Syndrome Condition: Myelodysplastic Syndrome (MDS) 2005-2012 Intervention: Drug: WT1 and PR1 Peptide Vaccine	

	This study will test whether certain patients with myelodysplastic syndrome (MDS), acute myeloid leukemia (AML) or chronic myeloid leukemia (CML) can safely be vaccinated with two peptide vaccines derived from proteins called proteinase 3 (PR1) and Wilm's tumor-1 (WT1). These proteins are produced in large amounts by cells of MDS, AML and CML patients. The peptides are combined with an "adjuvant" called Montanide to make the vaccines, and the vaccines are given with GM-CSF (sargramostim). Both Montanide and sargramostim help the immune system respond to the vaccines. The vaccines then activate the immune system to make specialized cells that search out and kill the MDS, AML and CML cells containing the two proteins. Patients with MDS, AML or CML who are 18 years of age or older may be eligible for this study. Candidates are screened with a medical history and physical examination, blood tests, chest x-ray, and bone marrow aspirate and biopsy. For the bone marrow biopsy, the area of the hip is anesthetized and a special needle is used to draw marrow from the hipbone. Participants receive an injection (shot) of each peptide vaccine into deep tissue of the upper arm, upper leg, or the abdomen and two separate shots of sargramostim in the same area as the vaccine shots. Patients' vital signs (heart rate, breathing rate, temperature, blood pressure) are measured before and after they receive the vaccines and they are watched for 2 hours after the shots for possible side effects, such as chills, pain at the injection site, stomach upset, allergic reaction, low blood counts, and infection. Patients return to the clinic 1, 2, 3 and 4 weeks after receiving the vaccines for a brief physical evaluation and blood tests. A chest x-ray is also done at the 4-week visit. Patients may receive whole blood or platelet transfusions if needed to treat the MDS, growth factors (filgrastim, erythropoietin, or others) if needed, and medications to treat any infections that may develop primary: To evaluate the safety of and toxicity assoc. with a single dose of a comb. of**PR1:169-177 and WT-1:126-134 peptide (in Montanide adjuvant)** vaccination admin. concomitantly with GM-CSF (Sargramostim) in selected patients with myeloid malignancie... The immunological graft-versus-leukemia (GVL) effect seen after allogeneic stem cell transplantation suggests that stimulating the patient's own T cell responses to MDS and leukemia with a vaccine might also retard disease progression and even achieve disease remissions. WT1 and PR1 were identified as target antigens because both antigens are highly expressed by CD34+ stem cells of most patients with myeloid malignancies but not by normal marrow cells. An immunotherapeutic approach to vaccinate against PR1 and WT1 antigens could induce T cell response against MDS and leukemic cells while sparing normal cells and by using a combination of two antigens the risk of disease escape by antigen down regulation should be further diminished. Therefore, we propose to evaluate a vaccine composed of peptides derived from two proteins over-expressed in MDS and leukemia stem cells - proteinase 3 (PR1) and Wilms tumor-1 (WT1). This protocol, the first in a series of planned research, will evaluate the safety of a single dose of a combination of two peptide vaccines, namely PR1:169-177 and WT-1:126-134 in Montanide adjuvant administered concomitantly with GM-CSF (Sargramostim) in select subjects diagnosed with MDS, AML and CML
Completed	Human Papillomavirus Vaccine Safety & Immunogenicity Trial in Healthy Young Adult Women With HPV Vaccine Conditions: Human Papillomavirus (HPV) Infection; Cervical Neoplasia Interventions: Biological: Cervarix TM; Biological: GSK Biologicals' HPV vaccine (GSK1674330A)
Completed	Autologous T-Cell Transplantation and the Immunotherapy of Residual Disease in Breast Cancer: Pilot Study of Vaccine-Driven T-Cell Expansion in Patients Treated With Dose-Intensive Chemotherapy Conditions: Breast Neoplasm; Neoplasm Metastasis 2006-2008 Interventions: Procedure: Autologous T cells; Drug: Interleukin-2

	Pilot Study of **Autologous T Cells and/or IL-2** for the Enhancement of Immune Reconstitution After Dose-Intensive Chemotherapy for Breast Cancer **Detailed Description**: The process of T cell immune reconstitution post-chemotherapy in breast cancer patients is impaired. Such a deficit in T cell immunity likely represents an important obstacle to tumor vaccine therapy in breast cancer patients. In an attempt to enhance T cell immune reconstitution, we have administered cryopreserved T cells and interleukin-2 to breast cancer patients post-chemotherapy. Initial data from the first 13 patients enrolled on this study suggests that the administration of T cells and IL-2 resulted in improved T cell reconstitution relative to untreated patients or patients receiving only IL-2. Importantly, recipients of the combination of T cells and IL-2 had an enhanced recovery of CD4+CD45RA+ T cells; because this T cell subset represents a naive T cell phenotype that generally maintains a capacity to respond to antigen, enhanced regeneration of this population may result in improved immune function and may allow for a more successful immune response to tumor vaccines. It will be important to now evaluate what effect T cell administration alone (without IL-2 treatment) has on immune reconstitution post-chemotherapy. Determination of the relative benefits of T cell and/or cytokine administration on T cell recovery post-chemotherapy may assist in the development of breast cancer vaccine protocols where a T cell-mediated immune response may be necessary for optimal response to the vaccine.		
Completed Has Results	Evaluation of Safety and Immunogenicity of Co-administering HPV Vaccine With Other Vaccines in Healthy Female Subjects		
	Conditions:	Human Papillomavirus Type-16/-18 Infection; Cervical Neoplasia	
	Interventions:	Biological: Boostrix TM; Biological: Different formulations of GSK Biologicals' HPV vaccine (580299); Biological: Menactra TM	
Active, not recruiting Has Results	An Investigational Study of Gardasil (V501) in Reducing the Incidence of Anogenital Warts in Young Men (V501-020)		
	Condition:	Condylomata Acuminata	
	Interventions:	Biological: (Gardasil) human papillomavirus (types 6, 11, 16, 18) recombinant vaccine; Biological: Comparator: placebo (unspecified)	
Active, not recruiting	Vaccination Therapy in Treating Patients With Limited-Stage Small Cell Lung Cancer		
	Condition:	Lung Cancer 1999-2012	
	Interventions:	Biological: BCG vaccine; Biological: monoclonal antibody BEC2	
	Detailed Description: OBJECTIVES: I. Determine the impact of adjuvant monoclonal antibody BEC2 and BCG on survival of patients with limited stage small cell lung cancer. II. Determine the safety of this regimen in these patients. III. Determine progression-free survival and quality of life of these patients treated with this regimen. OUTLINE: This is a randomized, multicenter study. Patients are stratified according to center, Karnofsky performance status (60-70% vs 80-100%), and response to first-line combined modality treatment (complete vs partial). Within 3-7 weeks after completion of prior induction chemoradiotherapy, responding patients are randomized to 1 of 2 treatment arms. Arm I: Patients receive best supportive care and are observed until disease progression is documented. Arm II: Patients receive adjuvant monoclonal antibody BEC2 and BCG intradermally on day 1 of weeks 0, 2, 4, 6, and 10. Treatment consists of 5 vaccinations over a period of 10 to 12 weeks in the absence of unacceptable toxicity or disease progression. Quality of life is assessed at baseline, at weeks 6, 12, and 24, and then every 6 months thereafter. Patients are followed every 3 months. PROJECTED ACCRUAL: Approximately 500 patients will be accrued for this study within 4 years.		

Completed	Cervical Intraepithelial Neoplasm (CIN)-Warts Efficacy Trial in Women (Gardasil)	
Has Results	Conditions: Cervical Cancer; Genital Warts	
	Interventions: Biological: V501; Biological: Comparator: Placebo; Biological: Human Papillomavirus (HPV) 16 Monovalent	
Completed	Human Papillomavirus (HPV) Vaccine (Cervarix TM) Efficacy, Immunogenicity & Safety Trial in Adult Japanese Women With	
Has Results	Conditions: Human Papillomavirus (HPV) Infection; Cervical Neoplasia	
	Interventions: Biological: HPV-16/18 vaccine (Cervarix™); Biological: Aimmugen™	
Completed	Chemotherapy and Peripheral Stem Cell Transplantation Followed By Immunotherapy in Treating Patients With Multiple	
	Conditions: Infection; Multiple Myeloma and Plasma Cell Neoplasm 2002-2009	
	Interventions: Biological: filgrastim; Biological: pneumococcal polyvalent vaccine; Biological: therapeutic autologous lymphocytes; Biological: therapeutic tumor infiltrating lymphocytes; Drug: carmustine; Drug: cyclophosphamide; Drug: melphalan; Procedure: bone marrow ablation with stem cell support; Procedure:	
	OBJECTIVES: •Determine the feasibility of expanding ex vivo autologous T cells and infusing these cells after high-dose chemotherapy and autologous peripheral blood stem cell rescue in patients with multiple myeloma. •Determine the response rate and progression-free survival of patients who receive anti-CD3/anti-CD28 expanded autologous T cells on either day 14 or day 100 post-transplantation. •Compare response and survival rates of these patients to historical controls. •Determine the optimal schedule for pneumococcal conjugate vaccine (PCV) to induce an anti-pneumococcal immune response post-transplantation in these patients. •Determine whether "vaccine education" of antigen-presenting cells (APCs) in the stem cell graft results in an earlier and/or enhanced immune response than with a graft containing "non-educated" APCs in these patients. •Determine whether an infusion of T cells presensitized to the PCV and expanded ex vivo contributes to the anti-pneumococcal immune response in these patients. OUTLINE: This is a randomized, multicenter study. Patients receive cyclophosphamide IV over 12 hours on day 1 and filgrastim (G-CSF) subcutaneously (SC) daily beginning on day 2. Patients undergo leukapheresis to collect mononuclear cells for autologous T cells (ATCs) and peripheral blood stem cells (PBSCs). ATCs are generated by ex vivo expansion for 8-14 days and selection for CD3+/CD28+ cells. Patients then receive high-dose therapy comprising carmustine IV over 2 hours on day -2 and melphalan IV over 20 minutes on day -1 or melphalan IV alone on days -2 and -1 (or day -1 only). Autologous PBSCs are reinfused on day 0. Patients also receive G-CSF SC beginning on day 1 and continuing until blood counts recover. Patients who choose to receive pneumococcal conjugate vaccine (PCV) are randomized to 1 of 4 treatment arms. •Arm I: Patients receive PCV intramuscularly prior to transplantation (10-14 days before lymphocyte collection) and post-transplantation (1 and 3 months) plus costimulated ATCs IV over 20-60 minutes around day 12-14 post-transplantation. •Arm II: Patients receive PCV as in arm I but receive ATCs around day 100 post-transplantation. •Arm III: Patients receive PCV post-transplantation only (at 1 and 3 months) plus ATCs as in arm I. •Arm IV: Patients receive PCV as in arm III and ATCs as in arm II. Patients who choose not to receive the PCV receive ATCs on about day 12-14 after PBSC transplantation. All patients are offered standard pneumococcal polysaccharide vaccine at 12 months. Patients are followed twice weekly until day 60, weekly for 4 months, monthly for 6 months, andthen every 3 months thereafter. PROJECTED ACCRUAL: A total of 40-48 patients will be accrued for this study within 14 months.	

Completed	Human Papillomavirus Vaccine Immunogenicity and Safety Trial in Young Adult Women With GSK Biologicals Novel HPV		
	Condition:	Prophylaxis for HPV Infections and Cervical Neoplasia	
	Interventions:	Biological: CervarixTM; Biological: HPV investigational vaccine GSK568893A, different formulations	
Recruiting	Vaccination With GM-K562 Cells in Patients With Advanced Myelodysplastic Syndrome (MDS) or Acute Myeloid Leukemia (AML) After Allogeneic Hematopoetic Stem Cell Transplantation		
	Conditions:	Acute Myeloid Leukemia; Chronic Myelomonocytic Leukemia; Myelodysplastic Syndrome-Refractory Anemia With Excess Blasts 2008-2012	
	Intervention:	Biological: GM-K562/leukemia cell vaccine	
	Primary: •To assess the safety of vaccination, as measured by vaccine related reactions and incidence of grade III-IV acute GVHD. 2 years] **Secondary** : •To assess the efficacy of vaccination with GM-K562/leukemia cell vaccine following allogeneic stem cell transplantation in this patient population. [2 year]. •To characterize the biologic responses and leukemia specific immune responses after vaccination with GM-K562/leukemia cell vaccine following allogeneic stem cell transplant. [2 years]•To determine duration of disease response, disease free and overall survival [2 years] Detailed Description: •Participants will be given the GM-K562/Leukemia call vaccine as in injection under the skin a total of six times. The first 3 vaccines will be given weekly and vaccines 4 through 6 will be given every other week. Therefore, it is expected that the vaccines will be completed over a period of 9 weeks. •During the 9 week vaccination period, participants will have physical exams to monitor for any side effects or graft-versus-host disease (GVHD). Bone marrow biopsies will be performed a the time of enrollment for this study, 4 weeks after completion of 6 GM-K562/Leukemia cell vaccines, and 1 year after the participants transplant. •As a way of testing whether the GM-K562/Leukemia cell vaccine is triggering any immune response to the participants leukemia, we will be injecting a small amount of leukemia cells (after they are killed with radiation) under the participants skin to see if the body will generate a reaction to the leukemia cells. This test is called a leukemia cell delayed hypersensitivity test (DTH). This test will be performed three times during the study, on the weeks of the 1st vaccine, 5th vaccine and 4 weeks after the 6th vaccine. •There are a total of 5 skin biopsies required as part of this study. Biopsies will be taken from the vaccination sites 2-3 days after the first and fifth vaccine. Similar biopsies will be taken from the DTH sites after the 1st vaccination, 5th vaccination and 4-6 weeks after the 6th vaccination.		
Completed	Human Papilloma Virus Vaccine Consistency and Non-Inferiority Trial in Young Adult Women With GSK Bio HPV-16/18		
	Conditions:	HPV-16/18 Infections; Cervical Neoplasia	
	Intervention:	Biological: HPV-16/18 L1/AS04	
Enrolling by invitation	Safe Study of Dendritic Cell (DC) Based Therapy Targeting Tumor Stem Cells in Glioblastoma		
	Conditions:	Glioblastoma; Brain Tumor 2009-2011	
	Intervention:	Biological: Dendritic cell vaccine with mRNA from tumor stem cells	

	The study induces an immune response towards the stem-cell like part of glioblastomas in combination with standard therapy. The aim is to define and characterize the feasibility, potential adverse effects of such therapy and measure time to progression and survival Primary: •Adverse events [Time Frame: During follow-up] [Designated as safety issue: Yes] Secondary : •Evaluation of immunological response, time to disease progression and survival time [Time Frame: 5 years]
Recruiting	Safety Study of Adjuvant Vaccine to Treat Melanoma Patients Condition: Melanoma 2010 Intervention: Biological: NY-ESO-1 protein; Poly-ICLC; Montanide
	Primary: •Phase I, to define the safety of subcutaneous vaccination with **NY-ESO-1 protein, Montanide and escalating doses of Poly-ICLC** [Time Frame: **Disease status is assessed at baseline, wks 4 & 12 and after 4th vaccination (wks 14 & 22). At wk 52, disease status is assessed through patient follow-up with study physicians or through contact with the patient's regular treating physician.**] Up to 3 cohorts of 3 patients will be given a subcutaneous vaccination of 100μg NY-ESO-1 protein emulsified in 1.1mL Montanide® ISA-51VG (day 1) with escalating doses of Poly-ICLC. Dose-escalation will continue if no DLTs are observed in the 3 patients in a given cohort. **Secondary** : •To evaluate the induction of **humoral and T cell (CD4+ and CD8+) immunity** to subcutaneous vaccination with NY-ESO-1 protein in combination with Poly-ICLC when given with or without Montanide. [Time Frame: Disease status is assessed at baseline, wks 4 & 12 and after 4th vaccination (wks 14 & 22). At wk 52, disease status is assessed through patient follow-up with study physicians or through contact with the patient's regular treating physician.] When Phase I is complete (no cohort 3 DLT observed) 24 new patients are randomized in **Phase II** to receive treatment under Arm A or Arm B. They receive s.c. vaccinations of 100μg NY-ESO-1 protein with Poly-ICLC alone dose TBD (Arm A); or with 100μg NY-ESO-1 protein, Poly-ICLC dose TBD and 1.1mL Montanide (Arm B). **Administrations occur every 3 wks on study wks 1,4,7,&10.** Injections may occur w/in +/-3 days of planned date. **Blood samples are obtained at baseline, 1 wk after vaccinations, and 1&3 months after last vaccination for assessment of NY-ESO-1 specific antibodies and CD4+ & CD8+ T cell** **Detailed Description:** This is a Phase I open label dose escalation study of the TLR3 agonist Poly-ICLC as an adjuvant for NY-ESO-1 protein vaccination in patients with high risk melanoma in clinical complete remission (cCr), followed by a randomized Phase II component in which patients will be randomized to subcutaneous vaccination of NY-ESO-1 protein with Poly-ICLC alone dose TBD (Arm A) or with NY-ESO-1 protein, Poly-ICLC dose TBD and Montanide® ISA-51 VG (Montanide) (Arm B). Patients with histological confirmed malignant melanoma, AJCC Stages: IIB, IIC, III or IV, who are in complete clinical remission (cCr) but at high risk of disease recurrence, will be eligible for enrollment, regardless of whether antigen expression in the autologous tumor can be demonstrated by either PCR or immunohistochemistry. **Primary Objectives: 1) P**hase I: To define the safety of subcutaneous vaccination with NY-ESO-1 protein, Montanide and escalating doses of Poly-ICLC. 2)•Phase II: To evaluate the induction of humoral and T cell (CD4+ and CD8+) immunity to subcutaneous vaccination with NY-ESO-1 protein in combination with Poly-ICLC when given with or without Montanide. **Exploratory:** 1) Evaluation of primary tumor expression of NY-ESO-1 by IHC or RT-PCR. 2) Histologic quantitation of original tumor TILs (tumor infiltrating lymphocytes), CD3+ cells, evaluation of mitotic index and correlation of this data with immunologic response. 3) orrelation of NY-ESO-1 specific T cell responses with HLA type. 4) Investigation of polymorphisms for TLR3 through germline SNP analysis. 5) Clinical Outcome (Time to Progression) reported descriptively. 6) kin section analysis of protein/adjuvant treated sites for immune cell infiltration and gene expression analysis
Completed	Human Papilloma Virus Vaccine Safety and Immunogenicity Trial in Young Adolescent Women With GSK Bio HPV-16/18. Conditions: HPV-16/18 Infections; Cervical Neoplasia

	Intervention:	Biological: HPV-16/18 L1/AS04
Completed	Efficacy Study of HPV-16/18 Vaccine (GSK 580299) to Prevent HPV-16 and/or -18 Cervical Infection in Young Healthy	
	Condition:	Papillomavirus Infections
	Interventions:	Biological: Cervarix; Biological: placebo
Completed	MDX-010 Antibody, MDX-1379 Melanoma Vaccine, or MDX-010/MDX-1379 Combination Treatment for Patients With	
	Conditions:	Melanoma; Metastases 2004-2011
	Interventions:	Drug: MDX-010 (anti-CTLA4) monoclonal antibody; Biological: MDX-1379 Melanoma Peptide Vaccine
	The purpose of this study is to determine the safety and efficacy of ipilimumab (anti-CTLA4) in combination with MDX-1379 (gp100, BMS-734019) in patients with previously treated, unresectable Stage III or IV melanoma. Survival time will be evaluated, as well as patient responses and time to disease progression. Eligible patients are those who in response to a single **regimen containing interleukin-2 (IL-2), dacarbazine, and/or temozolomide, have 1)** relapsed following an objective response (**partial response/complete response [PR/CR]**); 2) failed to demonstrate an objective response (PR/CR); or 3) could not tolerate such a regimen due to unacceptable toxicity. Patients will be randomized into one of three groups, and will receive one of the following treatments: MDX-010 alone, MDX-1379 alone, or MDX-010 in combination with MDX-1379. **Primary:** •Overall Survival (OS) (Time-to-Death) Difference Between MDX-010 in Combination With gp 100 Melanoma Peptide Vaccine Versus gp 100 Melanoma Peptide Vaccine Alone [Time Frame: From randomization until the end of the study, which was defined as the time at which 481 deaths were observed (264 weeks)] OS was defined as the time from randomization until death from any cause. If a participant did not expire, the subject was censored at the time of last contact (last known alive date). 95% confidence intervals (CI) for median were computed using Brookmeyer and Crowley method. **Secondary:** •Overall Survival (OS) (Time-to-Death) Difference Between MDX-010 Monotherapy Versus gp100 Melanoma Peptide Vaccine Alone and MDX-010 in Combination With gp100 Melanoma Peptide Vaccine Versus MDX-010 Monotherapy [From randomization until the end of the study, which was defined as the time at which 481 deaths were observed (264 weeks)] OS was defined as the time from randomization until death from any cause. If a participant did not expire, the subject was censored at the time of last contact (last known alive date). 95% confidence intervals (CI) for median were computed using Brookmeyer and Crowley method. •12-, 18-, and 24-Month Survival Rates [Month 12, Month 18, Month 24] The probability that a subject is alive at 12 months, 18 months, and 24 months following randomization, estimated via the non-parametric method (Kaplan-Meier method). For calculating 95% CI, bootstrap method was used with 20000 simulated trials. •Progression Free Survival (PFS) [From randomization until the end of the study, which was defined as the time at which 481 deaths were observed (264 weeks)] PFS was defined as the number of days between the date of randomization and the date of the progression or the date of death. A subject who died without prior progression was considered to have progressed on the date of death. PFS was determined by investigator. 95% confidence intervals (CI) for median were computed using Brookmeyer and Crowley method. •Percentage of Participants With Progression Free Survival (PFS) at Week 12 and Week 24 [Week 12, Week 24] PFS at Week 12 was defined as the probability that the subject was progression-free at 12 weeks and 24 weeks following the start of randomization. It was computed via Kaplan-Meier method, truncated at Week 12 and Week 24. PFS was determined by investigator. 95% confidence intervals (CI) for median were computed using Brookmeyer and Crowley method	

	•Time to Progression (TTP) [Time Frame: from time of randomization to date of PD or death due to PD (end of the study was defined as the time at which 481 deaths were observed [264 weeks])] [Designated as safety issue: No] TTP was defined as the number of days between the date of the randomization and date of PD or death due to PD. For subjects who had not progression and remained alive, TTP was censored on the date of last assessment; those who remained alive and had no recorded post-baseline assessment, TTP was censored on the date of randomization; those who remained alive and had randomized but were not treated, TTP was censored at the date of randomization; for those who died without reported disease progression, TTP was censored on the date of death. •Best Overall Response (BOR): Complete Response (CR), Partial Response (PR), Stable Disease (SD), Progressed Disease (PD) [Time Frame: BOR was determined between Weeks 12 and Week 24 confirmation at least 4 weeks later at Cycle 1.] [Designated as safety issue: No] Investigator's assessment, modified World Health Organization criteria. CR: disappearance of all lesions by 2 consecutive observations >=4 weeks apart, no evidence of PD. PR: >=50% ↓ in sum of products of longest diameter & greatest perpendicular diameter of all target lesions compared to baseline by 2 observations >=4 weeks apart. SD: Neither sufficient ↓ to qualify for PR nor sufficient ↑ to qualify for PD. PD: ↑ >=25% in sum of products of longest diameter & greatest perpendicular diameter of target lesions compared to smallest recorded sum during study, or appearance of >= 1 new lesion. •Determination of Best Overall Response Rate (BORR) [Time Frame: Up to week 24] [Designated as safety issue: No] Response was based on the investigators' assessment using modified WHO criteria. BORR is defined as the number of subjects whose BOR is complete or partial response (CR or PR) divided by the total number of subjects in the group. BORR was comprised of responder and non-responder. The definition of a responder in BORR was either confirmed CR or PR, and a non-responder was defined as stable disease (SD), progressed disease (PD), unconfirmed CR (uCR), unconfirmed PR (uPR), and not evaluated. •Time to Response [Time Frame: From randomization until the end of the study, which was defined as the time at which 481 deaths were observed (264 weeks)] [Designated as safety issue: No] Time to response was defined as the number of days from the date of randomization to the date when measurement criteria are met for BOR of CR or PR, as determined by investigator. •Duration of Response [Time Frame: from time of initial drug administration to date of PD or death due to PD (the end of the study was defined as the time at which 481 deaths were observed [264 weeks])] [Designated as safety issue: No] Kaplan-Meier medians along with Brookmeyer and Crowley 95% confidence intervals (CI) for were computed. Duration of response was defined in subjects whose BOR was CR or PR as the number of days between the date of response (CR or PR) and the date of PD or the date of death (whichever occurs first).

	•Disease Control Rate (DCR) [Time Frame: Up to week 24] [Designated as safety issue: No] Response was based on the investigators' assessment using modified WHO criteria. DCR is defined as the number of subjects whose BOR is CR, PR, or SD divided by the total number of subjects in the group. •Delayed Response (Response Beyond Week 24) [Time Frame: from Week 24 to end of study (the end of the study was defined as the time at which 481 deaths were observed [264 weeks])] [Designated as safety issue: No] Response was based on the investigators' assessment using modified World Health Organization (WHO) criteria. Delayed response is defined as post Week 24 overall response for the subjects who have PD before or at Week 24. Evaluation of delayed overall response is compared to baseline assessment. Delayed response includes delayed late CR, delayed late PR, delayed late SD, continued PD, unknown, and missing after Week 24. The delayed response of CR and PR also must have been confirmed. •Change From Baseline in Health-Related Quality of Life (QOL) as Measured by the European Organization for Research and Treatment of Cancer Core Quality of Life Questionnaire (EORTC QLQ-C30) Instrument at Week 12 [Time Frame: Baseline (Day 1, Cycle1), Week 12] [Designated as safety issue: No]•The 30 items were grouped into the following: 1 global QOL scale, 5 functional scales (Physical, Role, Cognitive, Emotional, Social), and 9 symptom scales/items (Fatigue, Nausea and Vomiting, Pain, Dyspnea, Sleep Disturbance, Appetite Loss, Constipation, Diarrhea, Financial Impact). All scores were linearly transformed to a 0 to 100 scale. For global QOL and functional items, a higher score represents a better level of functioning (100=best/0=worst). For symptom items, a higher score represents a higher level of symptoms (0=no symptom at all/100=very much severe). •Percentage of Participants With On-Study Adverse Events (AEs) and AEs With an Outcome of Death [Time Frame: On-study adverse events include all AEs reported between the first dose and 70 days after the last dose of study therapy (end of the study was defined as the time at which 481 deaths were observed [264 weeks]).] [Designated as safety issue: Yes] An AE was defined as any undesirable sign, symptom, clinically significant laboratory abnormality, or medical condition occurring after starting study treatment, even if the event was not considered to be treatment-related. Adverse events are graded using the Cancer Therapy Evaluation Program (CTEP) Common Terminology Criteria for Adverse Events (CTCAE), Version 3.0. If CTCAE grading does not exist for an adverse event, the intensity of mild (1), moderate (2), severe (3), and life-threatening (4) were used.

	•Percentage of Participants With Immune-Related Adverse Events (irAEs) [Time Frame: On-study adverse events include all AEs reported between the first dose and 70 days after the last dose of study therapy (end of the study was defined as the time at which 481 deaths were observed [264 weeks]).] [Designated as safety issue: Yes] An immune related adverse event (irAE) was defined as an adverse event of unknown etiology, associated with study drug exposure and consistent with an immune phenomenon. The irAEs were programmatically determined from a predefined list of MedDRA version 12.0 high-level group terms, high-level terms and preferred terms of all ipilimumab related adverse event. The category of "Other irAEs" includes blood, eye, immune, infections, renal, and respiratory systems. •Percentage of Participants With Worst On-Study Hematological Abnormalities [Time Frame: On-study laboratory results are results reported after the first dose date and within 70 days of last dose of study therapy (end of the study was defined as the time at which 481 deaths were observed [264 weeks]).] [Designated as safety issue: Yes] ANC=Absolute Neutrophil Count. CTCAE v3.0 Grades 0 through 4 of severity for each AE based on this general guideline: Grade 0=Normal, Grade 1=Mild AE, Grade 2=Moderate AE, Grade 3=Severe AE, Grade 4=Life-threatening or disabling AE. •Percentage of Participants With Worst On-Study Liver Abnormalities [Time Frame: On-study adverse events include all AEs reported between the first dose and 70 days after the last dose of study therapy (end of the study was defined as the time at which 481 deaths were observed [264 weeks]).] [Designated as safety issue: Yes] ALT=alanine aminotransferase; AST=aspartate aminotransferase. CTCAE v3.0 Grades 0 through 4 of severity for each AE based on this general guideline: Grade 0=Normal, Grade 1=Mild AE, Grade 2=Moderate AE, Grade 3=Severe AE, Grade 4=Life-threatening or disabling AE. •Percentage of Participants With Worst On-Study Renal Abnormalities [Time Frame: On-study adverse events include all AEs reported between the first dose and 70 days after the last dose of study therapy (end of the study was defined as the time at which 481 deaths were observed [264 weeks]).] [Designated as safety issue: Yes] CTCAE v3.0 Grades 0 through 4 of severity for each AE based on this general guideline: Grade 0=Normal, Grade 1=Mild AE, Grade 2=Moderate AE, Grade 3=Severe AE, Grade 4=Life-threatening or disabling AE. •Clinically Meaningful Changes in Vital Signs and Physical Examinations [Time Frame: vital signs and physical examination were evaluated at screening and at Weeks 1, 4, 7, 10, 12, 16, 20, 24, 28, 36, and every 3 months thereafter] [Designated as safety issue: Yes] Clinically meaningful changes were according to investigator. Vital sign measurements include height, weight, temperature, pulse, and resting systolic and diastolic blood pressure.
Recruiting	Vaccine Therapy in Treating Patients Who Have Undergone a Donor Stem Cell Transplant and Have Cytomegalovirus Infection That Has Not Responded to Therapy Condition: Cancer Interventions: Biological: cytomegalovirus pp65-specific cytotoxic T lymphocytes; Genetic: polymerase chain reaction; Other: flow cytometry; Other: immunologic technique; Other: laboratory biomarker analysis
Completed Has Results	Complementary Testing to Evaluate Immunogenicity of Human Papillomavirus (HPV) Vaccine (580299) in Healthy Female Conditions: Human Papillomavirus (HPV) Infection; Cervical Neoplasia Interventions: Biological: Placebo; Biological: Cervarix TM

Completed	Vaccine Responses to Influenza A H1N1/09 Immunization in High-risk Patients		
	Conditions:	HIV Infection; Rheumatic Disease; Cancer; Transplant; Pediatrics	
	Intervention:	Biological: Adjuvanted influenza A(H1N1) vaccines	
Recruiting	An Assessment of an Attenuated Live Listeria Vaccine in CIN 2+		
	Condition:	Cervical Intraepithelial Neoplasia (2010-2012)	
	Interventions:	Biological: ADXS11-001 (Lm-LLO-E7); Drug: Placebo Control	
	Cervical cancer is associated with Human Papilloma Virus. About 57% of cervical cancer is the result of infection by Human Papilloma Virus strain 16 (HPV-16). HPV is a very common virus that can affect the cells of the cervix. E7 is a substance that is made by the HPV virus which causes cervical cancer. The purpose of the study is to test the safety, tolerability (how the drug makes you feel), immunology (effects on the immune system) and efficacy (disease curing effects) of a vaccine called Lovaxin C against E7. The vaccine is designed to cause the immune system to react against the E7 substance in a manner that is intended to reverse the changes to the cervix and prevent cervical cancer from occurring. **Primary:** •The primary end point will be a histologic determination of whether CIN 2/3 present at entry had regressed. [11 months] **Secondary:** •Secondary efficacy endpoints include whether HPV DNA was reduced or eliminated and a comparison of their excised cervical tissue controls to assess the extent of disease in treated vs. untreated patients. [Time Frame: 11 months] Biological: ADXS11-001 (Lm-LLO-E7) ADXS11-001 at one of three dose levels given as 3 vaccinations separated by 4 weeks with an oral antibiotic regimen subsequent to dosing. Biological: ADXS11-001 (Lm-LLO-E7) ADXS11-001 at one of three dose levels given as 3 vaccinations separated by 4 weeks with an oral antibiotic regimen subsequent to dosing. Biological: ADXS11-001 (Lm-LLO-E7) ADXS11-001 at one of three dose levels given as 3 vaccinations separated by 4 weeks with an oral antibiotic regimen subsequent to dosing. Drug: Placebo Control 3 intravenous infusions of normal saline at 28 day intervals. All infusions will be preceded by prophylactic NSAID and antihistamine, and followed 3d later with antibiotic.		
Recruiting	HSPPC-96 Vaccine With Temozolomide in Patients With Newly Diagnosed GBM		
	Condition:	Brain and Central Nervous System Tumors 2009-2012	
	Intervention:	Biological: HSPPC-96	

	The Phase 2 trial is a single-arm investigation designed to evaluate safety, survival, and immune response in patients treated with an**autologous tumor-derived heat shock protein peptide-complex** (HSPPC-96) administered at **25 µg per dose injected intradermally once weekly for 4 consecutive weeks** and monthly following standard treatment with radiation and temozolomide **Primary:** •To evaluate the safety profile of HSPPC-96 administered concurrently temozolomide in patients with newly diagnosed GBM. [Time Frame: survival] • Survival Time [Time Frame: survival] **Secondary** : •To evaluate the immunologic response to vaccine treatment [Time Frame: survival] •Progression Free Survival from date of surgical resection [Time Frame: survival] **Biological: HSPPC-96** Patients will receive 4 weekly injections of HSPPC-96 followed by a 5th vaccine injection on the same day of the start of maintenance temozolomide administered 2 weeks (+ 4 days) following vaccine administration #4 on the same day of the start of maintenance temozolomide (Day 36). Monthly vaccine injections will then begin on day 21 (+/- 7 days) of the first 28 day temozolomide cycle (Day 56 of the study)3 weeks following vaccine administration #5 and will continue every 28 days until depletion of vaccine or progression. Immune monitoring will be completed pre-operatively, intra-operatively, 48-hours post-surgery, prior to vaccine administration #1, at prior to vaccine administration #5 and at weeks 09, 13, 37 and 53. The total volume of each vaccine or place provided is 0.47 mL. The total volume that should be administered is 0.4 mL (0.07 mL overage). Other Name: Heat Shock Criteria: I**nclusion Criteria:** Pre-surgery tissue acquisition Inclusion criteria. 2.Life expectancy of greater than 12 weeks.
Completed	Vaccine Therapy Plus Sargramostim Following Chemotherapy in Treating Patients With Stage III or Stage IV Non-Hodgkin's Condition: Lymphoma 2000-2010 Interventions: Biological: keyhole limpet hemocyanin; Biological: sargramostim; Biological: tumor cell-based vaccine therapy