

	<p>Primary Outcome: •Safety of intralymphatic autologous type-1-polarized dendritic cell vaccine and autologous mature dendritic cell vaccine. /•Cumulative increase in the sum of specific interferon gamma ELISPOTs against melanoma-specific A2-restricted peptides.</p> <p>Secondary Outcome: •Peripheral blood CD8+ and CD4+ T-cell response to HLA-presented melanoma epitopes and autologous tumor cells by interferon gamma and interleukin-5 ELISPOT assay. /•Delayed-type hypersensitivity (DTH) response to treatment /DTH response to keyhole limpet hemocyanin and pan-DR epitope (PADRE)./ •Correlation of treatment-associated changes in immune response with clinical outcome.</p> <p>patients are followed periodically for 10½ years and then annually thereafter</p>	
Recruiting	<p>Unimolecular Pentavalent (Globo-H-GM2-sTn-TF-Tn) Immunization of Patients With Epithelial Ovarian, Fallopian Tube, or</p> <p>Conditions: Fallopian Tubes; Ovarian Cancer; Peritoneal Cancer</p> <p>Intervention: Biological: Globo-H-GM2-sTn-TF-Tn-KLH conjugate, plus the immunological adjuvant QS-21 2010</p>	Unimolecular Pentavalent (Globo-H-GM2-sTn-TF-Tn) Immunization for Epithelial Ovarian, Fallopian Tube, or Peritoneal
	<p>Primary Outcome: •To determine immunologic response [6 months]. /immunization with the unimolecular pentavalent carbohydrate-based vaccine bearing Globo-H, GM2, sTn, TF and Tn on a single polypeptide backbone, conjugated to KLH, mixed with the immunological adjuvant QS-21, induces an IgG and IgM antibody response against these individual antigens and tumor cells expressing these antigens. /•To determine the toxicities following immunization with this unimolecular polyvalent vaccine. [2 years] /Toxicity will be graded in accordance with the Common Toxicity Criteria Version 4.0 developed by the National Cancer Institute (NCI). /•To determine the maximum tolerated dose over three dose levels. [2 years] /Six patients will be accrued to one of three pentavalent vaccine doses (25 mcg, 50 mcg and 100 mcg), and an expansion cohort of six patients will be enrolled at the highest dose level achieved. Secondary Outcome: •To record the progression free interval [2 years]</p>	
Not yet recruiting	<p>Survivin Vaccine Therapy for Patients With Malignant Gliomas</p> <p>Conditions: Adult Anaplastic Astrocytoma; Adult Anaplastic Oligodendroglioma; Adult Giant Cell Glioblastoma; Adult Glioblastoma; Adult Gliosarcoma; Adult Mixed Glioma; Recurrent Adult Brain Tumor</p> <p>Interventions: Drug: Montanide ISA-51/survivin peptide vaccine; Biological: sargramostim; Other: flow cytometry; Other: laboratory biomarker analysis; Other: immunoenzyme technique 2010</p>	Immunological Effects of SVN53-67/M57-KLH (012410-2) in Patients With Survivin-Positive Malignant Gliomas
	<p>Primary Outcome: •Toxicity of drug (012140-2) [after first dose for 24 weeks, death or progression]</p> <p>Secondary Outcome: •Immune response [weeks 2, 4, 6,12, 16, 20 and 24]. •Therapeutic efficacy [weeks 8 and 12]</p> <p>Detailed Description: PRIMARY OBJECTIVES: I. To determine the toxicity profile of the SVN53-67/M57-KLH peptide in Montanide ISA 51 plus with GM-CSF. SECONDARY OBJECTIVES: I. To measure the immune responses induced by SVN53-67/M57-KLH with Montanide ISA 51 with GM-CSF. TERTIARY OBJECTIVES: I. To collect preliminary data on therapeutic efficacy of this combination against malignant glioma. OUTLINE: Patients receive montanide ISA-51/survivin peptide vaccine subcutaneously (SC) followed by sargramostim SC on day 0. Treatment repeats every 2 weeks for 4 courses in the absence of disease progression or unacceptable toxicity. After completion of study treatment patients are followed up at weeks 16, 20, and 24</p>	
Active, not recruiting	<p>Vaccine Trial for Clear Cell Sarcoma, Pediatric Renal Cell Carcinoma, Alveolar Soft Part Sarcoma and Children With Stage IV</p> <p>Conditions: Sarcoma, Clear Cell; Sarcoma, Alveolar Soft Part; Renal Cell Carcinoma; Melanoma</p> <p>Intervention: Biological: GVAX 2005</p>	Vaccination With Autologous, Lethally Irradiated Tumor Cells Engineered by Adenoviral Mediated Gene Transfer to Secrete GM-CSF

	<p>Primary Outcome: •To determine the safety and feasibility of preparation and administration of vaccine in patients with metastatic or locally advanced clear cell sarcoma (CCS), alveolar soft part sarcoma (ASPS) and translocation associated renal cell carcinoma (RCC) [Years]</p> <p>Secondary Outcome: •To determine the disease response, immune response, and overall survival rate.</p> <p>Reaction of the immune system caused by the vaccine; This injection is measuring delayed type hypersensitivity, or DTH. The patient will be asked to undergo optional skin biopsies of the vaccine and DTH sites to see if an immune reaction is occurring at the injection sites 2 days after vaccine 1 and vaccine 5.</p> <p>At week 10 in the patient's treatment, or earlier if the doctor feels it is necessary, the patient will undergo a chest, abdomen and pelvic XT scan. A brain MRI will be performed if there were any abnormalities on the first brain MRI or if any new central nervous system symptoms have developed.</p>	
Active, not recruiting	<p>Vaccine Therapy in Treating Patients With Stage IIB, Stage IIC, Stage III, or Stage IV Melanoma</p> <p>Conditions: Intraocular Melanoma; Melanoma (Skin) 2006</p> <p>Interventions: Biological: mouse gp100 plasmid DNA vaccine; Procedure: adjuvant therapy</p>	Injection of AJCC Stage IIB, IIC, III and IV Melanoma Patients With Mouse gp100 DNA:
	<p>Primary Outcome: •Safety of particle-mediated epidermal delivery (PMED) of mouse gp100 plasmid DNA vaccine. /•Comparison of PMED-based DNA immunization with intramuscular jet immunization, based on T-cell response. Secondary Outcome: •Antitumor response.</p> <p>patients are followed periodically for 1 year.</p>	
Recruiting	<p>Randomized Study of Adjuvant WT-1 Analog Peptide Vaccine in Patients With Malignant Pleural Mesothelioma (MPM) After</p> <p>Condition: Malignant Pleural Mesothelioma 2010</p> <p>Interventions: Biological: WT-1-vaccine Montanide + GM-CSF; Biological: Montanide adjuvant + GM-CSF</p>	Adjuvant WT-1 Analog Peptide Vaccine in Patients With Malignant Pleural Mesothelioma (MPM)
	<p>Primary Outcome: •To assess the 1-year progression free survival in patients [Time Frame: 1 year] treated with WT-1 analog peptide vaccine + GM-CSF or Montanide + GM-CSF after completion of combined modality therapy for Malignant Pleural Mesothelioma (MPM).</p> <p>Secondary Outcome: •To confirm the immunogenicity of the WT-1 analog peptide vaccine [1 year]for MPM after completion of combined modality therapy. /•To assess the utility of using serum markers [1 year]. / (soluble mesothelin related protein (SMRP) and osteopontin) for MPM for disease progression.</p> <p>The addition of the WT1 proteins makes this therapy more directed to mesothelioma. The combination of WT1 vaccine with Montanide and GM-CSF has been tested in a prior trial including 9 patients with advanced mesothelioma. In that trial, the vaccine was safe and caused an immune response. The patient will have a 50% chance of being in each group. Neither the patient nor the doctor will be aware of which group they are in.</p>	
Recruiting	<p>Influenza Vaccine Post Allogeneic Transplant</p> <p>Conditions: Hematopoietic Stem Cell Transplant; Hematologic Malignancy</p> <p>Intervention: Biological: Influenza vaccine</p>	MT2010-08R Influenza Vaccine Specific Immune Responses After Allogeneic Hematopoietic Cell Transplantation: Are One or Two Vaccine Doses Needed?
Active, not recruiting	<p>Multiple-Vaccine Therapy in Treating Patients With Non-Small Cell Lung Cancer</p> <p>Condition: Non Small Cell Lung Cancer 福島医科大学</p> <p>Intervention: Biological: HLA-A*2402restricted URLC10, TTK, VEGFR1 and VEGFR2 2008</p>	Multiple-Vaccine Therapy Including Antiangiogenic Vaccine Using Epitope Peptide Restricted to HLA-A*2402 for

	<p>Primary Outcome: •Adverse effects, dose limiting toxicity, and maximum tolerated dose as measured by CTCAE ver3.0 pre treatment, during study treatment, and 3 months after treatment [3 months]</p> <p>Secondary Outcome: •Peptides specific CTL responses in vitro [3 months] . /•Objective response rate as assessed using RECIST criteria [6 months] . /•Changes in levels of regulatory T cells [3 months]</p> <p>Detailed Description: URLC10 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. We have determined the HLA-A*2402 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,</p>	
Recruiting	<p>Bivalent Vaccine With Escalating Doses of the Immunological Adjuvant OPT-821, in Combination With Oral β-glucan for High-Risk Neuroblastoma</p> <p>Condition: Neuroblastoma 2009</p> <p>Intervention: Biological: adjuvant OPT-821 in a vaccine containing two antigens (GD2L and GD3L) covalently linked to KLH</p>	<p>Bivalent Vaccine With Escalating Doses of the Immunological Adjuvant OPT-821, in Combination With Oral β-glucan for High-Risk Neuroblastoma</p>
	<p>Primary Outcome: Determine the maximally tolerated dose of OPT-821 in a vaccine containing two antigens abundantly expressed on neuroblastoma. [2 years]</p> <p>Secondary Outcome: •To obtain preliminary data on whether subcutaneous administration of the bivalent vaccine produces an immune response directed against the target antigens in patients with high-risk neuroblastoma. [2 years] . /•To obtain preliminary data on the anti-neuroblastoma activity of the bivalent vaccine plus oral β-glucan in patients, including measuring the molecular response in blood and bone marrow. [Time Frame: 2 years]</p> <p>We want the vaccine to cause the patient's immune system to make antibodies against the antigens. Antibodies are made by the body to attack cancer (and to fight infections). If the patient can make antibodies against the 2 antigens in the vaccine, those antibodies might also attach to neuroblastoma cells because a lot of each antigen is on neuroblastoma (and very little on other parts of the body). Then, the attached antibodies would attract the patient's white blood cells to kill the neuroblastoma. This protocol also uses β-glucan which is a kind of sugar from yeast. β-glucan is taken by mouth and can help white blood cells kill cancer. The best way to get the body to make antibodies against the 3 antigens is to link each antigen to a protein called KLH (which stands for: keyhole limpet hemocyanin) and to mix them with a substance called QS-21. But it is hard to get enough QS-21 so we are using an identical substance called OPT-821, which we can get easily in large amounts for use in patients. Studies in adults show that giving these antigens linked to KLH and mixed with QS-21 is safe but there can be some bad side effects on the liver and they can last as long as a few months. Instead of the QS-21, we want to know how much of the OPT-821 can be used safely in children. We want to find the highest dose of OPT-821 that is safe to use with the vaccine. We think that higher doses of OPT-821 are better for killing the cancer but we do not know if that is true.</p>	
Recruiting	<p>Alternate Dosing Schedules Study for HPV Vaccine</p> <p>Conditions: Cervical Cancer; Genital Warts</p> <p>Intervention:</p>	
Completed	<p>Vaccine Therapy in Treating Patients With Stage III or Stage IV Melanoma</p> <p>Condition: Melanoma (Skin) 2004</p> <p>Interventions: Biological: autologous tumor cell vaccine; Biological: therapeutic autologous dendritic cells</p>	<p>En Vivo Matured Dendritic Cell Therapy in Patients With Melanoma</p>

	<p>Primary: •Determine the dose-limiting toxicity and the maximum tolerated dose of autologous dendritic cells pulsed with autologous tumor cell lysate in patients with stage III or IV melanoma. /•Determine the safety and tolerability of this therapy in these patients.</p> <p>Secondary: •Determine the immune response, in terms of the type and degree of T-cell proliferation and delayed-type hypersensitivity responses, in patients treated with this therapy. Patients are followed at day 84 and then every 3 months thereafter</p> <p>Patients undergo leukapheresis for the collection of peripheral blood mononuclear cells (PBMC) on days -9, 19, and 47. Autologous dendritic cells (DC) are prepared from autologous PBMC exposed to sargramostim (GM-CSF), interleukin-4, and tumor necrosis factor alpha and pulsed with autologous tumor cell lysate. Patients receive autologous tumor cell lysate pulsed DC IV over 5-10 minutes on days 0, 28, and 56</p>	
Completed	<p>Evaluation of Influenza H1N1 Vaccine in Adults With Lymphoid Malignancies on Chemotherapy</p> <p>Conditions: Lymphoma; Multiple Myeloma; Influenza A Virus, H1N1 Subtype</p> <p>Intervention: Biological: AS03-adjuvanted H1N1 pandemic influenza vaccine</p>	Pandemic H1N1(2009) Influenza Vaccine in Adults With Lymphoid Malignancies on Active Systemic Treatment or Post Stem
Active, not recruiting	<p>Broad Spectrum HPV (Human Papillomavirus) Vaccine in 16 to 26 Year Old Women (V505-001)</p> <p>Conditions: Cervical Cancer; Vulvar Cancer; Vaginal Cancer; Genital Warts; Human Papillomavirus Infection</p> <p>Interventions: Biological: Comparator: V505 formulation 1; Drug: Comparator: V505 formulation 2; Biological: Comparator: V505 formulation 3; Biological: Comparator: Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant; Biological: Comparator: Placebo (unspecified)</p>	The purpose of this study is to evaluate the safety and immunogenicity of V505 in comparison to GARDASIL™
Recruiting	<p>Combination of Chemoradiation Therapy and Epitope Peptide Vaccine Therapy in Treating Patients With Esophageal Cancer</p> <p>Condition: Esophageal Cancer 2008 慶応大学</p> <p>Intervention: Biological: URLC10, TTK, KOC1, VEGFR1, VEGFR2, cisplatin, fluorouracil</p>	Chemoradiation Therapy With Epitope Peptide Vaccine Therapy in Treating Patients With Unresectable, Advanced or
	<p>Primary Outcome: •Safety(toxicities as assessed by NCI CTCAE version3) [3 months]</p> <p>Secondary Outcome: •Peptide specific CTL induction [3 months]. /•DTH to peptide [3 months]. /•Changes in levels of regulatory T cells [3 months]. /•Objective response rate as assessed by RECIST criteria [1 year]. /•Time to progression [1 year]. /•survival [1 year]</p> <p>Detailed Description: Up-regulated ling cancer 10 (URLC10), TTK protein kinase (TTK) and K homology domain containing protein over expressed in cancer (KOC1) were identified as new targets of tumor associated antigens using cDNA microarray technologies combined with the expression profiles of normal and cancer tissues. Furthermore, anti-angiogenic therapy is now considered to be one of promising approaches for treating cancer. Vascular endothelial growth factor receptor 1 (VEGFR1) and vascular endothelial growth factor receptor 2 (VEGFR2) are essential targets for tumor angiogenesis. Epitope peptides for these targets are able to induce cytotoxic T lymphocytes (CTL) restricted to HLA-A *2402 in vivo. On the other hand, chemotherapy (CDDP, 5-FU) plus radiation therapy has been to be a standard treatment for unresectable advanced esophageal cancer. In this clinical trial, we evaluate the safety and immune responses of different doses of multiple peptides (URLC10, TTK, KOC1, VEGFR1, and VEGFR 2) emulsified with Montanide ISA 51 in combination with chemotherapy (CDDP, 5-FU) plus radiation therapy in treating patients with unresectable, advanced or recurrent esophageal cancer.</p>	
Active, not recruiting	<p>A Study of V503 in Preadolescents and Adolescents</p> <p>Conditions: Cervical Cancers; Vulvar Cancer; Vaginal Cancer; Genital Lesions; PAP Test Abnormalities; HPV</p> <p>Intervention: Biological: V503 2009</p>	the Immunogenicity, Tolerability, and Manufacturing Consistency of V503 (A Multivalent Human Papillomavirus [HPV
Completed	<p>Cyclophosphamide and Fludarabine Followed by Vaccine Therapy, Gene-Modified White Blood Cell Infusions, and Aldesleukin in</p> <p>Condition: Melanoma (Skin) 2004</p> <p>Interventions: Biological: MART-1:27-35 peptide vaccine; Biological: aldesleukin; Biological: filgrastim; Biological: incomplete Freund's adjuvant; Biological: therapeutic autologous lymphocytes; Biological: therapeutic tumor</p>	Lymphodepleting Conditioning Followed by Infusion of Anti-MART-1 TCR-Gene Engineered Lymphocytes and Subsequent Peptide Immunization

	<p>Primary Outcome: •Safety /•Tumor regression Secondary Outcome: •In vivo survival of transplanted cells/•Clinical response RATIONALE: Inserting a laboratory-treated gene into a person's white blood cells may make the body build an immune response to kill tumor cells. Giving cyclophosphamide and fludarabine before a white blood cell infusion may suppress the immune system and allow tumor cells to be killed. Vaccines may make the body build an immune response to kill tumor cells. Aldesleukin may stimulate a person's white blood cells to kill tumor cells. Combining white blood cell infusion with vaccine therapy and aldesleukin may cause a stronger immune response and kill more tumor cells.</p>	
Active, not recruiting	Vaccine Therapy in Treating Patients With Stage IV Melanoma	
	Condition:	Melanoma (Skin)
	Interventions:	Biological: autologous tumor cell vaccine; Biological: therapeutic autologous dendritic cells 2005
	<p>Primary Outcome Measures: •Safety. /•Immunogenicity. /•Objective tumor response. /•Time to disease progression /•Progression-free interval /•Overall survival OBJECTIVES: •Determine the safety and tolerability of vaccine therapy comprising autologous dendritic cells (DC) transfected with autologous polymerase chain reaction-amplified tumor RNA in patients with stage IV cutaneous melanoma. /•Determine whether tumor RNA- or tumor antigen-specific T-cell responses are induced in patients treated with this vaccine. /•Determine whether there are major differences in the immunogenicity of DC transfected at immature stage or at mature stage in patients treated with this vaccine. •Determine objective tumor response in patients treated with this vaccine. /•Determine time to disease progression and progression-free interval in patients treated with this vaccine. •Determine overall survival of patients treated with this vaccine. Patients are followed periodically for up to 10 years.</p>	
Active, not recruiting	Vaccine Therapy With Immune Adjuvant in Treating Patients With Stage IIB, Stage IIC, Stage III, or Stage IV Melanoma	
	Condition:	Melanoma (Skin)
	Interventions:	Biological: gp100 antigen; Biological: sargramostim plasmid DNA melanoma vaccine adjuvant; Biological: tyrosinase peptide 2004
	<p>Primary Outcome: •Immunological efficacy in terms of T-cell response as measured by enzyme-linked immunospot. Primary: •Determine the maximum tolerated dose and recommended dose of sargramostim (GM-CSF) plasmid DNA adjuvant with a multi-epitope peptide vaccine comprising tyrosinase peptide and gp100 antigen in patients with stage IIB, IIC, III, or IV melanoma who are HLA-A2-positive. /•Determine the safety of this regimen in these patients. •Determine the pharmacokinetics of this regimen in these patients. /•Determine the dose-limiting toxic effects of this regimen in these patients. •Determine the immunogenicity of this regimen in these patients.</p>	
Completed	Peptide Vaccinations to Treat Patients With Low-Risk Myeloid Cancers	
	Conditions:	Myelodysplastic Syndrome (MDS); Acute Myeloid Leukemia (AML); Chronic Myeloid Leukemia (CML)
	Interventions:	Biological: WT1:126-134 Peptide; Biological: PR1:169-177 Peptide; Drug: WT1 and PR1 Peptide Vaccines; Drug: GM-CSF (Sargramostim); Biological: WT1 and PR1 Peptide Vaccines 2007
	<p>WT1 and PR1 Peptide Vaccination for Patients With Low Risk Myeloid Malignancies</p>	

	<p>Primary Outcome: •The efficacy and toxicity associated with 6 doses of a combination of WT-1:126-134 and PR1:169-177 peptide vaccines for myeloid malignancies.</p> <p>Secondary Outcome: •Changes in marrow blast cells, blood counts, transfusion dependence, time to disease progression, survival and response to booster vaccination.</p> <p>Therefore we propose this Phase II trial, the third in a series of planned peptide vaccine research protocols, which will evaluate the safety and efficacy associated with an immunotherapy approach using two peptide vaccines, namely PR 1 : 169- 177 and WT-1: 126-1 34 in Montanide adjuvant, administered concomitantly with GM-CSF (Sargramostim), every 2 weeks for 10 weeks (6 doses WT1 plus 6 doses PRI plus GM-CSF) in select patients diagnosed with MDS, AML or CML. Subjects</p>	
Completed	Evaluation of Safety and Immunogenicity of Co-administering Human Papillomavirus (HPV) Vaccine With Other Vaccines in	
Has Results	<p>Conditions: Cervical Intraepithelial Neoplasia; Papillomavirus Vaccines; Human Papillomavirus Infection</p> <p>Interventions: Biological: Boostrix ® Polio; Biological: GSK Biologicals' HPV-16/18 L1 AS04 vaccine (Cervarix TM)</p>	Evaluate the Immunogenicity and Safety of GSK Biologicals' HPV Vaccine (580299) Co-administered With Boostrix Polio (dTpa-IPV)
Completed	Vaccine Plus Interleukin-2 in Treating Patients With Advanced Melanoma	
	<p>Condition: Melanoma (Skin) 2000</p> <p>Interventions: Biological: aldesleukin; Biological: gp100 antigen; Biological: incomplete Freund's adjuvant</p>	Melanoma Vaccine (NSC #683472/675756, IND #6123) and Low-Dose, Subcutaneous Interleukin-2 in Advanced Melanoma
	<p>OBJECTIVES: •Determine clinical response rates in patients with advanced melanoma treated with gp100:209-217(210M) melanoma vaccine and low-dose interleukin-2.</p>	
Suspended	M-Vax + Low Dose Interleukin-2 Versus Placebo Vaccine in Metastatic Melanoma in Patients With Stage IV Melanoma	
	<p>Condition: Melanoma</p> <p>Intervention: Biological: M-Vax- autologous, hapten-modified melanoma vaccine 2007</p>	M-Vax Plus Low Dose Interleukin-2 Versus Placebo Vaccine Plus Low Dose Interleukin-2 for Stage IV Melanoma
	<p>Primary Outcome: •Best overall anti-tumor response. [Time Frame: 1 year] /•Survival - % patients surviving at two years [Time Frame: 2 years]</p> <p>Secondary Outcome: •Safety [Time Frame: 5 years]</p> <p>The primary endpoints of the study are: 1)Best overall anti-tumor response, and 2)Survival, measured by % surviving at two years. Patients will be evaluated for anti-tumor response by modified RECIST criteria between weeks 24 and 25 (i.e., 5-6 weeks after completion of IL2). At the 6-month point patients who remain on study will receive an additional single booster dose of M-Vax or Placebo Vaccine mixed with BCG. This will be followed by four more courses of IL2. Two additional evaluations for anti-tumor response will take place at the 38-39 week (month 9) and one-year points. Then patients will be regularly evaluated for tumor status and adverse events until evidence of tumor progression that requires new therapy. Patients who remain on-study will be followed until death but for a maximum of 5 years.</p>	
Active, not recruiting	Vaccine Therapy and Ganciclovir in Treating Patients With Mesothelioma	
	<p>Condition: Malignant Mesothelioma</p> <p>Biological: PA-1-STK ovarian carcinoma vaccine; Drug: ganciclovir 2000</p>	Treatment of Malignant Pleural Mesothelioma With Gene Modified Cancer Cell Lines
	<p>OBJECTIVES: I. Determine the safety and side effects of intrapleurally administered PA-1-STK modified ovarian carcinoma vaccine and ganciclovir in patients with stage I, II, or III malignant mesothelioma. II. Determine the maximum tolerated dose and dose limiting toxicities of this vaccine in these patients. III. Determine the immunologic response to this treatment regimen in these patients. IV. Determine the intrapleural pharmacokinetics of ganciclovir in these patients.</p> <p>OUTLINE: This is a dose escalation study of PA-1-STK modified ovarian carcinoma vaccine. Patients receive PA-1-STK modified ovarian carcinoma vaccine intrapleurally on day 1 followed by ganciclovir IV over 1 hour for 7 days beginning on day 1. Patients in the first 2 cohorts receive 1 course of treatment only. In all subsequent cohorts, treatment repeats every 3 weeks for a total of 3 courses in the absence of disease progression or unacceptable toxicity. Cohorts of 3 patients receive escalating doses of PA-1-STK modified ovarian carcinoma vaccine until the maximum tolerated dose is determined. /PROJECTED ACCRUAL: A total of 3-16 patients will be accrued for this study.</p>	

Completed	Vaccine Therapy in Treating Patients With Metastatic Melanoma		Intradermally Administered MART-1gp100/Tyrosinase Peptide-Pulsed Dendritic Cell Vaccine Matured With a Cytokine Cocktail for Metastatic Melanoma
	Conditions:	Intraocular Melanoma; Melanoma (Skin)	
	Interventions:	Biological: MART-1 antigen; Biological: gp100:209-217(210M) peptide vaccine; Biological: therapeutic autologous dendritic cells; Biological: tyrosinase peptide 2007	
	<p>Primary Outcome : •Overall survival. /•Progression-free survival / •Time to progression /•Toxicity. Primary: •Determine clinical response in HLA-A *0201-positive patients with metastatic melanoma treated with an intradermally administered vaccine comprising autologous dendritic cells pulsed with MART-1, gp100, and tyrosinase peptides and matured with a cytokine cocktail. Secondary: •Determine immunologic response in patients treated with this regimen.</p>		
Active, not recruiting	Extension Study of the Efficacy of the GSK 580299 Vaccine in Japanese Women Vaccinated in the Primary NCT00316693		the 580299 Vaccine in the Prevention of HPV-16 and/or HPV-18 Associated Cervical Intraepithelial Neoplasia (CIN) in Japanese
	Condition:	Human Papillomavirus Infection	
	Interventions:	Procedure: Blood sampling; Procedure: Liquid-based cytology (LBC) sampling	
Active, not recruiting	A Study to Evaluate the Safety, Immune Response, and Efficacy of Gardasil (V501) in Women		
	Has Results	Conditions:	Healthy; Papillomavirus Infection
	Interventions:	Biological: Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant Vaccine; Biological: Comparator: Placebo	
Active, not recruiting	Vaccine Therapy in Treating Patients Who Have Received First-Line Therapy for Hodgkin's Lymphoma		KGEL Vaccine After Initial Therapy of Hodgkin's Lymphoma
	Condition:	Lymphoma	
	Interventions:	Biological: Hodgkin's antigens-GM-CSF-expressing cell vaccine; Procedure: adjuvant therapy 2007	
	<p>Primary Outcome: •Immunologic response. /•Durability of immunologic response. /•Utility of Epstein-Barr virus reporter system for monitoring cellular vaccine responses. /•Safety and tolerability •Determine immunologic responses in patients who have completed first-line therapy for Hodgkin's lymphoma treated with Hodgkin's antigens-GM-CSF-expressing cell vaccine. •Determine the durability of these immunologic responses in these patients. /•Determine the utility of an Epstein-Barr virus reporter system for monitoring cellular vaccine responses. •Determine the safety and tolerability of this vaccine in these patients. /OUTLINE: Beginning 4-6 months after last chemotherapy, patients receive Hodgkin's antigens-GM-CSF-expressing cell vaccine on day 1. Treatment repeats every 3 weeks for up to 4 courses. /Immunologic responses are serially monitored along with disease status</p>		
Completed	Immunogenicity and Safety of GlaxoSmithKline Biologicals' HPV Vaccine 580299 in Healthy Females 10 - 25 Years of Age.		
	Conditions:	HPV-16/18 Infections; Papillomavirus Vaccines; Cervical Neoplasia	
	Interventions:	Biological: CervarixTM; Biological: Placebo vaccine (Al(OH)3)	
Terminated	Vaccine Therapy Following Chemotherapy and Peripheral Stem Cell Transplantation in Treating Patients With Non-Hodgkin's		Evaluate Immune Response Using Idiotype Vaccines Following High-Dose Chemotherapy and Hematopoietic Stem Cell Transplantation for Follicular Lymphoma
	Has Results	Condition:	
	Interventions:	Biological: autologous tumor cell vaccine; Biological: keyhole limpet hemocyanin; Biological: sargramostim; Procedure: adjuvant therapy 2000	

	<p>Primary Outcome: •Humoral and Cellular Immune Response. /evaluate the humoral immune responses and cellular immune responses to idiotype vaccine with KLH and GM-CSF adjuvant given to patients with follicular lymphoma following high-dose chemotherapy and autologous stem cell transplantation</p> <p>Secondary Outcome: •Safety. /To evaluate the safety and toxicity of idiotype vaccine with KLH and GM-CSF adjuvant in the post-transplant setting /•Toxicity. /To evaluate the safety and toxicity of idiotype vaccine with KLH and GM-CSF adjuvant in the post-transplant setting /•Changes in Quantitative Bcl-2 [Time Frame: 1 year].</p> <p>To evaluate changes in quantitative bcl-2 of the blood and bone marrow prior to and at various time points following the series of idiotype vaccines.</p> <p>OBJECTIVES: •Determine the humoral and cellular immune responses in patients with follicular non-Hodgkin's lymphoma treated with autologous lymphoma-derived idiotype vaccine with keyhole limpet hemocyanin plus sargramostim (GM-CSF). /Determine the safety and toxicity of this regimen in these patients in the post-transplant setting.</p> <p>•Determine the changes in quantitative bcl-2 in the blood and bone marrow of these patients before and at various times after the series of idiotype vaccines.</p> <p>Patients are followed every 3 months for 2 years, every 6 months for 2 years</p>	
Recruiting	<p>Safety Study of DNA Vaccine Delivered by Intradermal Electroporation to Treat Colorectal Cancer</p>	
	Condition:	Colorectal Cancer
	Interventions:	Biological: tetwtCEA DNA (wt CEA with tetanus toxoid Th epitope); Device: Derma Vax (electroporation device); Biological: GM-CSF; Drug: Cyclophosphamide 2010
	Immunogenicity of Intradermal Electroporation of tetwtCEA DNA in Patients With Colorectal Cancer	
	<p>Primary Outcome: •To evaluate the safety and immunogenicity of a DNA immunisation approach where tetwtCEA DNA will be administered in combination with electroporation.</p> <p>Secondary Outcome: •To assess the efficiency of priming immunological responses to CEA by intradermal administration of tetwtCEA DNA in combination with electroporation.</p> <p>•To assess the efficiency of boosting immunological responses to CEA by intradermal administration of tetwtCEA DNA in combination with electroporation in subjects already vaccinated with CEA DNA /•To compare effects (safety and immunogenicity) of additional adjuvance with GM-CSF.</p> <p>The purpose of this study is to evaluate the safety and immunogenicity of a CEA DNA immunisation approach in patients with colorectal cancer. The DNA plasmid, tetwtCEA, encodes wild type human CEA fused to a tetanus toxoid T helper epitope. The vaccine will be delivered using an intradermal electroporation device, Derma Vax (Cyto Pulse Sciences). The following will be assessed:</p>	
Completed	<p>Human Papilloma Virus (HPV) Vaccine Immunogenicity and Safety Trial in Young and Adult Women With GSK Biologicals' HPV-</p>	
Has Results	Conditions:	Cervical Intraepithelial Neoplasia; Human Papillomavirus Infection
	Intervention:	Biological: Cervarix™
Suspended	<p>GM-CSF With or Without Vaccine Therapy After Combination Chemotherapy and Rituximab as First-Line Therapy in Treating</p>	
	Condition:	Lymphoma
	Interventions:	Drug: autologous immunoglobulin idiotype-KLH conjugate vaccine; Drug: cyclophosphamide; Drug: doxorubicin hydrochloride; Drug: prednisone; Drug: rituximab; Drug: sargramostim; Drug: vincristine; Procedure: Intervention/procedure; Procedure: antibody therapy; Procedure: biological therapy; Procedure: chemotherapy; Procedure: colony-stimulating factor therapy; Procedure: cytokine therapy; Procedure: monoclonal antibody therapy; Procedure: non-specific immune-modulator therapy; Procedure: therapeutic procedure; Procedure: tumor cell derivative vaccine; Procedure: vaccine therapy
	Double-Blind, Randomized, Placebo-Controlled Trial of FavID® (Id/KLH) and GM-CSF Following CHOP/Rituximab as First-Line Therapy in Subjects With High-Intermediate and High-Risk Diffuse Large B-Cell Lymphoma	

	<p>Primary: •Compare the 3-year disease-free survival of patients with high-intermediate- or high-risk bulky stage II or stage III or IV diffuse large B-cell lymphoma treated with sargramostim (GM-CSF) with or without autologous immunoglobulin idiotype-KLH conjugate vaccine (Favld®) after combination chemotherapy comprising cyclophosphamide, doxorubicin, vincristine, prednisone, and rituximab (CHOP-R).</p> <p>Secondary: •Compare the 2-year disease-free survival, duration of response, time to progression, overall survival, and safety in patients treated with these regimens.</p> <p>•Estimate the rate of immune reactivity to Favld®. Patients are followed periodically for up to 2 years</p>	
Active, not recruiting	<p>Vaccine Therapy With or Without Sargramostim in Treating Patients With High-Risk or Metastatic Melanoma</p> <p>Condition: Melanoma (Skin)</p>	Peptide Based Vaccine Therapy in Patients With High-Risk or Metastatic Melanoma
	<p>Interventions: Biological: MAGE-10.A2; Biological: MART-1 antigen; Biological: NY-ESO-1 peptide vaccine; Biological: sargramostim; Biological: tyrosinase peptide 2002</p>	
	<p>OBJECTIVES: •Compare the safety of melanoma peptide vaccine with or without sargramostim (GM-CSF) in patients with high-risk or metastatic melanoma.</p> <p>•Compare changes in peptide-specific cellular and humoral immunologic profiles in patients treated with these regimens.</p> <p>•Compare tumor response in patients treated with these regimens.</p> <p>OUTLINE: This is a randomized, open-label study. Patients are randomized to 1 of 2 treatment arms.</p> <p>•Arm I: Patients receive melanoma peptide vaccine comprising tyrosinase leader injected at 2 separate sites, Melan-A ELA injected at another site, NY-ESO-1a and NY-ESO-1b combined and injected at one site, and MAGE-10.A2 injected at another site, intradermally once weekly on weeks 1-6.</p> <p>•Arm II: Patients receive vaccine as in arm I. Patients also receive sargramostim (GM-CSF) subcutaneously daily beginning 2 days before each vaccination and continuing for 5 days.</p>	
Active, not recruiting	<p>Vaccine Therapy With or Without Interleukin-12 in Treating Patients With Stage III or Stage IV Melanoma</p> <p>Conditions: Intraocular Melanoma; Melanoma (Skin)</p>	Vaccine Combining Tyrosinase/gp100 Peptides Emulsified With Montanide ISA 51 With and Without Interleukin-12 for Patients With Resected Stages III and IV Melanoma
	<p>Interventions: Biological: gp100 antigen; Biological: incomplete Freund's adjuvant; Biological: recombinant interleukin-12; Biological: tyrosinase peptide 1999</p>	
	<p>Detailed Description: OBJECTIVES: I. Evaluate immune reactivity to tyrosinase and gp100 peptides emulsified with Montanide ISA-51 (ISA-51) with or without interleukin-12 following surgical resection in HLA-A2 positive patients with stage III or IV melanoma.</p> <p>OUTLINE: This is a randomized, parallel study. Patients are stratified by prior therapy (immunotherapy or chemotherapy vs surgery only). Patients are randomized to receive 1 of 2 treatment arms: Arm I: Following surgery, patients receive tyrosinase and gp100 peptides emulsified with Montanide ISA-51 (ISA-51) subcutaneously (SQ) once weekly during weeks 0, 2, 4, 6, 10, 14, 18, and 26 for a total of 8 vaccinations. Arm II: Following surgery, patients receive treatment as in Arm I followed by interleukin-12 SQ once weekly during weeks 0, 2, 4, 6, 10, 14, 18, and 26 for a total of 8 vaccinations. Patients are followed at 2-4 weeks, then every 3 months for 2 years after resection, then every 6 months for 3 years, and then yearly if without evidence of disease.</p>	
Recruiting	<p>Imatinib Mesylate, Interferon Alfa, and GM-CSF Compared With Imatinib Mesylate and Vaccine Therapy in Treating Patients</p> <p>Condition: Leukemia 2006</p>	Interferon + GM-CSF Versus K562/GM-CSF Vaccination for CML
	<p>Interventions: Biological: GM-K562 cell vaccine; Biological: recombinant interferon alfa; Biological: sargramostim</p>	

	<p>Primary Outcome: •Progression-free survival at 1 year. /•Rate of molecular complete remission.</p> <p>Secondary Outcome: •Time to Philadelphia chromosome (Ph) negativity as measured by polymerase chain reaction /•Disease-free survival. /•Percent molecular complete remission. /•Toxicity . /•Time to progression.</p> <p>Primary: •Compare clinical response, in terms of 1-year progression-free survival and rate of molecular complete remission, in patients with Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML) in chronic phase who have achieved a complete cytogenetic remission to single-agent imatinib mesylate treated with imatinib mesylate, interferon alfa, and sargramostim (GM-CSF) vs imatinib mesylate and GM-K562 cell vaccine.</p> <p>Secondary: •Compare time to Ph-negativity by polymerase chain reaction after randomization. /•Compare disease-free survival and percent molecular complete remissions. /•Determine the toxicity of these treatment regimens in these patients.</p> <p>Patients are followed periodically for up to 1 year.</p>	
Active, not recruiting	Vaccine Therapy in Treating Patients With Stage IV Melanoma	
	Condition: Melanoma (Skin) 1999	Phase I Trial of a Dendritic Cell Vaccine for Melanoma
Interventions:	Biological: dendritic cell-MART-1 peptide vaccine; Biological: gp100 antigen; Biological: therapeutic tumor infiltrating lymphocytes; Biological: tyrosinase peptide	
	<p>OBJECTIVES: I. Determine the dose-limiting toxicities, maximum tolerated dose, recommended phase II dose, and rate of sensitization of T cells at each dose level in patients with melanoma receiving dendritic cell vaccine. II. Determine the overall (complete and partial) response rate, duration of response, and optimal route of administration in this patient population.</p> <p>OUTLINE: This is a dose escalation study. Patients are randomized to one of three treatment arms. All patients undergo leukopheresis to obtain lymphocyte and myeloid origin mononuclear cell fractions for preparation of dendritic cell (DC) vaccine. In each arm, cohorts of up to 5 patients receive escalating doses of vaccine. The maximum tolerated dose (MTD) is defined as the dose preceding that at which 2 or more of 5 patients experience dose-limiting toxicity. Randomization ceases if the MTD has been reached in 2 arms, although accrual may continue. Treatment repeats every 2 weeks for a total of 4 doses. Arm I: Patients receive 3 different doses of peptide pulsed DC vaccine IV, each divided into 3 different peptide pulsed pools administered over 30 minutes. Arm II: Patients receive 3 different doses of peptide pulsed DC vaccine subcutaneously/intradermally to sites with no evidence of disease. At the lowest dose, patients receive 3 different peptide pulsed pools, each administered at a separate site. At the higher doses, patients receive 3 injections further subdivided into 6 and administered at 6 distinct sites. Arm III: Patients receive peptide pulsed DC vaccine intranodally in groin or ancillary lymph nodes at the lower 2 doses of the 3 administered to arms I and II. At the lower dose, patients receive 3 different peptide pulsed pools, each administered into a different node. At the higher dose, patients receive 3 injections further subdivided into 6 and administered at 6 distinct sites. Patients are followed at 2 weeks and then monthly for 3 months.</p>	
Recruiting	Evaluating the Safety and the Biological Effects of Intratumoral Interferon Gamma and a Peptide-Based Vaccine in Patients	
	Condition: Melanoma 2009	Intratumoral Injection of Interferon Gamma During Vaccination in Patients With Subcutaneous or Cutaneous
	Intervention: Biological: A combination of intratumoral IFN-gamma plus systemic vaccination with MELITAC 12.1	