	Primary Outcome: •Safety: To determine the safety of administration of intratumoral interferon gamma with a peptide-based vaccine in patients with cutaneous or subcutaneous metastases of melanoma. [6 months]. /•Biologic effect: To evaluate the biological effects of **vaccine plus IFN-gamma at the tumor site**, to include expression of **CXCR3 ligands (CXCL9, CXCL10 & CXCL11)** and the magnitude of infiltration of **CD8+ CXCR3+ T cells and vaccine-specific T cells.** [6 months] **Secondary Outcome**: •To estimate the effects of vaccine on **CXCR3 expression by circulating antigen-experienced CD4 and CD8 T cells**. [6 months]. /•To estimate the effects of vaccine plus IFN-gamma on changes in the **percentage of FoxP3+ CD25hi CD4+ (putative regulatory T cells, Tregs) among tumor infiltrating T cells**. [6 months]. /•To obtain preliminary data on the variability of immunologic parameters among multiple biopsies of subcutaneous or cutaneous metastases of melanoma. [6 months]. /•To obtain preliminary data on the clinical response of **cutaneous or subcutaneous metastases of melanoma** to the proposed combination regimen. **[6 months]** It is generally agreed that one mechanism to improve the immunologic outcomes of vaccine therapy is to optimize T cell trafficking to the tumor site. CXCR3 is the chemokine receptor on T cells which directs them to sites of inflammation by following the chemokine gradient. The ligands for CXCR3 (CXCL9 (MIG), CXCL10 (IP-10) and CXCL11 (I-TAC)) are known to be induced by interferon gamma. This protocol proposes administering a peptide vaccine to activate tumor antigen-specific CD8+ T cells expressing CXCR3, followed by intratumoral interferon gamma to increase CXCR3 ligands (CXCL9-11) at the tumor site and recruit the CXCR3+ T cells.	
Recruiting	Rituximab and Cyclophosphamide Followed by Vaccine Therapy in Treating Patients With Relapsed Hodgkin Lymphoma Condition: Lymphoma Interventions: Biological: Hodgkin's antigens–GM–CSF–expressing cell vaccine; Biological: filgrastim; Biological: rituximab; Drug: cyclophosphamide	Rituximab, High Dose Cyclophosphamide, and GM–CSF Based Immunotherapy for Relapsed Hodgkin's Lymphoma
	Primary: •Determine the safety and tolerability of **rituximab and high-dose cyclophosphamide** followed by vaccine therapy comprising an **allogeneic vaccine that expresses Hodgkin's tumor antigens and sargramostim (GM-CSF)** (KGEL vaccine) as salvage therapy in patients with relapsed Hodgkin lymphoma. /• Determine the **immunologic response** to this vaccine in these patients. **Secondary:** •Determine the 3-year relapse-free and overall survival of patients treated with this regimen./•Determine the patterns of cellular immune reconstitution in patients treated with this regimen. Patients receive **rituximab IV on days -10 and -7 and then on days 29, 36, 43, and 50** (weeks 4-7) and high-dose (transplant-dose) cyclophosphamide IV on days -3 to 0 without stem cell rescue. Patients receive filgrastim (G-CSF) subcutaneously once daily beginning on day 6 and continuing until blood counts recover. Patients also receive vaccine therapy comprising an allogeneic vaccine that expresses Hodgkin's tumor antigens and GM-CSF (KGEL vaccine) intradermally on day	
Active, not recruiting	Vaccine Therapy and Imatinib Mesylate in Treating Patients With Chronic Phase Chronic Myelogenous Leukemia Condition: Leukemia Interventions: Biological: GM–K562 cell vaccine; Drug: imatinib mesylate	Vaccination for CML Patients With Persistent Disease on Imatinib Mesylate
	Primary: •Determine the maximum tolerated dose of GM-K562 cell vaccine when administered with imatinib mesylate in patients with persistent chronic phase chronic myelogenous leukemia in first hematologic response. /•Determine the safety and toxic effects of GM-K562 cell vaccination in patients. **Secondary:** •Determine the disease response by serial BCR-ABL quantitative polymerase chain reaction measurements in patients treated with this regimen. /• Determine the development of tumor immunity in patients treated with this regimen. /OUTLINE: This is a dose-escalation study of GM-K562. Patients continue to receive oral imatinib mesylate at the same stable dose as before study entry. Patients receive GM-K562 subcutaneously on days 1, 8, 15, 29, 43, 57, 85, 113, and 141 in the absence of disease progression or unacceptable toxicity. Cohorts of 10 patients receive escalating doses of GM-K562 until the maximum tolerated dose (MTD) is determined. The MTD is defined as the dose preceding that at which 3 of 10 patients experience dose-limiting toxicity. Patients are followed periodically for 20 years.	
Active, not	Broad Spectrum HPV (Human Papillomavirus) Vaccine Study in 16–to 26–Year–Old Women (V503–001)	Double–Blinded (With In–House Blinding),

recruiting	Conditions:	Cervical Cancer; Vulvar Cancer; Vaginal Cancer; Genital Warts; Human Papillomavirus Infection	Controlled With GARDASIL, Dose-Ranging, Tolerability, Immunogenicity,
	Interventions:	Biological: Comparator: GARDASIL(R); Biological: Comparator: V503	
Withdrawn	DCVax-L Vaccination With CD3/CD28 Costimulated Autologous T-Cells for Recurrent Ovarian or Primary Peritoneal Cancer		Maintenance Vaccination Combined With Metronomic Cyclophosphamide w/wo Adoptive Transfer of CD3/CD28-CoStimulated T-Cells for Recurrent Ovarian or Primary Peritoneal Cancer Previously Vaccinated DCVax-L
	Conditions:	Ovarian Cancer; Primary Peritoneal Cancer	
	Intervention:	Biological: DCVax-L and T Cells 2008	
	Subjects with recurrent epithelial ovarian carcinoma or primary peritoneal cancer, who have previously undergone vaccination in clinical study UPCC-11807 with DCVax-L, an autologous vaccine with DC loaded in vitro with autologous tumor lysate. Phase I Subjects enrolled in this study will receive leukapheresis; followed by cyclophosphamide/fludarabine-induced lymphodepletion; followed by adoptive transfer of ex vivo CD3/CD28-costimulated vaccine-primed peripheral blood autologous T cells; followed by a single DCVax-L vaccination, to establish feasibility and safety of this approach. **Primary Objectives of Phase** I: To determine the feasibility and safety of administering vaccine-primed, **ex vivo CD3/CD28-costimulated autologous peripheral blood T cells in combination with DCVax-L vaccination**, following lymphodepletion with **high dose cyclophosphamide/fludarabine.** Phase II: **Twenty-two additional subjects will be randomized to receive either:** •ARM-IIA: maintenance DCVax-L vaccination, in combination with oral metronomic cyclophosphamide, or •ARM-IIB: leukapheresis, followed by cyclophosphamide/fludarabine-induced lymphodepletion, followed by adoptive transfer of ex vivo CD3/CD28-costimulated vaccine-primed peripheral blood autologous T cells, followed by maintenance DCVax-L vaccination, plus oral metronomic cyclophosphamide. **Primary Objective of Phase II**: To assess the distribution of progression-free survival at 6 months for patients treated with maintenance DCVax-L vaccination plus oral metronomic cyclophosphamide as well as patients treated with ex vivo CD3/CD28-costimulated vaccine-primed peripheral blood autologous T cells after lymphodepletion with high dose cyclophosphamide / fludarabine, followed by DCVax-L boost vaccination and metronomic oral cyclophosphamide. Primary Outcome : •Disease status will be assessed with CT (or MRI) of chest/abdomen/pelvis at enrollment, after vaccine 2 and at the conclusion of the study . Rates of disease progression will be recorded at the time of study conclusion. [3 months after enrollment]		
Active, not recruiting	A Study of V503 in Females 12-26 Years of Age Who Have Previously Received GARDASIL™ (V503-006)		Placebo-Controlled, Double-Blind Clinical Trial to Study the Tolerability and Immunogenicity of V503, a Multivalent Human Papillomavirus
	Conditions:	Cervical Cancers; Vulvar Cancers; Vaginal Cancers; Genital Warts; Human Papillomavirus (HPV) Infection	
	Interventions:	Biological: V503; Biological: Comparator: Placebo to V503 2010	
Not yet recruiting	Feasibility of Autologous Tumor Cell-TLR9 Agonist Vaccination for Metastatic Colorectal Cancer		Autologous Tumor Cell-TLR9 Agonist Vaccination Prior to Autologous Hematopoietic and Immune Cell Rescue in Metastatic Colorectal Cancer
	Conditions:	Colorectal Neoplasms; Anal, Colon, and Rectal Cancers	
	Interventions:	Biological: Autologous tumor cell + CpG vaccine; Procedure: Autologous hematopoietic and immune cell rescue (transplantation) 2008	

	Recently, the Strober lab developed a preclinical model that effectively treated colon cancer in mice by combining immunotherapy and autologous bone marrow transplantation in order to markedly augment the anti-tumor potency of immunotherapy. They used the **CT26 colon cancer** as the therapeutic target either as a single subcutaneous tumor nodule, as a disseminated tumor in the lungs and peritoneum, or as a metastatic tumor in the liver depending on the route of administration of the tumor cells in BALB/c mice. Mice were vaccinated mice with established primary tumors or disseminated/ metastatic disease with irradiated tumor cells mixed with the adjuvant CpG, and found that vaccination alone had no effect on tumor growth. Similarly radiation conditioning of tumor bearing hosts followed by transplantation of bone marrow and spleen cells or purified T cells and hematopoietic stem cells from unvaccinated donors of the same strain had no effect. In contrast, radiation conditioning of mice followed by transplantation of hematopoietic and immune cells from donors of the same strain vaccinated with tumor cells and CpG cured almost all subcutaneous primary as well as disseminated and metastatic tumors in the hosts. A similar result was obtained after autologous transplantation of hematopoietic and immune cells from tumor bearing mice that had been vaccinated after tumor establishment. Investigation of tumor infiltrating cells showed that the injected donor T cells do not accumulate in the tumors unless the host has been irradiated before injection.
	Based on this model, we have assembled a team of Stanford University faculty members with expertise in gastrointestinal cancers, immunotherapy, radiation oncology, and bone marrow transplantation in the Departments of Medicine and Pathology to translate the preclinical findings into a Phase I safety and feasibility clinical study for the treatment of 10 patients with metastatic colorectal cancer. Resected tumor cells will be irradiated and mixed with CpG to create a vaccine. Patients will receive subcutaneous vaccination at weeks 1 and 2 after resection. Six weeks later, immune T cells and then G-CSF "mobilized" purified blood progenitor cells will be harvested from the blood and cryopreserved. If needed patients will receive chemotherapy for tumor reduction. When disease is controlled off chemotherapy, patients will receive a conditioning regimen of fludarabine (30mg/m2 daily x 3 days) followed by intensive fractionated total body irradiation. The dose of fTBI will be escalated using a 3+3 design to ensure safety and will range from 400 to 800 gray. The patient will then undergo hematopoietic and immune cell rescue. They will undergo a third vaccination within 7-14 days after transplant. Thereafter, serial monitoring of tumor burden will continue. Immune monitoring will occur before and after vaccination as well as after transplantation. Tests will include in vitro anti-tumor immune responses of T cells (proliferation, cytotoxicity, cytokine secretion etc.) to stimulation with whole tumor cells and tumor cell lysates pulsed on to antigen presenting cells, anti-tumor antibody responses, and immune reconstitution after transplantation. **Primary Outcome**: •To assess the feasibility of using an autologous tumor cell vaccine in combination with standard chemotherapy followed by investigational autologous hematopoietic and immune cell rescue in terms of acceptable clinical toxicity. **Secondary Outcome**: •Preliminary efficacy in terms of response and time to progression. /•Ex vivo analysis of immune response
Completed	Human Papillomavirus (HPV) Vaccine Consistency and Non-inferiority Trial in Young Adult Women.
Has Results	Conditions: Papillomavirus Type 16/18 Infection; Cervical Intraepithelial Neoplasia
	Intervention: Biological: Cervarix™
Completed	Immunogenicity and Safety of GlaxoSmithKline Biologicals' Huma Papillomavirus (HPV) Vaccine 580299 in Healthy Females 15 -
Has Results	Condition: HPV-16/18 Infections and Cervical Neoplasia
	Intervention: Biological: Cervarix TM
Completed	A Study to Evaluate the Immunogenicity and Safety of GSK Biologicals' HPV Vaccine in Healthy Women Aged 18-35 Years.
	Conditions: Human Papillomavirus (HPV) Infection; Associated Cervical Neoplasia
	Intervention: Biological: HPV-16/18 L1 VLP AS04
Recruiting	RNActive®-Derived Therapeutic Vaccine — RNActive®-Derived Therapeutic Vaccine in

	Condition:	Hormone Refractory Prostate Cancer	Advanced or Metastatic Hormone Refractory Prostate Cancer
	Intervention:	Biological: CV9103 2006	
	The Phase I part of the study consists of a staggered inclusion of subjects in two cohorts of 3, to confirm the safety of the intended dose (320 µg RNA per antigen), with a lower dose to be considered in case of dose-limiting toxicity (DLT) being reported in greater than or equal to 2 out of 3-6 subjects; in this way, the recommended dose (RD) for the Phase IIa part of the study will be established. In the Phase IIa part of the study, additional subjects will be included at the RD, to confirm the safety and explore the activity of that dose. **Primary Outcome**: •Phase I: Assessment of safety and tolerability of the trial regimen [9 Weeks]. /•Phase I: Evaluation of induction of immune response CV9103 is an mRNA-based vaccine for the treatment of human prostate cancer that is based on CureVac's RNActive® technology. CV9103 encodes for 4 prostate specific antigens. Because these antigens are present in prostate cancer cells, they are appropriate targets for intervention. These antigens have been shown to correlate frequently with the progression of prostate cancer, and are known to be immunogenic in humans, where they induce antigen specific T-cell or B cell expansion. As an RNA-based vaccine, CV9103 features several advantages over other approaches: it is highly specific, there is no restriction to the patient's MHC genotype, and it does not need to cross the nuclear membrane to be active. Finally, in the absence of reverse transcriptase, RNA can not be integrated into the genome.		
Recruiting	Trial for Vaccine Therapy With Dendritic Cells – Transfected With hTERT–, Survivin– and Tumor Cell Derived mRNA + ex Vivo		Dendritic Cells – Transfected With hTERT–, Survivin– and Tumor Cell Derived mRNA + ex Vivo T Cell Expansion and Reinfusion in Patients With Metastatic Malignant
	Condition:	Metastatic Malignant Melanoma	
	Interventions:	Biological: Dendritic cells – transfected with hTERT–, survivin– and tumor cell derived mRNA + ex vivo T cell expansion and reinfusion; Drug: Temozolomide 2010	
	Primary Outcome: •Safety and toxicity of vaccination with DC transfected h-TERT mRNA, survivin mRNA and tumor cell mRNA, lymphodepletion treatment and T cell expansion and reinfusion in patients with metastatic malignant melanoma. [followed up for two years after start of vaccination] **Secondary Outcome**: •Evaluation of immunological responses, time to disease progression and survival time. [5 years of follow-up.] The investigators have also included hTERT and survivin mRNA in the vaccine. Finally, the investigators want to introduce ex vivo T cell expansion after lymphodepletion for the patients who show an immune response.		
Completed	A Safety and Immunology Study of a Modified Vaccinia Vaccine for HER-2(+) Metastatic Breast Cancer		MVA-BN-HER2 Following 1st- or 2nd-Line Chemotherapy for HER-2-Positive Metastatic Breast Cancer
	Condition:	Breast Cancer	
	Intervention:	Biological: MVA-BN-HER2 2010	

	MVA-BN®-HER2 is a candidate breast cancer immunotherapy product comprised of a highly attenuated non-replicating vaccinia virus, MVA-BN®, engineered to encode a modified form of the Her-2 protein. MVA-BN® is a well-characterized, clonal strain of modified vaccinia virus Ankara (MVA) being developed as a smallpox vaccine, suitable for use in high-risk (e.g., immunocompromised) individuals. MVA-BN®-derived vectors encoding heterologous antigens are being developed for use as vaccines for infectious diseases such as HIV, and for the treatment of cancer. A large database exists from safety evaluations in animals and in humans for MVA-BN®, and MVA-BN®-derived vectors. Her-2 is overexpressed in 20-30% of human breast cancers. It is an oncogene/growth factor receptor critical for malignant phenotype of Her-2 expressing tumors. It is an immunogenic target, and immune responses to this protein have been shown to mediate potent anti-tumor activity in multiple animal models. Means to stimulate anti-Her-2 reactivity are now being studied clinically. Sponsor, collaborators, and others have used both Protein and DNA vaccine forms of Her-2, and a safety database is developed and no significant adverse events have resulted from Her-2 directed vaccination. MVA-BN®-HER2 encodes a modified form of the Her-2 protein, hereinafter referred to as HER2. HER2 contains the extracellular domain of Her-2 but lacks the intracellular, cell signaling domain. In addition, HER2 includes two universal T-cell epitopes from tetanus toxin to facilitate the stimulation of an immune response to Her-2, a self-protein. The current trial, BNIT-BR-002, will evaluate the safety and biological activity of a fixed dose of MVA-BN®-HER2, with and without Herceptin, following 1st- or 2nd-line chemotherapy in patients with metastatic breast cancers which overexpress Her-2. Patients will receive 3 subcutaneous vaccinations at 3 week intervals and have tumor followed by CT/MRI imaging and blood drawn for immune function analysis	
Completed	Safety and Immunogenicity Study of the New dHER2 Vaccine to Treat HER2-positive Metastatic Breast Cancer Condition: Metastatic Breast Cancer Biological: GSK Biologicals' 719125 2005	the dHER2 Recombinant Protein Combined With Immunological Adjuvant AS15 in Patients With Metastatic Breast Cancer Overexpressing HER2/Neu
	Primary Outcome; •Vaccine-related Grade 3 or 4 toxicity (other than skin toxicity and influenza-like symptoms) according to the Common Terminology Criteria for Adverse Events version 3.0. /•Objective clinical response (CR or PR) **Secondary Outcome**: •Stable disease. /•Mixed response /•Time to disease progression. /•Time to onset of response, defined as time from first vaccination to the initial response. /•The duration of overall response is measured from the time that measurement criteria are met for complete response or partial response until the first date that recurrent or progressive disease is objectively documented. /•Anti-dHER2, anti-HER2 ECD and anti-HER2 ICD seropositivity. /•Functional activity in vitro. /•Frequency of cellular immune response in vitro to dHER2, HER2 ECD and HER2 ICD. /•Adverse events of Grades 3 and 4. /•Adverse events related to potential cardiotoxicity. /•Solicited local and general signs and symptoms (recorded by the patients on diary cards) [four days following each administration]. /• Unsolicited adverse events (serious and non-serious). /•Unsolicited serious adverse events. /•Any documented toxicity. /•Left ventricular ejection fraction. /• Laboratory values: hematological and biochemical variables (including coagulation). /•Vital signs. /•Electrocardiographic results [Time Frame: at the end of cycle 1 and cycle 2 and at first follow-up visit]. /•Results of physical examination.	
Active, not recruiting	Safety and Immunogenicity of a Melanoma DNA Vaccine Delivered by Electroporation Conditions: Melanoma (Skin); Intraocular Melanoma 2007 Interventions: Biological: Xenogeneic Tyrosinase DNA Vaccine; Device: TriGrid Delivery System for Intramuscular	Safety and Immunogenicity of a Xenogeneic Tyrosinase DNA Vaccine Melanoma

	Primary Outcome: •Evaluate the safety and feasibility of electroporation mediated intramuscular delivery of a mouse tyrosinase plasmid DNA vaccine in patients with stage IIB, IIC, III, or IV melanoma. [one year], /•Assess the magnitude and frequency of tyrosinase specific immunologic responses in the immunized patients **Secondary Outcome**. /•Assess patients with measurable tumor for evidence of anti-tumor response following immunization. This study is designed to evaluate administration of a xenogeneic DNA vaccine encoding the melanosomal antigen tyrosinase by in vivo electroporation in patients with malignant melanoma. The objectives of the study are to characterize the safety and immunogenicity of a DNA vaccine encoding the murine tyrosinase gene delivered administered intramuscularly using the electroporation based TriGrid Delivery System (Ichor Medical Systems). We will assess the nature, frequency, and severity of any toxicity associated with vaccination at escalating pINGmuTyr doses and then expand enrollment at then expand enrollment at the Maximum Tolerated Dose to assess immunologic responses to the tyrosinase antigen.	
Completed	Lymphocyte-Depleting Nonmyeloablative Preparative Chemotherapy Followed By Autologous Lymphocyte Infusion, Peptide Condition: Melanoma (Skin) Interventions: Biological: NY-ESO-1 peptide vaccine; Biological: aldesleukin; Biological: filgrastim; Biological: incomplete Freund's adjuvant; Biological: therapeutic autologous lymphocytes; Drug: cyclophosphamide; Drug: fludarabine phosphate 2004	Metastatic Melanoma Using Nonmyeloablative But Lymphocyte Depleting Regimen Followed By The Administration Of In Vitro Sensitized Lymphocytes Reactive With ESO-1 Antigen
	Primary: •Determine the clinical tumor regression in patients with metastatic melanoma treated with a lymphocyte-depleting nonmyeloablative preparative chemotherapy regimen followed by autologous lymphocyte infusion, ESO-1 peptide vaccination comprising ESO-1:157-165 (165V) and Montanide ISA-51, andIL-2. **Secondary**: •Determine the survival of the infused lymphocytes in patients treated with this regimen./•Determine the long-term immune status of patients treated with this regimen. /OUTLINE: Patients are stratified according to type of lymphocyte infusion (ESO-1-reactive tumor-infiltrating lymphocytes [TIL] vs ESO-1 reactive peripheral blood lymphocytes [PBL]). /•Autologous lymphocyte collection and expansion: Autologous PBL or TIL are collected from patients during leukapheresis or biopsy. The cells are sensitized in vitro with ESO-1:157-165 (165V) melanoma antigen and expanded. /•Lymphocyte-depleting nonmyeloablative preparative chemotherapy: Patients receive lymphocyte-depleting nonmyeloablative preparative chemotherapy comprising cyclophosphamide IV over 1 hour on days -7 and -6 and fludarabine IV over 15-30 minutes on days -5 to -1. /•Autologous lymphocyte infusion: Autologous PBL or TIL are reinfused on day 0*. Patients also receive filgrastim (G-CSF) subcutaneously (SC) once daily beginning on day 1 and continuing until blood counts recover /•ESO-1 peptide vaccination: Patients receive ESO-1 peptide vaccination comprising ESO-1:157-165 (165V) peptide emulsified in Montanide ISA-51 SC on days 0*-4, 11, 18, and 25. /•Interleukin therapy: Patients receive interleukin-2 IV over 15 minutes 3 times daily on days 0*-4. /NOTE: *Day 0 is 1-4 days after the last dose of fludarabine. Patients are followed at 4-5 weeks, every 3-4 months for 2 years, and then annually thereafter.	
Active, not recruiting	Vaccination With Autologous Breast Cancer Cells Engineered to Secrete Granulocyte-Macrophage Colony-Stimulating Factor Condition: Breast Cancer Intervention: Biological: Autologous, Lethally Irradiated Breast Cancer Cells 2004	Autologous, Lethally Irradiated Breast Cancer Cells Engineered by Adenoviral Mediated Gene Transfer to Secrete GM-CSF

	The purpose of this trial is to test the safety of a vaccine made from a patient's own breast cancer cells, and determine if this vaccine will delay or stop the growth of the cancer. The vaccine is made by genetically modifying a patient's own tumor cells to secrete GM-CSF to activate the immune response. **Primary Outcome**: •To determine the doses of lethally irradiated, autologous breast cancer cells engineered by adenoviral mediated gene transfer to secrete GM-CSF that can be manufactured for metastatic breast cancer [3 years]. /•to determine the safety and biologic activity of this vaccination in metastatic breast cancer **Secondary Outcome**: •To determine the time to progression and overall survival of metastatic breast cancer patients treated with this vaccine These cells will help to measure how the patient's immune system is reacting to the tumor cells. This is called Delayed-Type Hypersensitivity (DTH). With vaccine #1 and #5, the patient will also receive a DTH injection. Two to three days after the vaccine and DTH injection, skin biopsies will be taken of both sites. At week 10 in the study treatment, or earlier if necessary, the patient will have a chest, abdomen, and pelvic CT scan to determine if the vaccine therapy has had an effect on their disease. A brain MRI will be performed if there were any abnormalities on the first brain MRI or if new symptoms have developed.	
Completed	Peptide Vaccine, Montanide ISA 51 and ISA 51 VG, and CpG 7909 in Treating Patients With Resected Stage IIC, Stage III, or	Vaccine Combining Multiple Class I Peptides With Montanide ISA 51 and ISA 51 VG and CpG Adjuvant 7909 for Resected Stages IIC/III and IV Melanoma
	Conditions: Intraocular Melanoma; Melanoma (Skin) 2004	
	Interventions: Biological: gp100 antigen; Biological: incomplete Freund's adjuvant; Biological: recombinant MAGE-3.1 antigen; Biological: tyrosinase peptide; Drug: agatolimod sodium; Procedure: adjuvant therapy	
	Primary Outcome: •Immunological response as measured by ELISPOT assy, tetramer assay, and chromium release assay **Secondary Outcome** : •Toxicity [Designated as safety issue: Yes] •Time to relapse •Determine the safety and tolerability of a multipeptide (gp100 antigen, MAGE-3, and tyrosinase peptide) melanoma vaccine, Montanide ISA 51 and ISA 51 VG, and CpG 7909 in patients with resected stage IIC, III, or IV melanoma. /•Determine the immune reactivity of this regimen in these patients. OUTLINE: This is a pilot study. Patients are stratified according to class I haplotype (HLA-A1 vs HLA-A3/A11). Patients receive gp100 antigen, MAGE-3, tyrosinase peptide, Montanide ISA 51 and ISA 51 VG, and CpG 7909 subcutaneously on weeks 0, 2, 4, 6, 8, 10, 14, 18, 22, 26, 38, 50, and then every 6 months for 2 years (for a total of 16 vaccinations) in the absence of unacceptable toxicity.	
Active, not recruiting	Effectiveness, Safety and Immunogenicity of GSK Biologicals' HPV Vaccine GSK580299 (Cervarix TM) Administered in Healthy	
	Conditions: Human Papillomavirus (HPV) Infection; Papillomavirus Vaccines	
	Interventions: Biological: GSK Biologicals' HPV Vaccine GSK580299; Biological: Engerix-B™	
Completed	Chemotherapy Consisting of Fludarabine and Cyclophosphamide Followed By White Blood Cell Infusion, Vaccine Therapy, and	Metastatic Melanoma Using Lymphocytes Reactive With the GP100 Antigen With Immunization Using a Recombinant RF-GP100P209 Virus Encoding a GP100 Peptide Following a Nonmyeloblative Lymphocyte
	Condition: Melanoma (Skin)	
	Interventions: Biological: aldesleukin; Biological: filgrastim; Biological: fowlpox virus vaccine vector; Biological: gp100 antigen; Biological: therapeutic autologous lymphocytes; Biological: therapeutic tumor infiltrating lymphocytes; Drug: cyclophosphamide; Drug: fludarabine phosphate	

	Primary: •Determine complete clinical tumor regression in patients with recurrent or refractory metastatic melanoma treated with lymphocyte-depleting nonmyeloablative preparative chemotherapy comprising fludarabine and cyclophosphamide followed by autologous lymphocyte infusion, recombinant fowlpox virus encoding gp100 peptide, and aldesleukin. **Secondary:** •Determine the survival of patients treated with this regimen. •Determine the safety of this regimen in these patients. OUTLINE: Patients are stratified according to the availability of suitable reactive cells (peripheral blood lymphocytes [PBL] vs tumor-infiltrating lymphocytes [TIL]). •Autologous lymphocyte activation and expansion: Autologous PBL or TIL are activated in vitro with gp100:209-217 (210M) antigen (gp100) and expanded. •Lymphocyte-depleting nonmyeloablative preparative regimen: Patients receive cyclophosphamide IV on days -7 and -6 and fludarabine IV over 15-30 minutes on days -5 to -1. •Autologous lymphocyte infusion: Autologous PBL or TIL are reinfused over 20-30 minutes on day 0*. Patients also receive filgrastim (G-CSF) subcutaneously (SC) once daily beginning on day 1 or 2 and continuing until blood counts recover. •Fowlpox vaccine administration: Patients receive recombinant fowlpox virus encoding gp100 peptide IV over 1-2 minutes on days 2 and 28 (if treated with high-dose aldesleukin [IL-2], as below) OR days 2 and 43 (if treated with low-dose IL-2, as below). •IL-2 therapy: Patients receive high-dose IL-2 IV over 15 minutes every 8 hours on days 0*-4 (beginning within 24 hours after lymphocyte infusion) and 28-32 OR low-dose IL-2 SC on days 0*-4 (beginning within 24 hours after lymphocyte infusion), 7-11, 14-18, 21-25, 28-32, 35-39, 50-54, 57-61, 64-68, 71-75, 78-82, and 85-89. NOTE: *Day 0 is 1-4 days after the last dose of fludarabine. Patients are evaluated between days 72-86 (if treated with high-dose IL-2) OR days 98-123 (if treated with low-dose IL-2). Patients with stable disease or a minor, mixed, or partial response may receive up to 2 retreatment courses as above. Patients with progressive disease after IV lymphocyte infusion may be retreated with intra-arterial lymphocytes along with all other agents outlined above. After completion of study treatment, patients are followed at 2-4 weeks (if treated with high-dose IL-2) OR at 3 weeks (if treated with low-dose IL-2) and then annually thereafter. PROJECTED ACCRUAL: A total of 68 will be accrued for this study
Completed	Study of Combination Immunotherapy for the Generation of HER-2/Neu Specific Cytotoxic T Cells Condition: Breast Cancer Intervention: Biological: HER2 CTL vaccine (plus trastuzumab)
	This will be a single arm phase I-II single institution clinical trial in patients with HER2 overexpressing Stage IV breast and ovarian cancer who are on maintenance trastuzumab alone after being treated with chemotherapy and trastuzumab or trastuzumab alone to NED or stable disease. Patients will receive a monthly vaccination for 6 months with a HER2 CTL peptide-based vaccine. Phase I-II Study of Combination Immunotherapy for the Generation of HER-2/Neu (HER2) Specific Cytotoxic T Cells (CTL) in Vivo **Primary Outcome Measures:** •Safety [Time Frame: 5 years] •Immune response [Time Frame: 1.5 years] **Secondary Outcome Measures:** •Overall survival [Time Frame: At least 5 years] [Designated as safety issue: No] Biological: HER2 CTL vaccine (plus trastuzumab) HER2 CTL peptide-based vaccine; administered intradermally every month for 6 total doses
Active, not recruiting	GARDASIL™ Vaccine Impact in Population Study Condition: Human Papillomavirus Infections Intervention:
Active, not	Vaccine Therapy and Sargramostim in Treating Adults With Metastatic Cancer

recruiting	Conditions:	Breast Cancer; Colorectal Cancer; Ovarian Cancer; Unspecified Adult Solid Tumor, Protocol Specific
	Interventions:	Biological: falimarev; Biological: inalimarev; Biological: sargramostim
	Background: •Many cancers produce two proteins, carcinoembryonic antigen (CEA) and mucin-1 (MUC-1). •The PANVAC-V priming vaccine and PANVAC-F boosting vaccine contain human genes that cause production of CEA and MUC-1, which can be used as a target for the immune system to attack the cancer. The vaccines also contain genes that cause production of other proteins that enhance immune activity. •Sargramostim is a protein that boosts the immune system. **Objectives:** •To evaluate the safety and effectiveness of PANVAC-V and PANVAC-F in patients with advanced cancer. •To document the immune response to the vaccines and any anti-tumor responses that may occur. Eligibility: Patients 18 years of age and older with advanced cancer whose tumors produce CEA or MUC-1 protein **Design:** •This trial has four arms: the first arm includes 10 patients with advanced colorectal cancer; the second arm includes 10 to 15 patients with any advanced non-colorectal cancer that produces either EA or MCU-1; the third arm includes about 12 patients with advanced breast cancer; the fourth arm includes about 12 patients with advanced ovarian cancer. •All patients receive PANVAC-V on study day 1, followed by PANVAC-F on days 15, 29 and 43. The vaccines are given by injection under the skin. Sargramostim is injected at the vaccination site on the day of each vaccination and for the next 3 days following vaccination. •Patients whose disease has not worsened after the last boosting vaccination may receive up to 12 additional monthly boosting vaccinations. Following the 12 vaccinations, patients may receive vaccine every 3 months. Patients whose scans show that their disease has progressed, but who are otherwise clinically stable may revert back to monthly injections. •Patients undergo apheresis to collect white blood cells (lymphocytes) on day 1 and day 71 of the study to measure the immune response to the treatment. Blood is collected through a needle placed in one arm and directed through a cell separator machine where the lymphocytes are extracted. The rest of the blood components are returned to the patient through the same needle. •Patients are monitored with frequent blood tests and periodic imaging tests (scans) to monitor for safety and the response to treatment. Drug: PANVAC-V [Recombinant-Vaccinia-CEA (D609)/MUC-1(L93)/TRICOM] Drug: PANVAC-F [Recombinant-Fowlpox-CEA (D609)/MUC-1(L93)/TRICOM] Drug: Leukine (Sargramostim)	
Active, not recruiting	Vaccine Therapy in Treating Patients With Myelodysplastic Syndromes	
	Condition:	Myelodysplastic Syndromes
	Interventions:	Biological: GM-K562 cell vaccine; Genetic: cytogenetic analysis; Genetic: fluorescence in situ hybridization; Other: flow cytometry; Other: immunoenzyme technique; Other: laboratory biomarker analysis

	RATIONALE: Vaccines made from cancer cells may help the body build an effective immune response to kill abnormal cells. PURPOSE: This clinical trial is studying how well vaccine therapy works in treating patients with myelodysplastic syndromes (MDS). **Primary Outcome Measures:** •Safety, •Hematologic response, defined as achieving a major response in ≥ 1 lineage as described by an erythroid increase > 2 g/dL, platelet increase of 30,000/mm³, or neutrophil increase by 100%, •Cytogenetic response, defined as normalization of pretreatment cytogenetic abnormalities [Designated as safety issue: No] **Secondary Outcome Measures:** •Immune response to common myeloid antigens (e.g., Wilms' tumor-1 [WT-1], survivin, or proteinase-3) as measured by Elispot assay, •Correlation of immune response with clinical response (hematologic response, resolution of cytogenetic abnormalities, or decrease in other parameters, such as WT-1 mRNA levels) **OUTLINE: This is an open-label study**. Patients receive GM-K562 cell vaccine subcutaneously once in weeks 0, 3, 6, 9, and 17 in the absence of disease progression or unacceptable toxicity. Blood and tissue samples are collected periodically for correlative and biomarker studies. Samples are analyzed by cytogenetic studies, fluorescent in situ hybridization (FISH), and flow cytometry. Elispot is used to quantify cellular cytotoxic T-cell response to Wilms' tumor-1 (WT-1), survivin, and proteinase 3. After completion of study treatment, patients are followed every 3 months for 1 year. PROJECTED ACCRUAL: A total of 15 patients will be accrued for this study.	
Completed	Vaccine Therapy in Treating Patients With Stage I or Stage II Pancreatic Cancer Condition: Pancreatic Cancer Intervention: Biological: vitespen	
	RATIONALE: Vaccines made from a person's cancer cells may make the body build an immune response to and kill tumor cells. Combining vaccine therapy with surgery may be an effective treatment for pancreatic cancer. PURPOSE: Phase I trial to study the effectiveness of vaccine therapy in treating patients with stage I or stage II pancreatic cancer that has been surgically removed. A Phase I Pilot Trial of Immunotherapy With Autologous Tumor-Derived gp96 Heat Shock Protein - Peptide Complex (HSPPC-96) in Patients With Resected Pancreatic Adenocarcinoma OBJECTIVES: I. Study the safety of autologous tumor derived gp96 heat shock protein peptide complex (HSPPC-96) in patients with resected pancreatic adenocarcinoma. II. Examine the immune response to HSPPC-96 in this group of patients. OUTLINE: This is a dose escalation study. Six weeks after surgery patients are given autologous tumor derived gp96 heat shock protein peptide complex (HSPPC-96) subcutaneously once a week for 4 weeks. Five patients are initially enrolled at each of two dose levels. An additional three patients may be enrolled at each dose level to determine the optimal dose of HSPPC-96. Patients are followed at weeks 1, 4, and 12 after treatment. PROJECTED ACCRUAL: A maximum of 16 patients will be accrued for this study.	
Recruiting	Study of EMD531444 in Subjects With Stage III Unresectable Non-small Cell Lung Cancer (NSCLC) Following Primary Condition: Non-small Cell Lung Cancer メルクセローノが日本でも治験を実施 Interventions: Biological: cyclophosphamide + EMD531444(LBLP25 or BLP25リポゾームワクチン) + BSC; Biological: Saline + Placebo + BSC 糖蛋白ワクチンの一つであるL-BLP25は、リポペプチドを生成する25のアミノ酸から構成される	EMD531444(L-BLP25 or BLP25 Liposome Vaccine) in Subjects With Stage III Unresectable Non-small Cell Lung Cancer Following Primary Chemoradiotherapy
	Primary Outcome Measures: •Overall survival time [Time Frame: The date of randomization; week 1, 2, 3, 4, 5, 6, 7, 8, 9, 14; every 6 weeks after week 14; 6 weeks after last vaccination; 12 weeks after last vaccination. Additional inquires on survival until death.] [Designated as safety issue: No] **Detailed Description:** Phase I part is designed to evaluate the safety of EMD531444 1000mcg dose to be used in phase II. Phase II part is designed to be conducted as randomized, double blind, placebo controlled study to compare overall survival time in all randomized subjects.	