	HER-2/neu by serum antibody titers, delayed hypersensitivity to HER-2/neu-derived peptides, and CD4+ T-cell resp. by ELISPOT. Bone scans, and tumor markers **Primary:** Determine the safety of vaccination comprising allogeneic sargramostim (GM-CSF)-secreting breast cancer cells with or without immunomodulation using cyclophosphamide and doxorubicin in women with stage IV breast cancer. /Determine the doses of cyclophosphamide and doxorubicin that maximize vaccine-induced immunity, in terms of immune response to HER2/neu, in patients treated with these regimens. /Compare in vivo immune response induced by these regimens, as measured by immunohistochemical analysis of vaccine site biopsies from these patients, with responses seen in prior preclinical and clinical studies. **Secondary:** Determine the time to disease progression in patients treated with these regimens.	
Recruiting	Dendritic Cell Cancer Vaccine for High-grade Glioma Condition: Glioblastoma Multiforme 2010 Interventions: Drug: Trivax, Temozolomide, Surgery, Radiotherapy; Drug: Temozolomide, Surgery, Radiotherapy	Tumour-lysate Charged Dendritic Cells. OS +PFS. Trivax(autologous DC cancer vaccine charged with autologous tumour protein)との比較.
	Primary: Progression free survival [Time Frame: 12 months]. /Progression free survival measured as percentage of non-progressive patients with newly diagnosed GBM 12 months after a post-operative MRI scan treated according to the current standard (surgical resection, irradiation, oral chemotherapy with Temozolomide), and Trivax, an autologous DC cancer vaccine charged with autologous tumour protein, as add-on therapy (group A), in comparison to patients receiving standard treatment without Trivax (group B). **Secondary**: Quality of Life [Time Frame: 24 months] /Quality of life in patients treated with Trivax as an add-on therapy using ECOG (Eastern Cooperative Oncology Group) performance status compared to quality of life of patients receiving standard therapy (for study patients older 18 years). /Progression free survival at 18 and 24 months [Time Frame: 24 months]. /Progression free survival measured as percentage of non-progressive patients at 18 and 24 months post initiation of treat-ment. Overall survival [Time Frame: 24 months] /The percentage of survival will be assessed at 12, 18, and 24 months.	
Recruiting	Comparison of the Human Papillomavirus (HPV) Type 16 E7-Specific Immune Response Between a Normal Population and Patients With Cervical Lesions Condition: Cervical Cancer Intervention:	immunologic responses to HPV type 16 E7 antigen
Active, not recruiting	In-Situ Therapeutic Cancer Vaccine for Metastatic Cancer Combining AlloStim With Tumor Cryoablation Condition: Metastatic Cancer Interventions: Biological: AlloStim-7; Procedure: percutaneous tumor cryoablation; Biological: AlloStim8 or AlloStim-9	AlloStim8 or AlloStim-9. antigen is generated by freezing a tumor
	This is a Phase I/II clinical study to investigate the feasibility of creating a personalized anti-tumor vaccine within the body of patients with advanced cancers. The aim of the study is to evaluate the safety of administration and anti-tumor effect of a vaccine protocol that has three separate phases. Cancer patients generally present with an immune response to cancer biased to a Th2 response, while a Th1 response is considered necessary for mediating anti-tumor immunity. The first step of the study consists of three (3) weekly intradermal priming doses of AlloStim. The aim of this step is to create Th1 immunity to the alloantigens in AlloStim, thus increasing the number of Th1 cells in circulation. The second step of the protocol involves the cryoablation of a selected tumor lesion followed by an intratumoral AlloStimTM injection. The aim of this step is to generate tumor-specific CTL killer cells in the circulation. The final step is an intravenous infusion of AlloStim. The aim of this step is to activate circulating Th1 cells, killer cells, and natural killer cells The further aim of this step is to create an inflammatory environment that can break-down the ability of the tumor to avoid an anti-tumor immune response.	

Active, not recruiting	GVAX in Advanced Prostate Cancer Patients Made Lymphopenic		GM-CSF gene transduced allogeneic cell vaccine:
	Condition:	Prostate Cancer	
	Intervention:	Biological: GM-CSF gene transduced allogeneic vaccine GVAX 2005	
	GVAX.tumor vaccine-specific, PSMA-specific T cells. titer of vaccine-specific antibodies. tumor vaccine-specific CD4+ and CD8+ T cells. serum PSA levels and tumor response. **Purpose :** Androgen (a male sex hormone) deprivation is the standard therapy for metastatic prostate cancer and results in regression or control of disease in 80-85% of patients. This hormone therapy results in a progression-free survival of 12-18 months and overall survival of 24-30 months. However, all patients ultimately develop hormone-refractory prostate cancer (HRPC). Management of HRPC patients is a significant challenge for both patient and physician. Neither past nor current chemotherapy regimens have shown curative potential in patients with HRPC. Thus new treatment strategies are a high priority. A major focus of new treatment strategies is to enlist the aid of the immune system, particularly the development of prostate cancer vaccines. There has been a number of studies using dendritic cell based vaccines and the treatment has been well tolerated. Specific T-cell immune responses have been observed and occasional evidence for tumor regression. A reduction in serum prostate-specific antigen (PSA) has been observed as well. Lengthening the time-to-progression and delays in the onset of bone pain have been observed in subsets of patients with HRPC. The initial preclinical observations suggesting that a granulocyte-macrophage colony-stimulating factor (GM-CSF) gene transduced allogeneic (GVAX) prostate cancer vaccine may be efficacious in poorly immunogenic cancers were reported. The objective of this study is to evaluate the safety and immunologic effects of vaccinations with Allogeneic Prostate GVAX® (CG1940 & CG8711) in patients made lymphopenic by treatment with chemotherapy and infused with autologous peripheral blood mononuclear cells (PBMC). Clinical observations and laboratory measurements will be monitored to evaluate safety, toxicity and immune responses. Additionally, the effects of treatment on serum PSA levels and tumor response will be evaluated.		
Recruiting	Trastuzumab, Cyclophosphamide, and Vaccine Therapy in Treating Patients With High-Risk or Metastatic Breast Cancer		allogeneic GM-CSF-secreting breast cancer cell vaccine with Trastuzumab.
	Condition:	Breast Cancer	
	Interventions:	Biological: allogeneic GM-CSF-secreting breast cancer vaccine; Biological: trastuzumab; Drug: cyclophosphamide; Other: flow cytometry; Other: immunoenzyme technique; Other: immunohistochemistry staining method; Other: laboratory biomarker analysis; Other: pharmacological study; Procedure: biopsy	

	HER2/neu-specific immune response ; delayed-type hypersensitivity response to HER2/neu-derived peptides. PFS **Primary:** To evaluate the safety of allogeneic sargramostim (GM-CSF)-secreting breast cancer vaccine in combination with trastuzumab (Herceptin®) and cyclophosphamide in patients with high-risk or metastatic HER2/neu-overexpressing breast cancer. To measure the HER2/neu-specific CD4+ T-cell response by delayed-type hypersensitivity. To measure the magnitude of HER2/neu-specific CD8+ T-cell responses by ELISPOT. **Secondary:** To assess the impact of trastuzumab on immune priming in vivo by IHC. / To measure the impact of cyclophosphamide pretreatment on CD4+CD25+ regulatory T cells by flow cytometry. /To determine the time to disease progression. **Tertiary:** To develop the tandem tetramer/CD107a cytotoxicity assay for HER2/neu-specific CD8+ T cells. To measure novel T-cell responses induced by trastuzumab and cyclophosphamide-modulated vaccination. Patients also receive cyclophosphamide IV over 30 minutes on day -1 and allogeneic sargramostim (GM-CSF)-secreting breast cancer vaccine intradermally on day 0. Treatment with cyclophosphamide and the vaccine repeats every 27-42 days for up to 3 courses in the absence of disease progression or unacceptable toxicity. Patients then receive a fourth course of cyclophosphamide and vaccine approximately 6-8 months after the first course. Patients undergo delayed-type hypersensitivity testing and blood sample collection at baseline and periodically during study for immunologic laboratory studies. Blood samples are analyzed for serum GM-CSF levels by pharmacokinetic studies and for immune monitoring by ELISPOT and flow cytometry. Skin punch biopsies are also performed periodically and analyzed by IHC	
Terminated	Vaccine Treatment for Advanced Breast Cancer Condition: Breast Cancer Intervention: Biological: HyperAcute – Breast cancer vaccine 2004	HyperAcute – Breast cancer vaccine: Alpha(1,3)Galactosyltransferase Expressing Allogeneic Tumor Cells from Breast Cancer.

	Primary: To determine the safety and efficacy of administration of HyperAcute Breast (HAB) cancer cells by injection into women with recurrent or refractory breast carcinoma [Time Frame: 4 months] **Secondary** : To conduct correlative scientific studies of patient samples to determine the mechanism of any observed anti-tumor effect. [Time Frame: 4 months] According to 2002 statistics of the American Cancer Society, an estimated 203,500 individuals will be diagnosed with breast cancer and 39,600 will die of the disease this year despite all current therapy. This protocol attempts to exploit an approach to breast cancer gene therapy using a naturally occurring barrier to xenotransplantation in humans in attempt to vaccinate patients against their breast cancer. The expression of the murine alpha (1,3) galactosyltransferase [alpha (1,3) GT] gene results in the cell surface expression of alpha (1,3) galactosyl-epitopes (alpha-gal) on membrane glycoproteins and glycolipids. These epitopes are the major target of the hyperacute rejection response that occurs when organs are transplanted from non-primate donor species into man. Human hosts often have pre-existing anti-alpha-gal antibodies that bind alpha-gal epitopes and lead to rapid activation of complement and cell lysis. The pre-existing anti-alpha-gal antibodies found in most individuals are thought to be due to exposure to alpha-gal epitopes that are naturally expressed on normal gut flora leading to chronic immunological stimulation. These antibodies may comprise up to 1% of serum IgG. In this Phase I/II trial, patients with relapsed or refractory breast cancer will undergo a series of four intradermal injections with a vaccine composed of irradiated allogeneic breast cancer cell lines (HAB-1 and HAB-2) that have been transduced with a recombinant Moloney murine leukemia virus (MoMLV)-based retroviral vector expressing the murine alpha (1,3) GT gene. Endpoints of the study include determination of dose-limiting toxicity (DLT), maximum tolerated dose (MTD), tumor and immunological responses. This 2-phase study will determine the safety of treating patients with breast cancer with the genetically engineered HyperAcute-Breast cancer vaccine. It will establish the proper vaccine dose and will examine side effects and potential benefits of the treatment. The vaccine contains killed breast cancer cells containing a mouse gene that causes the production of a foreign pattern of protein-sugars on the cell surface. It is hoped that the immune response to the foreign substance will stimulate the immune system to attack the patient's own cancer cells that have similar proteins without this sugar pattern, causing the tumor to remain stable or shrink. Patients 18 years of age or older with breast cancer that has recurred or no longer responds to standard treatment may be eligible for this study. Candidates will be screened with medical history and physical examination, blood tests, urinalysis, chest x-rays and CT scans. MRI, PET, and ultrasound scans may be obtained if needed.	
Completed	Vaccine Treatment for Surgically Resected Pancreatic Cancer Condition: Pancreatic Cancer Intervention: Biological: HyperAcute-Pancreatic Cancer Vaccine 2005	Alpha(1,3)Galactosyltransferase Expressing Allogeneic Tumor Cells in Patients With Pancreatic Cancer

	Primary: To assess the side effects, dose-limiting toxicity and maximum tolerated dose. [Time Frame: 6 months] **Secondary**: To assess the rate of recurrence after treatment. [Time Frame: 6 months] According to statistics of the American Cancer Society, an estimated 31,000 individuals will be diagnosed with pancreatic cancer and 25,000 will die of the disease, making it the fifth leading cause of U.S. cancer deaths this year despite all current therapy. This protocol attempts to exploit an approach to pancreatic cancer immunotherapy using a naturally occurring barrier to xenotransplantation in humans in an attempt to vaccinate patients against their pancreatic cancer. The expression of the murine alpha (1,3) galactosyltransferase [alpha (1,3) GT] gene results in the cell surface expression of alpha (1,3) galactosyl-epitopes (alpha-gal) on membrane glycoproteins and glycolipids. These epitopes are the major target of the hyperacute rejection response that occurs when organs are transplanted from non-primate donor species into man. Human hosts often have pre-existing anti-alpha-gal antibodies that bind alpha-gal epitopes and lead to rapid activation of complement and cell lysis. The pre-existing anti-alpha-gal antibodies found in most individuals are thought to be due to exposure to alpha-gal epitopes that are naturally expressed on normal gut flora leading to chronic immunological stimulation. These antibodies may comprise up to 1% of serum IgG. In this Phase I/II trial, patients with surgically resected pancreatic cancer will undergo a series of twelve intradermal injections with a vaccine composed of irradiated allogeneic pancreatic cancer cell lines (HAPa-1 and HAPa-2) that have been transduced with a recombinant Moloney murine leukemia virus (MoMLV)-based retroviral vector expressing the murine alpha (1,3) GT gene. Endpoints of the study include determination of dose-limiting toxicity (DLT), maximum tolerated dose (MTD), tumor and immunological responses.	
Completed	Vaccine Treatment for Hormone Refractory Prostate Cancer Condition: Prostate Cancer Intervention: Biological: HyperAcute-Prostate Cancer Vaccine 2005	Alpha (1,3) Galactosyltransferase Expressing Allogeneic Tumor Cells form Refractory Prostate Cancer
	Primary: Safety and efficacy of administration of HyperAcute-Prostate (HAP) cancer cells by injection into men with hormone refractory prostate carcinoma [6 months **Secondary**: Correlative scientific studies of patient samples to determine the mechanism of any observed anti-tumor effect [Time Frame: 6 months] This 2-phase study will determine the safety of treating patients with prostate cancer with the genetically engineered HyperAcute-Prostate cancer vaccine. It will establish the proper vaccine dose and will examine side effects and potential benefits of the treatment. The vaccine contains killed prostate cancer cells containing a mouse gene that causes the production of a foreign pattern of protein-sugars on the cell surface. It is hoped that the immune response to the foreign substance will stimulate the immune system to attack the patient's own cancer cells that have similar proteins without this sugar pattern, causing the tumor to remain stable or shrink. Patients 19 years of age or older with hormone refractory prostate cancer that has recurred or no longer responds to standard treatment may be eligible for this study. Candidates will be screened with medical history and physical examination, blood tests, urinalysis, chest x-rays and CT scans. MRI, PET, and ultrasound scans may be obtained if needed. Participants will receive twelve vaccinations two weeks apart from each other. The vaccines will be injected under the skin, similar to the way a tuberculosis skin test is given. Phase I of the study will treat successive groups of patients with increasing numbers of the vaccine cells to evaluate side effects of the treatment and determine the optimum dose. Phase II will look for any beneficial effects of the vaccine given at the highest dose found to be safe in Phase I. Monthly blood samples will be drawn during the 6 months of vaccine treatment. In addition, patient follow-up visits will be scheduled every 2 months for the remaining first year (6 months) after vaccination and then every 3 months for the next 2 years for the following tests and procedures to evaluate treatment response and side effects	
Terminated	Tumor-Pulsed Dendritic Cells Used as a Tumor Vaccine Condition: Metastatic Colorectal Cancer Intervention: Drug: Interleukin-2 (IL-2) 2005	Tumor-Pulsed Dendritic Cells as a Tumor Vaccine Administered With IL-2.

	This study is being conducted to determine the efficacy, side effects, and toxicity of an investigational vaccine that consists of tumor-pulsed dendritic cells administered with an immune stimulating drug called interleukin-2 (IL-2). Dendritic cells are immune cells that are obtained from a subject's blood and are important in the body's immune response to foreign substances. This study will examine the response of a subject's immune system after receiving several vaccinations containing their own dendritic cells which have been exposed to dead fragments of their cancer cells in the laboratory. This may result in sensitizing a subject's dendritic cells to their cancer cells so that their dendritic cells will react with other cells of the immune system and attack the cancer. It has been shown in the laboratory that dendritic cells exposed to cancer cell fragments can provide lymphocytes (a type of white blood cell) with signals they require in order to become fully activated and acquire the ability to kill cancer cells.	
Completed	Tumor Vaccine and Interferon Gamma in Treating Patients With Refractory Epithelial Ovarian Cancer Condition: Ovarian Cancer Interventions: Biological: ALVAC-hB7.1; Biological: recombinant interferon gamma 1999	ALVAC-hB7.1 with IFN-γ. Autologous Therapeutic Tumor intraperitoneal (IP) injections of epithelial ovarian carcinoma
	OBJECTIVES: Determine whether intraperitoneal (IP) injections of epithelial ovarian carcinoma cells infected with ALVAC-hB7.1 and IP interferon gamma have acceptable toxicity and produce any clinical responses in patients with refractory ovarian epithelial cancer. **OUTLINE:** This is a dose-escalation study of ALVAC-hB7.1 infected tumor cells. Patients receive ALVAC-hB7.1 infected tumor cells intraperitoneally (IP) on days 4, 11, and 18. Patients also receive interferon gamma IP on days 8, 10, 15, and 17. In the absence of disease progression, up to 6 courses of therapy may be given. If insufficient tumor cells are available to continue treatment with tumor cell derived vaccine, interferon gamma may be given alone. Cohorts of 3 to 6 patients receive escalating doses of ALVAC-hB7.1 infected tumor cells until the maximum tolerated dose (MTD) is determined. The MTD is defined as the dose at which no more than 2 of 6 patients experience dose-limiting toxicity. Patients are followed every 6 months until disease progression.	
Completed	Treating High Risk Leukemia With CD40 Ligand & IL-2 Gene Modified Tumor Vaccine Condition: Leukemia Intervention: Biological: Tumor Vaccine: CD40 LIGAND AND IL-2 GENE MODIFIED AUTOLOGOUS SKIN FIBROBLASTS AND TUMOR CELLS 2003	CD40 ligand + IL-2 gene-modified autologous skin fibroblasts and tumor cells.
	Purpose: This research study is to determine the safety and dosage of special cells that may make the patients own immune system fight the leukemia. To do this we will put special genes into cells called fibroblasts that we have grown in the laboratory from a skin sample. The genes we put in these fibroblasts make them produce substances called CD40 Ligand (CD40L) and interleukin-2 (IL-2). These are natural substances that may help the immune system kill leukemia cells. Some of these fibroblasts producing CD40L and IL-2 mixed with a small quantity of the leukemic cells will then be put back into the body. Studies of cancers in animals and in cell lines suggest that substances like CD40L and IL-2 when mixed with cancer cells do help the body to recognize and kill these cancer cells. A treatment using IL-2 has been previously used in more than 40 children with neuroblastoma and similar treatments are being used in adults with other cancers. Some of the patients have shown significant tumor responses. However, we do not know if this treatment will work and we do not know the right amount of each of the special cells to use, so different patients will get different combination and numbers of cells. The purpose of this study is to learn the side effects and safe dosage of these special cells.	
Active, not recruiting	The Use of Dendritic Cell/Tumor Hybridomas as a Novel Tumor Vaccine in Patients With Advance Melanoma Condition: Metastatic Melanoma Intervention: Biological: DC/tumor fusion vaccine 2008	Dendritic Cell/Tumor Hybridomas as a Novel Tumor Vaccine in Patients With Advance Melanoma.

	Primary Outcome: To assess the toxicity, cellular and humoral immunity and tumor response in patient with melanoma receiving the DC/tumor fusion vaccine **Detailed Description:** To assess the toxicity associated with vaccination of melanoma patients with dendritic cell (DC)/tumor fusions. To determine if cellular and humoral immunity can be induced by serial vaccination with DC/tumor fusions cells. To determine if vaccination DC/tumor fusions results in a tumor response.	
Not yet recruiting	Androgen Ablation Therapy With or Without Vaccine Therapy in Treating Patients With Prostate Cancer Condition: Prostate Cancer 2008 Interventions: Biological: GVAX prostate cancer vaccine; Drug: bicalutamide; Drug: goserelin; Drug: leuprolide acetate	GVAX prostate cancer vaccine. Androgen-Ablation Combined With Cell-Based CG1940/CG8711 Immunotherapy
	Primary Outcome: Median PSA recurrence-free survival in patients in patients responding to the study treatments **Secondary Outcome:** Safety. /Effects of 6-month androgen ablation on thymic production of naïve T cells. /Median time to metastatic disease development **Purpose:** RATIONALE: Androgens can cause the growth of prostate cancer cells. Androgen ablation therapy, such as bicalutamide, leuprolide, and goserelin, may lessen the amount of androgens made by the body. Vaccine therapy may help the body build an effective immune response to kill tumor cells. It is not yet known whether androgen ablation therapy is more effective with or without vaccine therapy in treating patients with prostate cancer.	
Completed	A Pilot Study of NY-ESO-1b Peptide Plus CpG 7909 and Montanide ISA-51 in Patients With Cancer. Conditions: Cancer; Neoplasm Intervention: Biological: NY-ESO-1b peptide plus CpG 7909 and Montanide ISA-51 2005	NY-ESO-1b peptide plus CpG 7909 and Montanide ISA-51. Patients With Cancer Expressing NY-ESO-1 or LAGE-1.
	Primary: NY-ESO-1 specific humoral immunity. /NY-ESO-1 specific cellular immunity. /DTH to NY-ESO-1b peptide. /Toxicities and adverse events **Secondary Outcome: Tumor response** **Detailed Description:** This is a pilot study of patients of HLA-A2 phenotype whose tumor expresses the NY-ESO-1 or LAGE-1 antigen. Patients will receive NY-ESO-1b peptide mixed with 0.5mL of Montanide ISA-51 and 1mg of CpG7909 given every three weeks for four doses by subcutaneous injection. There will be a three-week follow-up period after the fourth injection making the cycle 13 weeks long. In the absence of toxicity and progressive disease, a second cycle will be offered to patients who have received four vaccinations. / The primary objective is to evaluate the immune response (antibodies, CD8+ T cells, and DTH) and safety to vaccination with NY-ESO-1b peptide mixed with CpG 7909 and Montanide in patients with cancer expressing NY-ESO-1 or LAGE-1. The secondary objective is to document tumor responses in patients with evaluable or measurable disease.	
Completed	Allogeneic Cellular Vaccine 1650-G for Non-Small Cell Lung Cancer Condition: Non-small Cell Lung Cancer Intervention: Drug: 1650-G Vaccine 2008	1650-G Vaccine: Cellular Vaccine 1650-G for Non-Small Cell Lung Cancer. Immunological Response
	Primary: Primary Outcome Measure: Immunological Response [Evaluated for 52 weeks] **Detailed Description:** The study is an open label investigation of the cellular vaccine called 1650-G. Patients receive 2 vaccine injections intradermally in the thigh given 4 weeks apart. Patients will be followed weekly after each vaccine injection and then monthly for 4 months. Patient follow-up continues with evaluations at 6 months and 1 year after receiving the first vaccine injection. Immunologic responses to the vaccine will be assessed from blood samples obtained at each visit following immunizations	
Completed	Safety and Immune Response to a Multi-component Immune Based Therapy (MKC1106-MT) for Patients With Melanoma. Conditions: Advanced Melanoma; Stage III and IV Melanoma Interventions: Biological: Biological: MKC1106-MT; Biological: Biological: MKCC1106-MT 2008	MKC1106-MTとMKCC1106-MT. MKC1106-MT, consists of 1 plasmid dose and 2 peptides doses designed to stimulate an immune

	Primary : Is to assess the safety and tolerability of MKC1106-MT regimen [Time Frame: 6 weeks] **Secondary**: To assess the immune response (by tetramer and ELISPOT analysis) of MKC1106-MT when administered to subjects with advanced melanoma [6 Weeks. /To determine pMEL-TYR plasmid level in the blood by PCR analysis [6 Weeks]. /To determine target antigen expression (Melan A and tyrosinase) and beta2 microglobulin expression in the tumor tissue [6 Weeks]. /To document any preliminary evidence of clinical response [Time Frame: 6 Weeks] **Detailed Description:** The multi-component active immunotherapy, MKC1106-MT, consists of 1 plasmid dose and 2 peptides doses designed to stimulate an immune reaction to two tumor associated antigens (Melan-A and tyrosinase). The plasmid component will be administered on Days 1,4, 15 and 18 of each treatment cycle followed by administration of peptides on Days 29 and 32 of the treatment cycle. All components will be administered separately into superficial inguinal lymph nodes under ultrasound guidance.	
Recruiting	Safety Study of a Liposomal Vaccine to Treat Malignant Melanoma Condition: Melanoma Intervention: Biological: Lipovaxin-MM 2010	Lipovaxin-MM:
	Primary: Adverse events [Time Frame: Within 112 days after first dose]. /Immunogenicity [Within 112 days of first dose] **Secondary** : Anti-cancer activity (RECIST criteria) [Time Frame: Within 112 days of first dose] The purpose of this study is to determine whether Lipovaxin-MM, a new anti-cancer vaccine, is safe and effective in improving the body's ability to destroy cancer cells in patients with metastatic melanoma.	
Completed	RNA-Loaded Dendritic Cell Cancer Vaccine Condition: Renal Cell Carcinoma Intervention: Biological: Dendritic cell vaccine 2004	Dendritic cell vaccine
	The purpose of this trial is to examine the safety, feasibility, immunological response, and clinical antitumor activity of administering a dendritic cell vaccine to patients with metastatic renal cell carcinoma	
Recruiting	Ovarian Cancer Vaccine for Patients in Remission Condition: Epithelial Ovarian Cancer Intervention: Biological: MUC1 Dendritic Cell Vaccine (CVac) 2010	MUC1 Dendritic Cell Vaccine (CVac) a MUC1 Dendritic Cell Vaccine PFS.
	Primary: To evaluate the safety of CVac administration in this population. [: 2 years] /Progression Free Survival [2 years] **Secondary:** Overall survival [2 years]. / Evaluation of immunologic parameters subsequent to CVac administration. [2 years]	
Recruiting	Four Doses of MAGE Vaccine for Patients With Squamous Cell Carcinoma of the Head and Neck Conditions: Squamous Cell Carcinoma; Head and Neck Cancer Intervention: Biological: MAGE-A3 HPV-16 vaccine 2008	MAGE-A3 HPV-16 vaccine. Four Doses of MAGE-A3/HPV 16 Trojan Peptides
	Purpose: Squamous Cell Carcinoma of the Head and Neck (SCCHN) effects 43,000 individuals in the United States annually with an estimated overall survival of 50%. For some patients who develop local or distant metastases following primary therapy, surgery is not an option. This study is being done to test the safety of experimental cancer vaccines made of MAGE-A3 and HPV-16 antigens. We also hope to learn what doses of the vaccine will best stimulate the immune system. There will be 2 cohorts in this study, based on the results of tumor testing: Cohort 1: Patients with tumor that is HPV 16 positive Cohort 2: Patients with tumor that is MAGE-A3 positive **Primary**: to test the safety of the experimental cancer vaccines made of MAGE-A3 and HPV-16 antigens [Time Frame: ongoing **Secondary**: to learn what doses of the vaccine will best stimulate the immune system	

Not yet recruiting	Safety, Immune and Tumor Response to a Multi-component Immune Based Therapy (MKC1106-MT) for Patients With Melanoma	MKC1106-MT: consists of 1 plasmid dose and 2 peptides doses designed to stimulate an immune reaction to two tumor associated antigens (Melan-A and tyrosinase).
	Condition: Stage III Melanoma, Stage IV Melanoma	
	Intervention: Biological: MKC1106-MT 2009	
	Primary: To evaluate the objective response, where response is defined as either complete response (CR), partial response (PR), or stable disease (SD) for 12 weeks or longer (CR, PR, and SD are defined according to RECIST 1.1 criteria) [Time Frame: 12 Months] **Secondary**: To assess clinical efficacy of MKC1106-MT in subjects with advanced melanoma measured at 6 months and 1 year by (1) time to progression, progression-free survival [Time Frame: 12 Months]. /To identify and characterize correlations between biological activity (immune response), target antigen expression and clinical efficacy. [Time Frame: 12 months]. /To further assess the safety profile and tolerability [Time Frame: 12 months] **Detailed Description:** The multi-component active immunotherapy, MKC1106-MT, consists of 1 plasmid dose and 2 peptides doses designed to stimulate an immune reaction to two tumor associated antigens (Melan-A and tyrosinase). The plasmid component will be administered on Days 1, 4, 15 and 18 of each treatment cycle followed by administration of peptides on Days 29 and 32 of the treatment cycle. All components will be administered separately into non-diseased superficial inguinal lymph nodes under ultrasound guidance	
Not yet recruiting	Allogeneic Whole Cell Cancer Vaccine for Metastatic Epithelial Tumors	Allogeneic whole epithelial tumor cells, DNP-conjugated and irradiated
	Conditions: Colorectal Cancer; Ovarian Cancer; Gastric Cancer; Breast Cancer; Lung Cancer	
	Intervention: Biological: Allogeneic whole epithelial tumor cells, DNP-conjugated and irradiated 2008	
	Purpose This study is based on the finding that tumor cells that are grown in the laboratory can be modified in such a way that, when injected to the patient, they will stimulate his/her immune response. This approach will be evaluated in patients with colorectal, gastric, ovarian, breast or lung epithelial cancer. Tumor cells grown in the laboratory will be modified to make them stimulatory to the immune system, irradiated to kill them, and injected to the patient eight times at two-week intervals . This protocol is expected to prolong survival of metastatic epithelial cancer patients.	
Recruiting	A Phase I Cancer Vaccine Study for Patients With Metastatic Breast Cancer	Dendritic Cell Vaccination: Autologous Dendritic Cells Loaded With Oncofetal Antigen/iLRP.
	Condition: Metastatic Breast Cancer	
	Intervention: Biological: Dendritic Cell Vaccination 2008	
	Primary: toxicity [Time Frame: 24 months] [Designated as safety issue: Yes] **Secondary** : Response, Survival, Immunological Monitoring, Time to Disease Progression [Time Frame: 24 months] **Detailed:** The study is an open-label study to assess safety and immune responses to the universal tumor antigen OFA/iLRP. All patients will be immunized with 1 x 107 viable OFA/iLRP-loaded mature, autologous monocyte-derived dendritic cells (DCs). The DC vaccine will be administered intradermally into the proximal medial upper extremity, contralateral to the original site of breast cancer once every month for 3 months. Changes in the tumor will be documented. The patient will remain in the study unless toxicity or adverse side effects require discontinuation following RECIST and CTC guidelines, or if the patient withdraws for any other reason.	
Terminated	Clinical Trial Studying a Personalized Cancer Vaccine in Patients With Non-Metastatic Kidney Cancer	HSPPC-96: Adjuvant Oncophage® Versus Observation.
	Conditions: Kidney Cancer; Renal Cell Carcinoma 2005	
	Intervention: Biological: HSPPC-96: protein peptide complex consisting of a 96 kDa heat shock protein (Hsp), gp96	

	Primary: To determine whether patients randomized to receive adjuvant HSPPC-96 (treatment) after surgical resection of the kidney cancer have improved recurrence-free survival as compared to patients who did not receive adjuvant treatment (observation) **Secondary**: To determine whether patients randomized to receive adjuvant HSPPC-96 have improved overall survival as compared to patients in the observation group (without adjuvant treatment). /To further characterize the safety profile of HSPPC-96 **Detailed:** This is an international, open label, randomized Phase 3 trial in which patients with surgically removable kidney cancer will be randomly selected post-operatively to receive adjuvant treatment with HSPPC-96 or no adjuvant treatment. All patients will undergo complete surgical removal of their tumors. The primary objective of the study is to determine whether patients who receive adjuvant autologous HSPPC-96 (treatment group) after surgical resection of locally advanced renal cell carcinoma have improved recurrence-free survival as compared to patients who are not receiving adjuvant treatment (observation group). Eligible patients will have a 50% chance of receiving adjuvant treatment with HSPPC-96. Patients in the treatment arm of the trial will receive the vaccine once a week for 4 weeks, and then every other week until vaccine depletion or disease recurrence. Both groups of patients will be followed regularly for assessment of their disease status. HSPPC-96 is an investigational, immunotherapeutic agent made from an individual patient's own tumor, which is collected at the time of surgery. A portion of the tumor tissue is sent to Antigenics' manufacturing facility where it will undergo processing to create a vaccine.	
Completed	NY-ESO-1 Protein With Montanide and CpG 7909 as Cancer Vaccine in Several Tumors Condition: Tumors Intervention: Biological: NY-ESO-1 protein with CpG 7909 and Montanide 2006	NY-ESO-1 protein with CpG 7909 and Montanide. Vaccination With NY-ESO-1 Recombinant Protein Mixed With CpG7909 and Montanide
	Purpose] This is a phase I, open-label, randomized study of NY-ESO-I protein with immune adjuvants CpG 7909 and Montanide® ISA-51 and NY-ESO-I protein 400 µg with immune adjuvants CpG 7909 and Montanide® ISA-51 in patients with tumors that often express NY-ESO-1. The vaccinations will be administered subcutaneously every 3 weeks for 4 doses. Patients with any malignancy that is known to frequently express NY-ESO-1 will be eligible, regardless of whether antigen expression in the autologous tumor can be demonstrated or not by either PCR or immunohistochemistry. **Primary objective:** safety. **Secondarily**, the study will evaluate whether patients develop a specific immunologic response to the NY-ESO-1 protein. Blood samples will be obtained at baseline, prior to each vaccination, one week after each vaccination, and at the last study visit for the assessment of NY-ESO-1 specific CD4+ and CD8+ T-cells. Cytokine secretion by NY-ESO-1 specific CD8+ and CD4+ T-cells, as a measure of T-cell activation, will be determined by FACS analysis. In addition, humoral immunity will be determined by the presence of NY-ESO-1 specific antibodies which will be assessed in all patients by ELISA. Disease status will be assessed at baseline and 2-4 weeks after the fourth vaccination in patients with evaluable (measurable and non-measurable disease).	
Recruiting	Study to Assess dHER2+AS15 Cancer Vaccine Given in Combination With Lapatinib to Patients With Metastatic Breast Cancer Condition: Metastatic Breast Cancer Interventions: Biological: dHER2 + AS15 ASCI; Drug: Lapatinib	dHER2 + AS15 ASCI: dHER2 antigen combined with the immunostimulant. AS15 ASCI:: liquid adjuvant diluent. humoral and cellular immune response
Recruiting	A Phase I Safety Study of a Cancer Vaccine to Treat HLA-A2 Positive Advanced Stage Ovarian, Breast and Prostate Cancer Conditions: Ovarian Neoplasms; Breast Neoplasms; Prostatic Neoplasms Intervention: Biological: DPX-0907 consists of 7 tumor-specific HLA-A2-restricted peptides, a universal T Helper peptide, a polynucleotide adjuvant, a liposome and Montanide ISA51 VG 2009	DPX-0907 consists of 7 tumor-specific HLA-A2-restricted peptides, a universal T Helper peptide, a polynucleotide adjuvant, a liposome and Montanide ISA51 VG. Cell mediated immunity

	Primary Outcome: The safety of dHER2+AS15 ASCI when administered in combination with Lapatinib measured by dose limiting toxicity. [Time Frame: 26 weeks] **Secondary Outcome:** The specific humoral and cellular immune response induced by the dHER2+AS15 ASCI upon co-administration of Lapatinib [26 weeks] This is a phase I/II study to determine the safety and gain insight into the immune response of the immunologic agent dHER2+AS15 ASCI when administered in combination with lapatinib. This study is for patients with metastatic breast cancer (invasive breast cancer with stage IV disease) that overexpresses HER2 and is resistant to trastuzumab (Herceptin). The dHER2 + AS15 candidate Antigen-Specific Cancer Immunotherapeutic (ASCI) contains a recombinant protein termed dHER2, which is a truncated version of the HER2 protein. HER2 is a protein that is commonly overexpressed in breast cancer. This protein is combined with the immunological adjuvant AS15 Adjuvant System from GSK (GlaxoSmithKline), which is a liposomal formulation containing three immunostimulatory components. Lapatinib is FDA approved for use in combination with capecitabine for the treatment of subjects with advanced or metastatic breast cancer overexpress HER2.	
Recruiting	Evaluation of a New Anti-cancer Vaccine for Patients With Non-small Cell Lung Cancer, After Tumor Removal by Surgery Conditions: Non-Small Cell Lung Cancer; Lung Cancer, Non-Small Cell Intervention: Biological: Immunotherapeutic GSK2302032A, different formulations 2009	Immunotherapeutic GSK2302032A, different formulations :
	[Purpose] This is a phase I/II study to determine the safety and gain insight into the immune response of the immunologic agent dHER2+AS15 ASCI when administered in combination with lapatinib. This study is for patients with metastatic breast cancer (invasive breast cancer with stage IV disease) that overexpresses HER2 and is resistant to trastuzumab (Herceptin). The dHER2 + AS15 candidate Antigen-Specific Cancer Immunotherapeutic (ASCI) contains a recombinant protein termed dHER2, which is a truncated version of the HER2 protein. HER2 is a protein that is commonly overexpressed in breast cancer. This protein is combined with the immunological adjuvant AS15 Adjuvant System from GSK (GlaxoSmithKline), which is a liposomal formulation containing three immunostimulatory components. Lapatinib is FDA approved for use in combination with capecitabine for the treatment of tumors overexpress HER2. **Primary** : The safety of dHER2+AS15 ASCI when administered in combination with Lapatinib measured by dose limiting toxicity. [Time Frame: 26 weeks] **Secondary**: The specific humoral and cellular immune response induced by the dHER2+AS15 ASCI upon co-administration of Lapatinib [Time Frame: 26 weeks ;	
Active, not recruiting	Trial to Compare the Routes of Administration of an Investigational, Personalized, Therapeutic Cancer Vaccine Oncophage (HSPPC-96) in Patients With Metastatic Renal Cell Carcinoma Condition: Renal Cell Carcinoma Intervention: Biological: autologous human tumor-derived HSPPC-96 2004	autologous human tumor-derived HSPPC-96. Oncophage (HSPPC-96) in Patients With Metastatic Renal Cell Carcinoma
	Detailed: The goal of this trial is to determine the safety of HSPPC-96 and which route of administration achieves a better response with the vaccine. HSPPC-96 is an immunotherapeutic agent made from an individual patient's tumor. The study is being conducted in Houston, Texas with patients enrolled into one of two treatment arms. The two treatment arms are either subcutaneous injection or intradermal injection, both with HSPPC-96. To be treated with HSPPC-96 patients must undergo surgery to remove the kidney tumor and a portion of this tissue will be sent to Antigenics' manufacturing facility for processing	
Active, not recruiting	Study of Repeat Intranodal Injection of Memgen's Cancer Vaccine, Ad-ISF35, in Subjects With Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) Conditions: Chronic Lymphocytic Leukemia; Small Lymphocytic Lymphoma Intervention: Biological: ISF35 2009	ISF35 : Adenovirus-CD 154 (Ad-ISF35) in Patients With CLL/ SLL. ISF35 is an abbreviation for Immune Stimulatory Factor 35

	Primary]: Determine and monitor clinical and biological responses in patients treated with repeat intranodal injections of Ad-ISF35. [Time Frame: 2 years (evaluation will be approx. 4 months per patient)] **Secondary]** : Determine the safety of repeat administration of Ad-ISF35 injected directly into lymph nodes of patients with CLL/SLL. [Time Frame: 2 years (evaluation will be approx. 1 year per patient)] /Determine pharmacodynamic parameters in patients treated with repeat intranodal injections of Ad-ISF35. [Time Frame: 2 years (evaluation will be approx. 4 months per patient)] [**Detailed]** : This is a phase II clinical trial in which study subjects will be treated with multiple doses of Ad-ISF35 given via intranodal injection using a fixed dose of 3.3 x 10^10 ISF35 viral particles. Intranodal injections will be administered every 2-4 weeks up to six total injections. Because this is the first time that repeat administration of Ad-ISF35 will be performed via intranodal injection, and in order to allow sufficient time to evaluate the safety and toxicity of this procedure, we will treat subjects 1 thru 3 at one month intervals and with inpatient admission for 24 hours observation. After subject three receives their second ISF35 injection we will proceed with enrollment of cohorts of four patients per month at one week intervals until study enrollment has been completed. These subjects will be treated as outpatients and will be observed for 3 hours prior to discharge. ISF35 has already been used in Phase I clinical trials. The trials demonstrated that ISF35 treatment is well-tolerated and patients did not experience any significant or unexpected adverse events. Patients reported flu-like symptoms from ISF35, which disappeared within one to three days	
Active, not recruiting	A Dose-Escalation Vaccine Trial In HER2-Overexpressing Patients With High-Risk Breast Cancer Condition: Breast Cancer Intervention: Biological: Investigational Cancer Vaccine 2003	dHER2 Protein With AS15 Adjuvant in HER2-Overexpressing Patients With High-Risk Breast Cancer
	Purpose] This trial will test how safe this vaccine is. It also tests whether its introduction induces an immune response by stimulating the patient's own immune system to recognize a specific target molecule called HER2, which is overexpressed in many breast cancers. The vaccine in this trial has not previously been administered to humans, and therefore the induction of the desired immune responses in humans remains to be established. Patients will receive 6 intramuscular vaccinations over a 14 week period, with 9 clinic visits and 3 follow up visits. In addition, patients are asked to revisit the study physician once a year for 5 years after the study ends to evaluate any long-term effects.	
Completed	Vaccine Therapy and Biological Therapy in Treating Patients With Advanced Cancer Conditions: Breast Cancer; Cervical Cancer; Colorectal Cancer; Lung Cancer; Ovarian Cancer; Pancreatic Cancer Interventions: Biological: aldesleukin; Biological: mutant p53 peptide pulsed dendritic cell vaccine; Biological: ras peptide cancer vaccine; Biological: sargramostim; Biological: therapeutic autologous lymphocytes; Biological: therapeutic tumor infiltrating lymphocytes	Biological: aldesleukin Biological: mutant p53 peptide pulsed dendritic cell vaccine Biological: ras peptide cancer vaccine Biological: sargramostim
	OBJECTIVES: I. Determine whether endogenous cellular immunity to a particular tumor-specific mutated p53 or ras protein is present in patients with tumors expressing mutant p53 or ras. II. Determine whether vaccination with antigen-presenting cells pulsed in vitro with synthetic peptide corresponding to the tumor's p53 or ras mutation in the presence of sargramostim (GM-CSF) can induce or boost patient cellular immunity to the mutated peptide in this patient population. III. Assess the type and characteristics of the cellular immunity generated. IV. Determine whether in vivo-primed T-cells generated against the p53 or ras mutation, expanded in vitro with corresponding peptide, and infused with subcutaneous interleukin-2 can enhance the activity of specific cytotoxic T-lymphocyte immune response and/or tumor response in these patients.	
Completed	Vaccine Therapy Plus Biological Therapy in Treating Adults With Metastatic Solid Tumors Conditions: Colorectal Cancer; Endometrial Cancer; Head and Neck Cancer; Liver Cancer; Lung Cancer; Melanoma (Skin); Pancreatic Cancer; Testicular Germ Cell Tumor; Unspecified Adult Solid Tumor, Protocol Specific Interventions: Biological: aldesleukin; Biological: ras peptide cancer vaccine; Biological: sargramostim; Drug: DetoxPC	Biological: aldesleukin Biological: ras peptide cancer vaccine Biological: sargramostim Drug: DetoxPC

	OBJECTIVES: Determine whether endogenous cellular immunity to a tumor-specific mutated ras protein is present in cancer patients. Determine whether vaccination with synthetic peptides corresponding to the tumor's ras mutation with DetoxPC adjuvant, interleukin-2 (IL-2), and/or sargramostim (GM-CSF) can induce or boost a patient's cellular immunity to that particular mutation. Determine the type and characteristics of the cellular immune response generated. Determine the tolerance to and toxicity spectrum of such peptides given with DetoxPC adjuvant along with IL-2 and/or GM-CSF. Correlate immune response with tumor response in patients treated with these regimens. OUTLINE: Patients are assigned to one of three treatment groups. Group I (closed to accrual 6/4/01): Patients receive tumor-specific ras peptide vaccine with DetoxPC subcutaneously (SC) once every 5 weeks for 3 courses. Beginning 4 days after vaccination, patients receive interleukin-2 (IL-2) SC 5 days a week for 2 weeks. Group II (closed to accrual 6/4/01): Patients receive sargramostim (GM-CSF) SC daily beginning 1 day prior to the vaccination and continuing for 4 days. Patients receive the vaccination as in group I immediately followed by GM-CSF on day 2. Patients are vaccinated once every 4 weeks for 3 courses. Group III: Patients receive the vaccination and IL-2 as in group I and GM-CSF as in group II. In all groups, patients receive up to 15 vaccinations in the absence of disease progression. Patients are followed every 2 months.	
Completed	Vaccine Therapy in Treating Patients With Colon, Pancreatic, or Lung Cancer Conditions: Recurrent Colon Cancer; Extensive Stage Small Cell Lung Cancer; Stage III Pancreatic Cancer; Stage III Rectal Cancer; Limited Stage Small Cell Lung Cancer; Recurrent Pancreatic Cancer; Recurrent Rectal Cancer; Stage III Non-Small Cell Lung Cancer; Stage I Pancreatic Cancer; Stage II Non-Small Cell Lung Cancer; Stage IVB Pancreatic Cancer; Stage II Pancreatic Cancer; Stage III Colon Cancer; Stage IVA Interventions: Drug: Detox-B adjuvant; Drug: ras peptide cancer vaccine	Drug: Detox-B adjuvant Drug: ras peptide cancer vaccine
	Detailed Description: OBJECTIVES: I. Determine whether endogenous cellular or humoral immunity to a tumor-specific mutated ras protein is present in patients with colorectal, pancreatic, or lung cancer. II. Determine whether vaccination with a synthetic peptide corresponding to the tumor's ras mutation combined with Detox-B adjuvant can induce or boost cellular immunity to that particular mutation in this patient population. III. Determine the type and characteristics of any cellular immunity generated in these patients treated with this regimen. IV. Determine the tolerance and toxicity spectra of such peptides given with Detox-B adjuvant in these patients. V. Determine the immune response associated with each peptide dose in these patients. VI. Assess any tumor response that may occur with treatment in these patients treated with this regimen. PROTOCOL OUTLINE: This is a dose-escalation study. Patients receive tumor-specific mutated ras peptide combined with Detox-B adjuvant subcutaneously monthly for 3 months. Treatment continues in the absence of disease progression or unacceptable toxicity. Patients with stable or responding disease or with a specific immunologic response may receive 3 additional monthly vaccinations. Cohorts of 3-6 patients receive escalating doses of tumor-specific mutated ras peptide combined with Detox-B adjuvant until the maximum tolerated dose (MTD) is determined. The MTD is defined as the dose preceding that at which 2 of 3 or 2 of 6 patients experience dose-limiting toxicity.	
Completed	Vaccine Therapy Plus QS21 in Treating Patients With Advanced Pancreatic or Colorectal Cancer Conditions: Colorectal Cancer; Pancreatic Cancer Interventions: Biological: QS21; Biological: ras peptide cancer vaccine	Biological: QS21 Biological: ras peptide cancer vaccine

	Detailed Description: OBJECTIVES: I. Determine the toxicity of ras peptide cancer vaccine plus immunological adjuvant QS21 in patients with advanced pancreatic or colorectal adenocarcinoma. II. Determine the immunologic effects of this treatment regimen in these patients. III. Determine the antitumor effect of this treatment regimen in these patients. **OUTLINE**: This is a dose escalation study of ras peptide cancer vaccine. Patients receive ras peptide cancer vaccine mixed with immunological adjuvant QS21 subcutaneously monthly for 4 doses, every 2 months for 4 doses, every 4 months for 3 doses, every 6 months for 2 doses, and then annually thereafter in the absence of unacceptable toxicity. Cohorts of 3 to 6 patients receive escalating doses of ras peptide cancer vaccine until the maximum tolerated dose (MTD) is determined. The MTD is defined as the dose preceding that at which at least 2 of 3 or 2 of 4 patients experience dose limiting toxicity. PROJECTED ACCRUAL: Approximately 15-20 patients will be accrued for this study within 30 months.	
Completed	Vaccine Therapy With or Without Interleukin-2 in Treating Patients With Locally Advanced or Metastatic Colorectal Cancer Condition: Colorectal Cancer 2001 Interventions: Biological: aldesleukin; Biological: ras peptide cancer vaccine; Procedure: adjuvant therapy	Biological: aldesleukin Biological: ras peptide cancer vaccine Procedure: adjuvant therapy
	Primary : Response rate every 3 months for up to a year after completion of study treatment **OBJECTIVES: D**etermine the frequency of immunologic response in patients with locally advanced or metastatic colorectal cancer treated with ras peptide-pulsed dendritic cell vaccine with or without interleukin-2. Determine the tumor response and survival time in patients with metastatic colorectal cancer treated with vaccine plus interleukin-2. Determine the time to progression in patients with locally advanced colorectal cancer treated with adjuvant vaccine. **OUTLINE:** Patients are assigned to 1 of 2 treatment groups according to extent of disease. Patients with prior locally advanced disease are assigned to treatment group A, while those with metastatic disease are assigned to treatment group B. **Group A**: Patients are vaccinated against influenza on day -6. Patients undergo collection of peripheral blood mononuclear cells (PBMC) on day -4. The PBMC are cultured with sargramostim (GM-CSF) and interleukin-4 for 5 days and CD40 ligand for 24 hours and then pulsed for 2 hours with the appropriate peptide to form a vaccine. Patients receive ras peptide-pulsed dendritic cell vaccine IV over 5 minutes on days 1, 15, 29, 43, and 57. **Group B**: Patients undergo collection of PBMC and receive vaccination as in group A. Patients also receive interleukin-2 subcutaneously on days 2-6 and 9-13. Treatment in both groups repeats every 2 weeks for up to 5 vaccinations in the absence of disease progression or unacceptable toxicity. Patients are followed every 75-90 days and [illegible]	
Active, not recruiting	Vaccine Therapy Plus Interleukin-12 in Treating Patients With Metastatic Prostate Cancer That Has Not Responded to Hormone Therapy Condition: Prostate Cancer Interventions: Biological: PSA prostate cancer vaccine; Biological: recombinant interleukin-12	Biological: PSA prostate cancer vaccine + recombinant interleukin-12 PSMA Peptide-Pulsed Autologous PBMC Plus rhIL-12

	Purpose RATIONALE: Vaccines made from a patient's white blood cells may make the body build an immune response to kill cancer cells. Interleukin-12 may kill cancer cells by stopping blood flow to the tumor and by stimulating a person's white blood cells to kill cancer cells. Combining vaccine therapy with interleukin-12 may kill more tumor cells. **PURPOSE:** Phase II trial to study the effectiveness of vaccine therapy combined with interleukin-12 in treating patients who have metastatic prostate cancer that has not responded to hormone therapy **OBJECTIVES:** Determine whether immunization with prostate-specific membrane antigen-pulsed autologous peripheral blood mononuclear cells and interleukin-12 can promote specific T-cell priming in patients with metastatic hormone-refractory prostate cancer. Determine the clinical response in patients treated with this regimen. OUTLINE: Patients receive prostate-specific membrane antigen-pulsed autologous peripheral blood mononuclear cells subcutaneously (SC) on day 1 and interleukin-12 SC on days 1, 3, and 5. Treatment repeats every 21 days for 3-9 courses in the absence of disease progression or unacceptable toxicity.	
Completed	Vaccine Therapy Combined With Adjuvant Chemoradiotherapy in Treating Patients With Resected Stage I or Stage II Adenocarcinoma (Cancer) of the Pancreas Condition: Pancreatic Cancer Interventions: Biological: GVAX pancreatic cancer vaccine; Drug: fluorouracil; Procedure: adjuvant therapy; Radiation: radiation therapy 2004	GVAX pancreatic cancer vaccine + fluorouracil + adjuvant therapy mesothelin-specific T-cell response
	RATIONALE: Vaccines made from gene-modified pancreatic cancer cells may make the body build an immune response to kill tumor cells. Drugs used in chemotherapy, such as fluorouracil, work in different ways to stop tumor cells from dividing so they stop growing or die. Radiation therapy uses high-energy x-rays to damage tumor cells. Giving vaccine therapy together with chemotherapy and radiation therapy after surgery may kill any remaining tumor cells. **Primary:** Determine overall and disease-free survival of patients with resected stage I or II adenocarcinoma of the pancreas treated with adjuvant chemoradiotherapy in combination with GVAX pancreatic cancer vaccine. **Secondary:** Correlate specific in vivo parameters of immune response (post-vaccination delayed-type hypersensitivity reactions to autologous tumor, mesothelin-specific T-cell response, and the degree of local eosinophil, macrophage, and T-cell infiltration at the vaccine site) with clinical responses in patients treated with this regimen. Determine the toxic effects associated with intradermal injections of this vaccine in these patients. **OUTLINE:** This is an open-label study. **Post surgery vaccination:** Within 8-10 weeks after pancreaticoduodenectomy, patients receive GVAX pancreatic cancer vaccine intradermally (ID) on day 0. Adjuvant chemoradiotherapy: Within 16-28 days after the first vaccination, patients receive fluorouracil (5-FU) IV continuously for 3 weeks. Approximately 1-2 weeks after completion of 5-FU, patients receive chemoradiotherapy comprising radiotherapy daily and 5-FU IV continuously for 26-28 weeks. Approximately 3-5 weeks after completion of chemoradiotherapy, patients receive 5-FU IV continuously for 4 weeks. 5-FU repeats every 6 weeks for 2 courses. Post chemoradiotherapy vaccination: Within 4-8 weeks after the completion of chemoradiotherapy, patients receive GVAX pancreatic cancer vaccine ID on days 0, 28, 56, and 196.	
Active, not recruiting	Vaccine Therapy in Treating Patients With Recurrent Prostate Cancer Condition: Prostate Cancer Interventions: Biological: PSA prostate cancer vaccine; Biological: incomplete Freund's adjuvant 2002	PSA prostate cancer vaccine + incomplete Freund's adjuvant. Prostate Specific Antigen-3 (PSA-3) With Montanide

	Detailed Description: OBJECTIVES: I. Determine the effect of PSA-3 peptide vaccine emulsified in Montanide ISA-51 on PSA levels in patients with recurrent prostate cancer. II. Determine the toxicity of this regimen in these patients. III. Determine whether the T lymphocyte immune response to PSA-3 and HLA-A2 antigen-presenting cells that endogenously produce PSA is increased in patients treated with this regimen. IV. Determine the duration of the PSA and/or immune responses in patients treated with this regimen. V. Correlate immune and PSA responses in patients treated with this regimen. VI. Determine the efficacy of a second (boost) vaccination with this regimen in patients with a PSA or immune response. **OUTLINE:** This is a multicenter study. Patients receive PSA-3 peptide vaccine emulsified in Montanide ISA-51 subcutaneously in 2 sites on days 1, 8, 15, and 22 in the absence of unacceptable toxicity. Patients who show an immune or prostate specific antigen (PSA) response are followed until disease progression, defined as a diminution or disappearance of an immune response or 2 consecutive increases in PSA over the nadir. Patients are eligible for a second series of injections at the time of progression. **PROJECTED ACCRUAL**: A total of 14-44 patients will be accrued for this study within 12-18 months.	
Completed	Vaccine Therapy and Sargramostim in Treating Patients With Non-Small Cell Lung Cancer Condition: Lung Cancer Interventions: Biological: ras peptide cancer vaccine; Biological: sargramostim 2000	ras peptide cancer vaccine + sargramostim (GM-CSF)
	OBJECTIVES: Determine whether a specific T-cell response can be induced in patients with stage IB-IV non-small cell lung cancer treated with mutant K-ras peptide vaccine (limited to the specific K-ras peptide mutation in their tumors) and sargramostim (GM-CSF). Determine whether skin test reactivity or HLA type correlates with the induction of anti-K-ras immune responses in patients treated with this regimen. Determine the toxicity of this regimen in these patients. OUTLINE: Patients receive sargramostim (GM-CSF) intradermally (ID) on days 1-10 beginning a maximum of 6 months after complete surgical resection. Patients receive mutant K-ras peptide vaccine (limited to the specific K-ras mutation in their tumors) ID on day 7. Treatment repeats every 4 weeks for 3 courses in the absence of disease progression or unacceptable toxicity. Patients are followed at 4 and 12 weeks.	
Active, not recruiting	Vaccine Therapy in Treating Patients With Metastatic Prostate Cancer That Has Not Responded to Hormone Therapy Condition: Prostate Cancer Interventions: Biological: PSA prostate cancer vaccine; Biological: therapeutic autologous dendritic cells 2000	PSA prostate cancer vaccine (rPSMA) +: therapeutic autologous dendritic cells.
	OBJECTIVES: I. Assess the safety of recombinant prostate-specific membrane antigen (rPSMA)-pulsed autologous dendritic cells (CaPVax) in patients with metastatic hormone-refractory prostate cancer. II. Determine the potential clinical response in patients treated with this regimen. III. Determine the effect of this treatment regimen on pain, physical function, and quality of life of these patients. **OUTLINE:** This is a dose-escalation, multicenter study. Patients undergo a delayed hypersensitivity skin test with 3 common recall antigens. Autologous dendritic cells (DC) are pulsed with recombinant prostate-specific membrane antigen (rPSMA). Patients receive rPSMA-pulsed autologous DC (CaPVax) intradermally. Treatment repeats every 4 weeks for a total of 4 courses in the absence of disease progression or unacceptable toxicity. Cohorts of 3-6 patients receive escalating doses of CaPVax until the maximum tolerated dose (MTD) is determined. The MTD is defined as the dose preceding that at which 2 of 6 patients experience dose-limiting toxicity. Quality of life questionnaires are completed five times over the course of the study. Patients are followed at 3 months. **PROJECTED ACCRUAL**: A total of 60 patients will be accrued for this study.	
Completed	Vaccine Therapy in Treating Patients With Myelodysplastic Syndrome Conditions: Leukemia; Myelodysplastic Syndromes Interventions: Biological: ras peptide cancer vaccine; Biological: sargramostim 2000	ras peptide cancer vaccine + sargramostim (GM-CSF)

	OBJECTIVES: I. Determine whether a specific T-cell response can be induced in patients with myelodysplastic syndrome treated with **mutant N-, K-, or H-ras peptide vaccine** (limited to the specific N-, K-, or H-ras peptide mutation in their bone marrow) and intradermal sargramostim (**GM-CSF**). II. Determine whether HLA type or the ability to respond immunologically to common recall antigens correlates with the induction of anti-ras immune responses in these patients treated with this regimen. III. Assess toxicity of mutant N-, K-, or H-ras peptide vaccine in these patients. **OUTLINE:** Patients receive sargramostim (GM-CSF) intradermally on days 1-10. Patients receive mutant N-, K-, or H-ras peptide vaccine (limited to the specific N-, K-, or H-ras mutation in their bone marrow) intradermally on day 7. Treatment repeats every 4 weeks for up to 5 courses in the absence of disease progression or unacceptable toxicity. Patients are followed at 2 and 6 weeks after the last vaccination. **PROJECTED ACCRUAL**: A total of 25-70 patients will be accrued for this study over 12-15 months.	
Completed	Vaccine Therapy in Treating Women With Metastatic Breast Cancer Condition: Breast Cancer Interventions: Biological: BCG vaccine; Biological: CD80 breast cancer vaccine; Biological: sargramostim 1999	CD80-Modified Allogeneic Breast Cancer Cell Line to Vaccinate HLA-A2-Positive. CD80-transfected MDA-MB-231.
	OBJECTIVES: Determine the safety and toxicity of vaccination strategies employing a **CD80-transfected allogeneic breast cancer cell line** (MDA-MB-231). Assess the immunologic response of lymphocytes isolated from lymph nodes draining the vaccination site following a single dose of CD80-transfected MDA-MB-231. Assess the development of systemic immunity following multiple injections of CD80-transfected MDA-MB-231. Observe for tumor regression. **OUTLINE:** This is a dose-escalation study. Patients receive intradermal vaccinations containing CD80-transfected cells with or without sargramostim (GM-CSF) or with or without BCG. Vaccinations are administered every 2 weeks for 6 weeks and then monthly for 3 months. Patients may receive 1 of 2 different doses of GM-CSF. GM-CSF is administered with the vaccination, then every 12 hours for 7 days. Monthly vaccinations may continue as long as response is shown. Cohorts of 5 patients each are treated at each dose/combination. Each cohort completes treatment before the next cohort is accrued. Patients are followed at weeks 4 and 8, then every 2 months for 6 months, then every 3 months for 1 year, and then every 6 months until disease progression.	
Active, not recruiting	Study of Repeat Intranodal Injection of Memgen's Cancer Vaccine, Ad-ISF35, in Subjects With Non-Hodgkin's Lymphoma (Follicular, Diffuse Large Cell, Mantle Cell, and Small Lymphocytic Lymphoma/Chronic Lymphocytic Leukemia Conditions: Non-Hodgkin's Lymphoma; Follicular Lymphoma; Diffuse Large Cell Lymphoma; Mantle Cell Lymphoma; Small Lymphocytic Lymphoma; Chronic Lymphocytic Leukemia Intervention: Biological: ISF35 2009	ISF35 : Adenovirus-CD154 (Ad-ISF35) in Patients With Non-Hodgkin's Lymphoma etc.

	Primary: Determine and **monitor biological responses** in patients with NHL including follicular lymphoma, diffuse large cell lymphoma, mantle cell lymphoma and SLL/CLL treated with repeat intranodal injections of **Ad-ISF35.** [Time Frame: 2 Years (evaluation will be approx. 4 months per patient)] **Secondary**: Determine the safety of repeat administration of Ad-ISF35 injected directly into lymph nodes of patients with NHL including follicular lymphoma, diffuse large cell **lymphoma, mantle cell lymphoma and SLL/CLL.** [Time Frame: 2 Years (evaluation will be approximately 1 year per patient)] /Determine pharmacodynamic parameters in patients treated with repeat intranodal injections of Ad-ISF35. [Time Frame: 2 Years (evaluation will be approximately 4 months per patient)] This is a phase II clinical trial in which study subjects will be treated with multiple doses of Ad-ISF35 given via intranodal injection using a*fixed dose of 3.3 x 10^10 ISF35 viral* particles. Intranodal injections will be administered every 2-4 weeks up to six total injections. This will be the first time that repeat administration of Ad-ISF35 will be performed via intranodal injection in subjects with a diagnosis other than CLL/SLL. Therefore, in order to allow sufficient time to evaluate the safety and toxicity of this procedure in non-CLL/SLL patients, we will treat the first three non-CLL/SLL subjects with inpatient admission for 24 hours observation at the GCRC-UCSD. If no serious adverse events are observed in these first three patients after they have received their first two injections of ISF35 and have been observed for at least 28 days, then we will proceed with enrollment of cohorts of four subjects per month. This will be done at one week intervals until study enrollment is completed. These subjects will be treated as outpatients at the GCRC and observed for 3 hours prior to discharge. All subjects with a diagnosis of CLL or SLL will be treated as outpatients at the GCRC and observed for 3 hours prior to discharge. These subjects will not need to be treated in an inpatient setting, based on our previous clinical experience with subjects enrolled on the phase II study of repeat intranodal injections of Ad-ISF35 ISF35 has already been used in Phase I clinical trials. The trials demonstrated that ISF35 treatment is well-tolerated and patients did not experience any significant or unexpected adverse events. Patients reported flu-like symptoms from ISF35, which disappeared within one to three days.
Recruiting	Vaccine Therapy and Aldesleukin in Treating Women With Metastatic Breast Cancer Condition: Breast Cancer Interventions: Biological: allogeneic large multivalent immunogen breast cancer vaccine; Biological: aldesleukin allogeneic large multivalent immunogen breast cancer vaccine + aldesleukin. Allogeneic tumor cell
	Primary: Disease Response [2 months]. /Percentage of patients achieving complete response, partial response, or disease stabilization as assessed by RECIST **Secondary**: Immune response [48 hours]. /Immune responses will be assessed by DTH responses to LMI, IFN-gamma production by CD8+ T cells using the ELISPOT assay, and CD8+ T cell binding to HLA-A2 multimers complexed with breast cancer-derived peptides (multimer analysis). Progression-free survival. /Progression free survival will be measured in months from time of response to time of disease progression as defined by RECIST (appendix II), "at least a 20% increase in the sum of the longest diameters of target lesions, taking as reference the smallest sum longest diameter recorded since the baseline measurements, or the appearance of one or more new lesion(s)." / Overall survival [1 Year and 2 Years] Overall survival at one and two years will be determined by longitudinal follow-up
	OUTLINE: Patients receive allogeneic large multivalent immunogen (LMI) vaccine intradermally on day 1 and aldesleukin subcutaneously on days 7 and 8. Treatment repeats every 28 days in the absence of disease progression or unacceptable toxicity. Patients with disease progression after 2 courses of vaccine therapy resume the chemotherapy regimen for which prior disease stabilization was achieved. Beginning 2-4 days after completion of chemotherapy, patients receive one dose of LMI vaccine followed by aldesleukin on days 7 and 8. Patients achieving at least stable disease continue to receive LMI vaccine and aldesleukin as above. Treatment repeats every 28 days in the absence of disease progression or unacceptable toxicity. Peripheral blood mononuclear cell samples are collected periodically for research studies. Samples are analyzed to assess the frequency of leukocyte subsets (including B cells, T cells, NK cells, and monocytes) via flow cytometry; frequency of T-regs (T cells that express CD4, CD25, and FoxP3); and responses to keyhole limpet hemocyanin and tetanus toxoid via ELISA assay. Other immunological studies are also performed.

Recruiting	Vaccine Therapy in Treating Patients With HER2/Neu Positive or Negative Stage IV Breast Cancer or Other HER2/Neu Positive Cancers		allogeneic GM-CSF-secreting breast cancer vaccine + IFN-α.. Vaccine Using Whole Cells From the SVBR- 1-GM Cell Line Genetically Engineered To GM-CSF
	Conditions:	Breast Cancer; Unspecified Adult Solid Tumor, Protocol Specific	
	Interventions:	Biological: allogeneic GM-CSF-secreting breast cancer vaccine; Biological: recombinant interferon alfa; Drug: cyclophosphamide 2004	
	OBJECTIVES: Determine the safety, tolerability, and feasibility of vaccine therapy comprising an allogeneic (non-self) tumor cell line transfected with the sargramostim (GM-CSF) gene combined with low-dose interferon alfa and low-dose cyclophosphamide in patients with stage IV breast cancer or other solid tumors. Determine the clinical response, time to progression, and survival of patients treated with this regimen. Correlate clinical response with immunological response in patients treated with this regimen. **OUTLINE:** Patients receive low-dose cyclophosphamide IV once 2-3 days before each tumor vaccine. Patients then receive tumor vaccine comprising HER2/neu-positive allogeneic (non-self) breast cancer cells transfected with the sargramostim (GM-CSF) gene intradermally (ID) on day 1. Patients also receive low-dose interferon alfa ID approximately 48 and 96 hours after each tumor vaccine. Treatment repeats every 2 weeks for 3 vaccinations and then monthly for 3 vaccinations in the absence of disease progression or unacceptable toxicity. Patients are followed at 2 weeks and then every 3 months thereafter.		
Active, not recruiting	Biological Therapy in Treating Patients With Metastatic Cancer		carcinoembryonic antigen RNA-pulsed DC cancer vaccine:
	Conditions:	Breast Cancer; Colorectal Cancer; Extrahepatic Bile Duct Cancer; Gallbladder Cancer; Gastric Cancer; Head and Neck Cancer; Liver Cancer; Lung Cancer; Metastatic Cancer; Ovarian Cancer; Pancreatic Cancer; Testicular Germ Cell Tumor	
	Intervention:	Biological: carcinoembryonic antigen RNA-pulsed DC cancer vaccine 2000	
	OBJECTIVES: I. Determine the safety and dose limiting toxicity of an intravenous vaccine of autologous, cultured, dendritic cells pulsed with carcinoembryonic antigen (CEA) RNA in patients with metastatic adenocarcinoma expressing CEA. II. Assess the cellular immune response to the CEA protein. III. Assess the clinical and biochemical response to the treatment and the duration of such response. **OUTLINE:** This a three tiered, open label, uncontrolled, dose escalation study. The first 3 patients receive a low dose of intravenous carcinoembryonic antigen (CEA) RNA-pulsed autologous dendritic cells (DC) at weeks 0, 1, 2, and 3. Patients are evaluated for dose limiting toxicity (DLT), immune response, and the antitumor response for at least 1 week before dose escalation may proceed. If there is no DLT in the first three, the next 3 patients are treated at a medium dose of CEA RNA-pulsed autologous DC at 0, 1, 2, and 3 weeks. Finally, if DLT is not seen at the medium dose, the final 6 patients receive intravenous infusions of a high dose of CEA RNA-pulsed autologous DC at weeks 0, 1, 2, and 3. If 1-2 patient(s) experience DLT at the either the low or medium dose levels, 3 more patients are entered at the same dose. If no further DLT occurs, then dose escalation continues. As soon as 3 toxic events occur in 3-6 patients at one dose level, accrual at that level ceases. The MTD is defined as the dose level immediately below that at which more than 3 of 6 patients develop DLT.		
Active, not recruiting	Immunotherapy in Treating Patients With Metastatic Breast Cancer		carcinoembryonic antigen RNA-pulsed DC cancer vaccine
	Condition:	Breast Cancer	
	Intervention:	Biological: carcinoembryonic antigen RNA-pulsed DC cancer vaccine 1999	

	OBJECTIVES: Evaluate the ability of active immunotherapy with carcinoembryonic antigen (CEA) RNA pulsed dendritic cells to induce CEA specific T cells in patients with metastatic breast cancer in complete remission following peripheral blood stem cell transplant. Determine the clinical efficacy in terms of overall and recurrence free survival of immunotherapy with CEA RNA pulsed dendritic cells in this patients population. **OUTLINE**: Dendritic cells are taken from the leukapheresis product obtained during the peripheral blood stem cell transplant procedure performed prior to treatment on this study. The dendritic cells are pulsed with carcinoembryonic antigen (CEA) RNA. Approximately 60-90 days after the peripheral blood stem cell transplant, patients receive CEA RNA pulsed dendritic cells IV every 3 weeks for a total of 4 doses. Patients undergo a second leukopheresis after the last dose of immunotherapy to obtain specimens for immunologic tests. Patients are followed every 3 months for the first year and annually thereafter.	
Completed	Immunotherapy in Treating Patients With Resected Liver Metastases From Colon Cancer	carcinoembryonic antigen RNA-pulsed DC cancer vaccine
	Conditions: Colorectal Cancer; Metastatic Cancer	
	Intervention: Biological: carcinoembryonic antigen RNA-pulsed DC cancer vaccine 1999	
	OBJECTIVES: Determine the cellular immune response to carcinoembryonic antigen pulsed dendritic cells in patients with adenocarcinoma of the colon metastatic. Evaluate the overall and recurrence free survival in this patient population. **OUTLINE:** Patients undergo leukapheresis for up to 4.5 hours to collect dendritic cells. The separated dendritic cells are pulsed with carcinoembryonic antigen (CEA) RNA. Patients receive CEA RNA pulsed dendritic cells intravenously every 2 weeks for a total of 4 doses. Patients undergo a second leukapheresis 2 weeks after the last dendritic cell infusion to obtain specimens for immunologic tests. Patients with extra doses of dendritic cells available may receive additional doses of CEA RNA pulsed dendritic cells every 2 months in the absence of unacceptable toxicity. Patients are followed at weeks 12, 24, 36, and 48, and every 6 months thereafter.	
Recruiting	Trial of Autologous, Hapten-Modified Vaccine, OVAX, in Patients With Relapsed Stage III or IV Ovarian Cancer	Autologous, DNP-Modified Ovarian Cancer Vaccine: tumor cells
	Condition: Adenocarcinoma of the Ovary	
	Intervention: Biological: OVax: Autologous, DNP-Modified Ovarian Cancer Vaccine 2008	
	Primary Outcome Measures: Cell-mediated immunity to autologous tumor cells [Time Frame: 3 months] Secondary Outcome Measures: Safety [Time Frame: 9 months]	
Not yet recruiting	Study of IMF-001 in Patients With Malignancies Expressing NY-ESO-1	IMF-001 is a CHP-NY-ESO-1 complex consisting of recombinant NY-ESO-1 protein and cholesteryl hydrophobized pullulan (CHP)
	Condition: NY-ESO-1 Positive Solid Tumors or Melanoma	
	Intervention: Biological: IMF-001 2010	