

	<p><b>Primary:</b> Phase I: Determination of the recommended dose (RD) for exploration in the phase IIa part of the study [ Time Frame: During the first 2-3 month of Phase I ]</p> <p>Phase II: Assessment of safety and tolerability of the treatment regimen [ Time Frame: Complete duration of Phase II ]</p> <p>Medical Need: Lung cancer is the leading cause of cancer mortality in developed countries; about 87% of lung cancers are of the NSCLC type. Patients with more advanced but non-metastatic disease (IIIA or IIIB) usually undergo chemotherapy and/or radiation therapy, with or without secondary surgical resection. Patients with progression after chemotherapy and/or radiotherapy may receive second-line treatment with targeted therapies. Despite these aggressive treatments, only about 5% of patients with metastatic disease survive for 5 or more years. Given these dismal statistics, it is clear that new therapeutic approaches for treatment of NSCLC are urgently needed.</p> <p>Potential Benefits: CV9201 is an mRNA-based vaccine for the treatment of human NSCLC that is based on CureVac's RActive® technology. As an mRNA-based vaccine, CV9201 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.</p>						
Not yet recruiting	<p><a href="#">Safety Study of Peptide Cancer Vaccine To Treat HLA-A*24-positive Advanced Small Cell Lung Cancer</a></p> <table border="1"> <tr> <td>Condition:</td> <td>Small Cell Lung Cancer</td> <td rowspan="2">HLA-A*2402-restricted CDCA1 and KIF20A peptides. PD:</td> </tr> <tr> <td>Intervention:</td> <td>Biological: HLA-A*2402-restricted CDCA1 and KIF20A peptides 2010</td> </tr> </table>		Condition:	Small Cell Lung Cancer	HLA-A*2402-restricted CDCA1 and KIF20A peptides. PD:	Intervention:	Biological: HLA-A*2402-restricted CDCA1 and KIF20A peptides 2010
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Intervention:	Biological: HLA-A*2402-restricted CDCA1 and KIF20A peptides 2010						
	<p>PD: Peptides specific CTL, Antigen cascade, Regulatory T cells, Cancer antigens and HLA levels. Efficacy: OS</p> <p><b>Detailed Description:</b> We previously identified three novel HLA-A*2402-restricted epitope peptides, which were derived from two cancer-testis antigens, CDCA1 and KIF20A, as targets for cancer vaccination against lung cancer. In this phase I trial, we examine using a combination of these two peptides the safety, immunogenicity, and antitumor effect of vaccine treatment for HLA-A*2402-positive advanced small cell lung cancer patients who failed to standard therapy.</p>						
Recruiting	<p><a href="#">Cancer Vaccine Study for Stage III, Unresectable, Non-small Cell Lung Cancer (NSCLC) in the Asian Population</a></p> <table border="1"> <tr> <td>Condition:</td> <td>Non-small Cell Lung Cancer 2009</td> <td rowspan="2">L-BLP25 or BLP25 liposome vaccine (Stimuvax) Efficacy: OST</td> </tr> <tr> <td>Interventions:</td> <td>Biological: L-BLP25 or BLP25 liposome vaccine (Stimuvax); Biological: Placebo</td> </tr> </table>		Condition:	Non-small Cell Lung Cancer 2009	L-BLP25 or BLP25 liposome vaccine (Stimuvax) Efficacy: OST	Interventions:	Biological: L-BLP25 or BLP25 liposome vaccine (Stimuvax); Biological: Placebo
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Interventions:	Biological: L-BLP25 or BLP25 liposome vaccine (Stimuvax); Biological: Placebo						
	<p><b>Primary:</b> Overall Survival Time [ Time Frame: , Dec 2009, until cut-off date expected Sept 2014 ]. /Time from randomization to death. Patients without event are censored at the date of last contact, or date lost to follow-up</p> <p><b>Secondary:</b> Safety - Adverse Events. /Time to Symptom Progression (TTSP) . /Time from randomization to symptomatic progression. Symptomatic progression is defined as an increase (worsening) of the ASBI (The Average Symptomatic Burden Index i.e., the mean of the six major lung cancer specific symptom scores of the LCSS subject scale). Worsening is defined as a 10% increase in the scale breadth from the baseline score. /Time to Progression (TTP) [ Time Frame: Dec 2009, until the cut-off date expected Sept 2014 ]. /Time from randomization to the radiological confirmation of progression performed according to Response Evaluation Criteria In Solid Tumors (RECIST). If radiological confirmation cannot be obtained but a subject is withdrawn from trial treatment due to PD, TTP will be measured from the date of randomization to the date of discontinuation of trial treatment. TTP of subjects without PD at the time of analysis will be censored at the time of last contact.</p> <p>Progression Free Survival (PFS) Time [ Time Frame:Dec 2009, until the cut-off date expected Sept 2014 ]. /Time from randomization to PD as determined by the investigator or death. PFS time for subjects without an event will be censored as of the date of last contact. /Time to Treatment Failure /Time from randomization to discontinuation of trial treatment for any reason as reported by the investigator. For subjects still receiving treatment at the time of analysis, the time between the date of randomization and the last date of treatment will be used as a censored observation in the analysis. Subjects who have missed two consecutive scheduled doses will be considered as treatment failures and the TTF will be calculated from the date of randomization to the date of their first missed treatment.</p>						
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Intervention:	Biological: HLA-A*0201 or HLA-A*0206-restricted URLC10 peptides 2010								
	<p><b>Primary:</b> Evaluation of safety (NCI CTCAE version3) and tolerability (maximum tolerated dose, MTD and dose limiting toxicity, DLT) as well as adverse effects of vaccination therapy, and determination of the recommended dose for next phase trial. [ Time Frame: 2 months ]</p> <p><b>Secondary:</b> Immunological responses: Peptides specific CTL, Antigen cascade, Regulatory T cells, Cancer antigens and HLA levels. [ Time Frame: 2 months]</p> <p>Evaluation of clinical efficacy: Objective response rate (RECIST1.1), Tumor markers, Overall survival, Progression free survival. [ Time Frame: 2 months]</p> <p>We previously identified three novel HLA-A*0201 or HLA-A*0206-restricted epitope peptides, which were derived from a cancer-testis antigen, URLC10, as targets for cancer vaccination against lung cancer. In this phase I trial, we examine using a combination of these three peptides the safety, immunogenicity, and antitumor effect of vaccine treatment for HHLA-A*0201 or HLA-A*0206-positive advanced non-small cell lung cancer patients who failed to standard therapy.</p>								
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	<p><b>Peptides specific CTL, Antigen cascade, Regulatory T cells, Cancer antigens and HLA levels.</b> /Tumor markers, <b>OS, PFS.</b></p> <p>We previously identified three novel HLA-A*2402-restricted epitope peptides, which were derived from three cancer-testis antigens, URLC10, CDCA1, and KIF20A, as targets for cancer vaccination against lung cancer. In this phase I trial, we examine using a combination of these three peptides the safety, immunogenicity, and antitumor effect of vaccine treatment for HLA-A*2402-positive advanced non-small cell lung cancer patients who failed to standard therapy.</p> <p>ARM1: Experimental: URLC10-CDCA1-KIF20A 1mg Patients will be vaccinated once a week for four weeks of a treatment cycle. On each vaccination day, the HLA-A*2402-restricted URLC10 peptide (1mg), CDCA1 peptide (1mg) and KIF20A peptide(1mg) mixed with Montanide ISA 51 will be administered by subcutaneous injection. Escalating doses of every peptide will be administered by subcutaneous injection on days 1, 8, 15 and 22 of each treatment cycle. Planned doses of peptides are 1.0mg, 2.0mg and 3.0mg.</p> <p>ARM2: perimental: URLC10-CDCA1-KIF20A 2mg Patients will be vaccinated once a week for four weeks of a treatment cycle. On each vaccination day, the HLA-A*2402-restricted URLC10 peptide (2mg), CDCA1 peptide (2mg) and KIF20A peptide(2mg) mixed with Montanide ISA 51 will be administered by subcutaneous injection. Escalating doses of every peptide will be administered by subcutaneous injection on days 1, 8, 15 and 22 of each treatment cycle. Planned doses of peptides are 1.0mg, 2.0mg and 3.0mg.</p> <p>ARM3: Experimental: URLC10-CDCA1-KIF20A 3mg Patients will be vaccinated once a week for four weeks of a treatment cycle. On each vaccination day, the HLA-A*2402-restricted URLC10 peptide (3mg), CDCA1 peptide (3mg) and KIF20A peptide(3mg) mixed with Montanide ISA 51 will be administered by subcutaneous injection. Escalating doses of every peptide will be administered by subcutaneous injection on days 1, 8, 15 and 22 of each treatment cycle. Planned doses of peptides are 1.0mg, 2.0mg and 3.0mg.</p>								
Completed	<table border="1"> <tr> <td colspan="2"><a href="#">The Use of Dendritic Cell/Tumor Fusions as a Novel Tumor Vaccine in Patients With Multiple Myeloma</a></td> <td rowspan="3">Dendritic Cell Tumor Fusion Vaccine. tumor specific cellular and humoral immunity with GM-CSF</td> </tr> <tr> <td>Condition:</td> <td>Multiple Myeloma</td> </tr> <tr> <td>Intervention:</td> <td>Biological: Dendritic Cell Tumor Fusion Vaccine</td> </tr> </table>	<a href="#">The Use of Dendritic Cell/Tumor Fusions as a Novel Tumor Vaccine in Patients With Multiple Myeloma</a>		Dendritic Cell Tumor Fusion Vaccine. tumor specific cellular and humoral immunity with GM-CSF	Condition:	Multiple Myeloma	Intervention:	Biological: Dendritic Cell Tumor Fusion Vaccine	
<a href="#">The Use of Dendritic Cell/Tumor Fusions as a Novel Tumor Vaccine in Patients With Multiple Myeloma</a>		Dendritic Cell Tumor Fusion Vaccine. tumor specific cellular and humoral immunity with GM-CSF							
Condition:	Multiple Myeloma								
Intervention:	Biological: Dendritic Cell Tumor Fusion Vaccine								

	<p><b>Detailed Description:</b> To create the study vaccine, cells will be removed from the participants tumor and fused (mixed) with powerful immune system stimulating cells (dendritic cells) obtained from the participants blood. /Not everyone who participates in this study will be receiving the same amount of study vaccine. A small group of people will be enrolled into the study and given a certain dose. If they tolerate it well, the next group of people enrolled will receive a higher dose. This will continue until the highest dose level tolerated is determined. /Once the screening tests are completed and it is determined the participant is eligible, they will undergo some baseline procedures. In an effort to make the study vaccine, tumor cells and dendritic cells will be collected from the participant. Tumor cells may be collected from bone marrow or from a collection of tumor cells called a plasmacytoma. A decision will be made based upon the location of the cancer. A bone marrow aspiration/biopsy will be performed during the following time points: at screening, prior to the first vaccination, and at 1 month, 3 months, and 6 months after the final study vaccination. These will be used to assess and follow the participants multiple myeloma. Leukapheresis will be performed to obtain dendritic cells. This procedure takes 2 to 4 hours to and involves the collection of a large number of white blood cells. Dendritic cells will be generated in the laboratory from white blood cells. If not enough white blood cells are collected, the participant may be asked to return to the clinic for an additional leukapheresis procedure. Before each vaccine is administered (weeks 0, 3, 6) the following study tests and procedures will be performed: skin test; blood test, physical exam and 24-hour urine collection. A physical exam and blood tests will be performed on the weeks when the participant does not receive the vaccine (weeks 1,2,4,5,7,8). The study schedule will consist of a fixed dose of the fused (mixed) cell vaccine under the skin every 3 weeks. Each study vaccine will be accompanied by an injection of GM-CSF. Participants will receive 2 or more vaccines depending upon the total number of fusion cells made, the dose the participant is assigned to receive and their response to the study vaccine. Follow-up after the vaccine treatment is completed will consist of the following: blood collection (1, 3 and 6 months after final study vaccination); bone marrow aspiration/biopsy (1, 3 and 6 months after final study vaccination); physical exam (1, 2, 3, 4, 5 and 6 months after final study vaccination); radiologic tumor assessment (1, 3 and 6 months after final study vaccination).</p>					
Active, not recruiting	<p><u><a href="#">Vaccine Therapy in Treating Patients With Stage IIIB or Stage IV Bronchoalveolar Lung Cancer</a></u></p> <table border="1"> <tr> <td data-bbox="257 823 436 854">Condition:</td> <td data-bbox="436 823 1630 854">Lung Cancer</td> </tr> <tr> <td data-bbox="257 854 436 885">Intervention:</td> <td data-bbox="436 854 1630 885">Biological: GVAX lung cancer vaccine 2003</td> </tr> </table>	Condition:	Lung Cancer	Intervention:	Biological: GVAX lung cancer vaccine 2003	GVAX lung cancer cell vaccine. Autologous Cancer Vaccine. OS + PFS.
Condition:	Lung Cancer					
Intervention:	Biological: GVAX lung cancer vaccine 2003					
	<p>Determine the progression-free and overall survival of patients with selected stage IIIB or stage IV bronchoalveolar carcinoma treated with GVAX lung cancer vaccine. Determine the response rate (confirmed and unconfirmed and complete and partial) in patients treated with this vaccine. Determine the frequency and severity of toxic effects of this vaccine in these patients. Determine the functional status of patients treated with this vaccine. Correlate systemic biologic activity (i.e., antigen-specific antitumor and systemic cytokine responses) with clinical outcome in patients treated with this vaccine. OUTLINE: This is a multicenter study. Patients are stratified according to prior systemic cancer therapy for bronchoalveolar carcinoma (BAC) (yes vs no) and pattern of BAC (diffuse vs nodular). After successful vaccine manufacturing from tumor tissue procured, patients receive GVAX lung cancer vaccine intradermally (ID) (6-7 injections per vaccination) on weeks 1, 3, 5, 7, and 9 for a total of 5 vaccinations. Treatment continues in the absence of disease progression or unacceptable toxicity. Quality of life is assessed at baseline and at weeks 9, 13, and 21.</p>					
Active, not recruiting	<p><u><a href="#">Vaccine Therapy With or Without Cyclophosphamide and Doxorubicin in Women With Stage IV Breast Cancer</a></u></p> <table border="1"> <tr> <td data-bbox="257 1270 436 1301">Condition:</td> <td data-bbox="436 1270 1630 1301">Breast Cancer</td> </tr> <tr> <td data-bbox="257 1301 436 1362">Interventions:</td> <td data-bbox="436 1301 1630 1362">Biological: allogeneic GM-CSF-secreting breast cancer vaccine; Drug: cyclophosphamide; Drug: doxorubicin hydrochloride 2004</td> </tr> </table>	Condition:	Breast Cancer	Interventions:	Biological: allogeneic GM-CSF-secreting breast cancer vaccine; Drug: cyclophosphamide; Drug: doxorubicin hydrochloride 2004	allogeneic GM-CSF-secreting breast cancer vaccine.
Condition:	Breast Cancer					
Interventions:	Biological: allogeneic GM-CSF-secreting breast cancer vaccine; Drug: cyclophosphamide; Drug: doxorubicin hydrochloride 2004					

	<p>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</p> <p><b>Primary:</b> 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.</p> <p><b>Secondary:</b> Determine the time to disease progression in patients treated with these regimens.</p>	
Recruiting	<p><a href="#">Dendritic Cell Cancer Vaccine for High-grade Glioma</a></p>	
	Condition:	Glioblastoma Multiforme 2010
	Interventions:	Drug: Trivax, Temozolomide, Surgery, Radiotherapy; Drug: Temozolomide, Surgery, Radiotherapy
	<p><b>Primary:</b> 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).</p> <p><b>Secondary:</b> 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 treatment.</p> <p>Overall survival [ Time Frame: 24 months ] /The percentage of survival will be assessed at 12, 18, and 24 months.</p>	
Recruiting	<p><a href="#">Comparison of the Human Papillomavirus (HPV) Type 16 E7-Specific Immune Response Between a Normal Population and Patients With Cervical Lesions</a></p>	
	Condition:	Cervical Cancer
	Intervention:	
	immunologic responses to HPV type 16 E7 antigen	
Active, not recruiting	<p><a href="#">In-Situ Therapeutic Cancer Vaccine for Metastatic Cancer Combining AlloStim With Tumor Cryoablation</a></p>	
	Condition:	Metastatic Cancer
	Interventions:	Biological: AlloStim-7; Procedure: percutaneous tumor cryoablation; Biological: AlloStim8 or AlloStim-9
	<p>AlloStim8 or AlloStim-9. antigen is generated by freezing a tumor</p>	
	<p>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 AlloStim™ 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.</p>	

Active, not recruiting	<a href="#">GVAX in Advanced Prostate Cancer Patients Made Lymphopenic</a>		GM-CSF gene transduced allogeneic cell vaccine:
	Condition:	Prostate Cancer	
	Intervention:	Biological: GM-CSF gene transduced allogeneic vaccine GVAX 2005	
<p>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.</p> <p><b>Purpose :</b> 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.</p> <p>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.</p> <p>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.</p> <p>The objective of this study is to evaluate the safety and immunologic effects of vaccinations with Allogeneic Prostate GVAX® (CG1940 &amp; 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.</p>			
Recruiting	<a href="#">Trastuzumab, Cyclophosphamide, and Vaccine Therapy in Treating Patients With High-Risk or Metastatic Breast Cancer</a>		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	

	<p>HER2/neu-specific immune response ; delayed-type hypersensitivity response to HER2/neu-derived peptides. PFS</p> <p><b>Primary:</b> 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.</p> <p>To measure the HER2/neu-specific CD4+ T-cell response by delayed-type hypersensitivity.</p> <p>To measure the magnitude of HER2/neu-specific CD8+ T-cell responses by ELISPOT.</p> <p><b>Secondary:</b> 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.</p> <p><b>Tertiary:</b> To develop the tandem tetramer/CD107a cytotoxicity assay for HER2/neu-specific CD8+ T cells.</p> <p>To measure novel T-cell responses induced by trastuzumab and cyclophosphamide-modulated vaccination.</p> <p>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.</p> <p>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</p>					
Terminated	<p><a href="#">Vaccine Treatment for Advanced Breast Cancer</a></p> <table border="1"> <tr> <td data-bbox="264 705 436 743">Condition:</td> <td data-bbox="436 705 1630 743">Breast Cancer</td> </tr> <tr> <td data-bbox="264 743 436 788">Intervention:</td> <td data-bbox="436 743 1630 788">Biological: HyperAcute – Breast cancer vaccine 2004</td> </tr> </table>	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.
Condition:	Breast Cancer					
Intervention:	Biological: HyperAcute – Breast cancer vaccine 2004					

	<p><b>Primary:</b> 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 ]</p> <p><b>Secondary :</b> To conduct correlative scientific studies of patient samples to determine the mechanism of any observed anti-tumor effect. [ Time Frame: 4 months ]</p> <p>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.</p> <p>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.</p> <p>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.</p>	
Completed	<p><a href="#">Vaccine Treatment for Surgically Resected Pancreatic Cancer</a></p> <p>Condition: Pancreatic Cancer</p> <p>Intervention: Biological: HyperAcute-Pancreatic Cancer Vaccine 2005</p>	Alpha(1,3)Galactosyltransferase Expressing Allogeneic Tumor Cells in Patients With Pancreatic Cancer

	<p><b>Primary:</b> To assess the side effects, dose-limiting toxicity and maximum tolerated dose. [ Time Frame: 6 months ]</p> <p><b>Secondary:</b> To assess the rate of recurrence after treatment. [ Time Frame: 6 months ]</p> <p>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.</p>	
Completed	<p><a href="#">Vaccine Treatment for Hormone Refractory Prostate Cancer</a></p> <p>Condition: Prostate Cancer</p> <p>Intervention: Biological: HyperAcute-Prostate Cancer Vaccine 2005</p>	Alpha (1,3) Galactosyltransferase Expressing Allogeneic Tumor Cells form Refractory Prostate Cancer
	<p><b>Primary:</b> Safety and efficacy of administration of HyperAcute-Prostate (HAP) cancer cells by injection into men with hormone refractory prostate carcinoma [ 6 months</p> <p><b>Secondary:</b> Correlative scientific studies of patient samples to determine the mechanism of any observed anti-tumor effect [ Time Frame: 6 months ]</p> <p>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.</p> <p>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.</p> <p>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</p>	
Terminated	<p><a href="#">Tumor-Pulsed Dendritic Cells Used as a Tumor Vaccine</a></p> <p>Condition: Metastatic Colorectal Cancer</p> <p>Intervention: Drug: Interleukin-2 (IL-2) 2005</p>	Tumor-Pulsed Dendritic Cells as a Tumor Vaccine Administered With IL-2.



	<p>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.</p>	
Completed	<p><a href="#">Tumor Vaccine and Interferon Gamma in Treating Patients With Refractory Epithelial Ovarian Cancer</a></p> <p>Condition: Ovarian Cancer</p> <p>Interventions: Biological: ALVAC-hB7.1; Biological: recombinant interferon gamma 1999</p>	<p>ALVAC-hB7.1 with IFN-<math>\gamma</math>. Autologous Therapeutic Tumor intraperitoneal (IP) injections of epithelial ovarian carcinoma</p>
	<p><b>OBJECTIVES:</b> 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.</p> <p><b>OUTLINE:</b> This is a dose-escalation study of ALVAC-hB7.1 infected tumor cells.</p> <p>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.</p> <p>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.</p> <p>Patients are followed every 6 months until disease progression.</p>	
Completed	<p><a href="#">Treating High Risk Leukemia With CD40 Ligand &amp; IL-2 Gene Modified Tumor Vaccine</a></p> <p>Condition: Leukemia</p> <p>Intervention: Biological: Tumor Vaccine: CD40 LIGAND AND IL-2 GENE MODIFIED AUTOLOGOUS SKIN FIBROBLASTS AND TUMOR CELLS 2003</p>	<p>CD40 ligand + IL-2 gene-modified autologous skin fibroblasts and tumor cells.</p>
	<p><b>Purpose:</b> 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.</p> <p>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.</p> <p>The purpose of this study is to learn the side effects and safe dosage of these special cells.</p>	
Active, not recruiting	<p><a href="#">The Use of Dendritic Cell/Tumor Hybridomas as a Novel Tumor Vaccine in Patients With Advance Melanoma</a></p> <p>Condition: Metastatic Melanoma</p> <p>Intervention: Biological: DC/tumor fusion vaccine 2008</p>	<p>Dendritic Cell/Tumor Hybridomas as a Novel Tumor Vaccine in Patients With Advance Melanoma.</p>

	<p><b>Primary Outcome:</b> To assess the toxicity, cellular and humoral immunity and tumor response in patient with melanoma receiving the DC/tumor fusion vaccine</p> <p><b>Detailed Description:</b> 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.</p>	
Not yet recruiting	<p><a href="#">Androgen Ablation Therapy With or Without Vaccine Therapy in Treating Patients With Prostate Cancer</a></p> <p>Condition: Prostate Cancer 2008</p> <p>Interventions: Biological: GVAX prostate cancer vaccine; Drug: bicalutamide; Drug: goserelin; Drug: leuprolide acetate</p>	GVAX prostate cancer vaccine. Androgen-Ablation Combined With Cell-Based CG1940/CG8711 Immunotherapy
	<p><b>Primary Outcome:</b> Median PSA recurrence-free survival in patients in patients responding to the study treatments</p> <p><b>Secondary Outcome:</b> Safety. /Effects of 6-month androgen ablation on thymic production of naïve T cells. /Median time to metastatic disease development</p> <p><b>Purpose:</b> 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.</p>	
Completed	<p><a href="#">A Pilot Study of NY-ESO-1b Peptide Plus CpG 7909 and Montanide ISA-51 in Patients With Cancer.</a></p> <p>Conditions: Cancer; Neoplasm</p> <p>Intervention: Biological: NY-ESO-1b peptide plus CpG 7909 and Montanide ISA-51 2005</p>	NY-ESO-1b peptide plus CpG 7909 and Montanide ISA-51. Patients With Cancer Expressing NY-ESO-1 or LAGE-1.
	<p><b>Primary:</b> NY-ESO-1 specific humoral immunity. /NY-ESO-1 specific cellular immunity. /DTH to NY-ESO-1b peptide. /Toxicities and adverse events</p> <p><b>Secondary Outcome:</b> Tumor response</p> <p><b>Detailed Description:</b> 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.</p>	
Completed	<p><a href="#">Allogeneic Cellular Vaccine 1650-G for Non-Small Cell Lung Cancer</a></p> <p>Condition: Non-small Cell Lung Cancer</p> <p>Intervention: Drug: 1650-G Vaccine 2008</p>	1650-G Vaccine: Cellular Vaccine 1650-G for Non-Small Cell Lung Cancer. Immunological Response
	<p><b>Primary:</b> Primary Outcome Measure: Immunological Response [Evaluated for 52 weeks ]</p> <p><b>Detailed Description:</b> 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</p>	
Completed	<p><a href="#">Safety and Immune Response to a Multi-component Immune Based Therapy (MKC1106-MT) for Patients With Melanoma.</a></p> <p>Conditions: Advanced Melanoma; Stage III and IV Melanoma</p> <p>Interventions: Biological: Biological: MKC1106-MT; Biological: Biological: MKCC1106-MT 2008</p>	MKC1106-MTとMKCC1106-MT. MKC1106-MT, consists of 1 plasmid dose and 2 peptides doses designed to stimulate an immune