

	<p>Primary Outcome Measures: Independent sample t-test will be used to compare 1) antibody change scores from before to after the first and second dose of vaccine, and 2) distress change scores from before to after the intervention [ Time Frame: length of protocol ]</p> <p>Secondary Outcome Measures: Multiple regression analyzes will be used to test changes in cortisol and changes in perceived risk of breast cancer; coping or social support mediate the effects of the intervention on antibody response to vaccine and distress [ Time Frame: length of protocol ] [ Designated as safety issue: No ]</p>	
Active, not recruiting	<p><u>Vaccine Therapy in Treating Patients With Non-Small Cell Lung Cancer</u></p>	
	<p>Condition: Lung Cancer</p> <p>Interventions: Biological: autologous tumor cell vaccine; Biological: therapeutic autologous dendritic cells; Procedure: conventional surgery 2001</p>	<p>Vaccination With Autologous Tumor Lysate-Pulsed Dendritic Cells</p>
	<p>Determine the safety and feasibility of immunization with autologous tumor lysate-pulsed dendritic cell vaccine in patients with non-small cell lung cancer. Determine the immunologic response in patients treated with this vaccine.</p> <p>OUTLINE: Patients undergo surgery to remove all or most of the gross evidence of tumor. Two months after surgery (or 4 months if chemotherapy and/or radiotherapy are required), patients undergo leukapheresis. Peripheral blood mononuclear cells are isolated and cultured with interleukin-4 and sargramostim (GM-CSF) to generate dendritic cells (DC). DC are then pulsed with tumor lysate prepared from previously removed tumor. Patients receive autologous tumor lysate-pulsed DC vaccine subcutaneously twice, 4 weeks apart. Patients are followed every 4 months for 2 years, every 6 months for 1 year, and then annually thereafter.</p> <p>PROJECTED ACCRUAL: A total of 10 patients will be accrued for this study within 2 years.</p>	
Recruiting	<p><u>MTD Study of Vaccine BP-GMAX-CD1 Plus AP1903 to Treat Castrate Resistant Prostate Cancer</u></p>	
	<p>Condition: Castrate Resistant Prostate Cancer (CRPC)</p> <p>Interventions: Biological: BPX-101; Drug: AP1903</p>	<p>Therapeutic Vaccine, BP-GMAX-CD1, Plus Activating Agent, AP1903, in Patients With Castrate Resistant Prostate Cancer</p>
	<p><b>Primary:</b> To determine the maximum tolerated dose (MTD) of BPX-101 and AP1903 when administered 24 hours apart [1 Year]/To determine other measures of safety and tolerability of BPX-101 and AP1903 when administered 24 hours apart to patients with castrate resistant prostate cancer (CRPC).</p> <p><b>Secondary:</b> To determine the pharmacokinetics of AP1903 when administered 24 hours after BPX-101 [1 Year ]/To assess immune responses and their association with clinical outcome as measured by changes in levels of interferon gamma (IFN)-producing T cells, the cytotoxic T lymphocyte (CTL) response, cytokines (IFN, IL-4, IL-10), activation markers, and other [2 Years]. /To assess PSA response and PSA dynamics (change in velocity, doubling time) [1 Year] /To assess reduction in the number of circulating tumor cells (CTC) [1 Year] /To assess cancer-related pain [1 Year] . /To assess pain medication usage [1 Year] . /To determine preliminary efficacy of BPX-101 at the maximum tolerated dose (MTD), based on tumor assessments using computed tomography (CT) or magnetic resonance imaging (MRI) and radionuclide bone scans [2 Years]</p>	
Completed	<p><u>Vaccine Therapy in Treating Patients With Advanced or Recurrent Cancer</u></p>	
	<p>Conditions: Anal Cancer; Cervical Cancer; Esophageal Cancer; Head and Neck Cancer; Penile Cancer; Vulvar</p> <p>Interventions: Biological: human papillomavirus 16 E7 peptide; Biological: synthetic human papillomavirus 16 E6 peptide 2001</p>	<p>IMMUNOLOGIC RESPONSES WITH HUMAN PAPILOMAVIRUS 16 E6 AND E7 PEPTIDES for METASTATIC OR LOCALLY ADVANCED CERVICAL CANCER</p>
	<p>Determine whether endogenous cellular immunity to the viral oncoproteins human papilloma virus 16 (HPV16) E6 and E7 is present in patients with advanced or recurrent carcinoma of the cervix or other carcinomas that carry HPV16. /Determine whether vaccination with antigen-presenting cells pulsed with synthetic peptide corresponding to the tumor's HPV16 E6 or E7 peptide can induce or boost patient cellular immunity to that particular peptide. /Determine the type and characteristics of the cellular immunity generated in patients treated with this regimen. /Determine the toxicity of this regimen in these patients. /Determine the tumor response in patients treated with this regimen. /Determine whether in vivo T cells generated specifically against HPV16 E6 or E7 peptide can be cloned and expanded in vitro against the corresponding peptide. //Patients are followed at 1 month.</p>	
Not yet recruiting	<p><u>Human Papillomavirus (HPV) Vaccination in Barretos (Pio XII Foundation - Barretos Cancer Hospital)</u></p>	
	<p>Conditions: Human Papillomavirus; HPV Infection; Vaccine</p>	

	Intervention: 2010	
	Evaluating the knowledge about the Pap test, cervical cancer, HPV, and vaccine in vaccinated girls and mothers (or legally responsible individuals) - before and after the vaccine program; Evaluating the vaccination program recruiting rate (school-based program); Evaluating adherence to the vaccination program.	
Not yet recruiting	BLP25 Liposome Vaccine and Bevacizumab After Chemotherapy and Radiation Therapy in Treating Patients With Newly Diagnosed Stage IIIA or Stage IIIB Non-Small Cell Lung Cancer That Cannot Be Removed by Surgery	L-BLP25 and Bevacizumab in Unresectable Stage IIIA and IIIB Non-Squamous Non-Small Cell Lung Cancer After Definitive Chemoradiation
	Condition: Lung Cancer	
	Interventions: Biological: BLP25 liposome vaccine; Biological: bevacizumab; Drug: carboplatin; Drug: cyclophosphamide; Drug: paclitaxel; Radiation: radiation therapy 2009	
	<p>Primary: To determine the safety of BLP25 liposome vaccine and bevacizumab after definitive chemoradiotherapy and consolidation chemotherapy in patients with newly diagnosed, unresectable stage IIIA or IIIB nonsquamous cell non-small cell lung cancer.</p> <p>Secondary: To evaluate the overall survival and progression-free in patients treated with this regimen. To evaluate the toxicity of this regimen in these patients.</p> <p>Chemoradiotherapy: Patients receive paclitaxel IV over 1 hour and carboplatin IV over 15-30 minutes once a week for 6 weeks. Patients also undergo concurrent definitive radiotherapy 5 days a week for 6½ weeks. Patients with complete response (CR), partial response (PR), or stable disease (SD) proceed to consolidation chemotherapy. patients are followed periodically for up to 5 years.</p>	
Completed	Vaccine Therapy Plus QS21 in Treating Patients With Progressive Prostate Cancer	Thompson-Friedenreich [TF(c)]-KLH Conjugate Plus the Immunological Adjuvant QS21: A Trial Comparing TF(c)-KLH Doses
	Condition: Prostate Cancer	
	Interventions: Biological: QS21; Biological: TF(c)-KLH conjugate vaccine; Biological: Thomsen-Friedenreich antigen; Biological: keyhole limpet hemocyanin 1999	
	<p>OBJECTIVES: I. Determine the optimal dose of Thompson-Friedenreich [TF(c)]-keyhole limpet hemocyanin (KLH) conjugate plus adjuvant QS21 that induces an antibody response in patients with prostate cancer. II. Determine the safety of the TF(c)-KLH conjugate prepared using an MBS heterobifunctional linker plus QS21. III. Assess postimmunization changes in prostate specific antigen levels and other objective parameters of disease in these patients.</p> <p>OUTLINE: This is a dose escalation study. Patients receive TF(c)-KLH conjugate with adjuvant QS21 subcutaneously weekly for 3 weeks, then once during weeks 7 and 19. Cohorts of 5 patients each receive escalating doses of TF(c)-KLH vaccine until the optimal dose, based on antibody response, is reached. Patients are followed monthly for 6 months, then every 3 months for 1 year.</p> <p>PRO.IECTED ACCRUIAL: A total of 20 patients will be accrued for this study within 6 months</p>	
Completed	Vaccine Therapy in Treating Patients With Ovarian Epithelial, Primary Peritoneal, or Fallopian Tube Cancer	NY-ESO-1b Peptide Plus Montanide ISA-51 In Patients With Ovarian, Primary Peritoneal, Or Fallopian Tube Cancer Expressing NY-ESO-1 or LAGE-1
	Conditions: Fallopian Tube Cancer; Ovarian Cancer; Peritoneal Cavity Cancer	
	Interventions: Biological: NY-ESO-1 peptide vaccine; Biological: incomplete Freund's adjuvant 2003	
	<p>OBJECTIVES: Determine the safety of NY-ESO-1b peptide vaccine and Montanide ISA-51 in patients with ovarian epithelial, primary peritoneal, or fallopian tube cancer expressing NY-ESO-1 or LAGE-1. /Determine the immunologic profile (NY-ESO-1 antibody, CD8+ cells, and delayed-type hypersensitivity) induced by this regimen in these patients.</p> <p>OUTLINE: This is an open-label study.</p> <p>Patients receive NY-ESO-1b peptide vaccine emulsified with Montanide ISA-51 subcutaneously once every 3 weeks on weeks 1, 4, 7, 10, and 13 in the absence of disease progression or unacceptable toxicity.</p> <p>Patients are followed at 3 weeks and then every 6-12 weeks for 2 years or until disease progression</p>	
Completed	Vaccine Therapy in Treating Patients With Recurrent Prostate Cancer	Prostate Specific Antigen Peptide 3A (PSA: 154-163 (155L)) (NSC #722932, IND#9787)
	Condition: Prostate Cancer	

	Interventions:	Biological: PSA:154-163(155L) peptide vaccine; Biological: incomplete Freund's adjuvant 2005	With Montanide ISA-51 (NSC #675756, IND # 9787) Vaccination
	<p>Primary Determine the T-lymphocyte immune response in patients with recurrent adenocarcinoma of the prostate treated with prostate-specific antigen (PSA) peptide vaccine (PSA-3A; PSA: 154-163 [155L]) emulsified in Montanide ISA-51.</p> <p>Secondary: Determine the toxicity of this vaccine in these patients. /Determine the effect of this vaccine on serum PSA level in these patients. patients are followed at 1 and 4 weeks. PROJECTED ACCRUAL: A total of 18-32 patients will be accrued for this study within 18-38 months.</p>		
Recruiting	<u>Banking of Chronic Lymphocytic Leukemia Tumor Cells for Vaccine Generation</u>		Banking of Chronic Lymphocytic Leukemia Tumor Cells for Vaccine Generation
	Condition:	Chronic Lymphocytic Leukemia	
	Intervention:	Procedure: Leukemia cell harvest	
	<p>To collect up to 20 patient samples per year that could potentially be used to prepare autologous tumor cell vaccines. [ 2 years]It is important to understand that even if the participant consents to allow us to save their leukemia cells, we cannot guarantee that they will be able to receive a vaccine. First, we may not be able to make enough vaccine from the collected cells. Second, they may not be able to participate in a vaccine study in the future for reasons related to the status of your overall health. Third, an appropriate vaccine trial may not be available in the future.</p> <p>In order to make the vaccine, leukemia cells will be collected by one or more of the following methods: drawing blood during one of two visits to the clinic; leukapheresis; bone marrow aspiration; or, surgery to remove a lymph node.</p> <p>The physician will discuss with the participant which approach is best in their case to ensure the highest number of tumor cells collected.</p>		
Completed	<u>Vaccine Therapy in Treating Patients With Advanced or Metastatic Cancer</u>		Immunotherapy With Autologous Dendritic Cells Infected With CEA-6D Expressing Fowlpox -Tricom In Patients With Advanced Or Metastatic Malignancies Expressing CEA
	Conditions:	Breast Cancer; Colorectal Cancer; Gallbladder Cancer; Gastric Cancer; Head and Neck Cancer; Liver	
	Interventions:	Biological: CMV pp65 peptide; Biological: autologous dendritic cells/CMV pp65 peptide mixture; Biological: recombinant fowlpox-CEA(6D)/TRICOM vaccine; Biological: tetanus toxoid; Biological: therapeutic autologous dendritic cells 2001	
	<p>Determine the safety and feasibility of active immunotherapy comprising autologous dendritic cells infected with recombinant fowlpox-CEA-TRICOM vaccine in patients with advanced or metastatic malignancies expressing CEA.</p> <p>Assess the CEA-specific immune response of patients treated with this regimen.</p> <p>Assess, in a preliminary manner, the clinical response rate of patients treated with this regimen.</p> <p>Patients are followed every 3 months for 1 year.</p>		
Active, not recruiting	<u>Vaccine Therapy in Treating Patients With Metastatic or Recurrent Cancer</u>		Active Specific Immunotherapy With MVF-HER-2(628-647) and CRL1005 Copolymer Adjuvant in Patients With Metastatic Cancer
	Conditions:	Breast Cancer; Gastric Cancer; Lung Cancer; Ovarian Cancer; Unspecified Adult Solid Tumor, Protocol	
	Intervention:	Biological: MVF-HER-2(628-647)-CRL 1005 vaccine 2001	
	<p>OBJECTIVES: I. Determine the optimum biologic dose of MVF-HER-2(628-647)-CRL 1005 vaccine that will induce anti-HER-2 antibody in patients with metastatic or recurrent cancer. II. Characterize the nature and severity of toxicity of this drug in these patients. III. Document any clinical responses to this drug in these patients.</p> <p>OUTLINE: This is a dose-escalation study. Patients receive MVF-HER-2(628-647)-CRL 1005 vaccine intramuscularly on days 1 and 29. Cohorts of 5 patients receive escalating doses of MVF-HER-2(627-647)-CRL 1005 vaccine until at least 2 of 5 patients experience dose-limiting toxicity. Patients are followed on days 43 and 57 and every 2 months for at least 1 year.</p>		
Recruiting	<u>Vaccine Therapy in Treating Patients With Head and Neck Cancer</u>		p53 Peptide Loaded DC-Based Therapy for Subjects With Squamous Cell Cancer of the Head and Neck
	Condition:	Head and Neck Cancer	
	Interventions:	Biological: mutant p53 peptide pulsed dendritic cell vaccine; Biological: tetanus toxoid helper peptide; Procedure: adjuvant therapy 2006	

	Primary Outcome Measures: Toxicity profile and overall toxicity rates. /Immunologic response rate as measured by ELISPOT assay prevaccination and at days 14 and 18 . /Toxicologic response rate	
Active, not recruiting	<u>Vaccine Therapy in Treating Patients With Metastatic Breast Cancer</u>	
	Condition:	Breast Cancer
	Intervention:	Biological: recombinant vaccinia DF3/MUC1 vaccine 1999
	<p>OBJECTIVES: I. Determine the toxicity associated with repeated vaccination with recombinant vaccinia DF3/MUC1 vaccine (rV-DF3/MUC1) in patients with metastatic breast cancer. II. Determine the maximum tolerated dose of rV-DF3/MUC1, based on cellular and humoral immunity, in these patients. III. Determine whether vaccination with rV-DF3/MUC1 is associated with antitumor activity in these patients.</p> <p>OUTLINE: This is an open label, dose escalation study. Patients receive recombinant vaccinia DF3/MUC1 vaccine (rV-DF3/MUC1) intradermally. Treatment repeats every month for 3 courses in the absence of disease progression or unacceptable toxicity. Cohorts of at least 6 patients receive escalating doses of rV-DF3/MUC1 until the maximum tolerated dose (MTD) or the highest dose level to be tested is reached. The MTD is defined as the dose preceding that at which 2 of 6 patients experience dose limiting toxicity. Patients are followed monthly for 6 months.</p>	
Completed	<u>Vaccine Therapy in Treating Patients With Liver Cancer</u>	
	Condition:	Liver Cancer
	Intervention:	Biological: AFP gene hepatocellular carcinoma vaccine 2000
	<p>antigen-specific immune response [ Time Frame: 1 month ] /Determine the antigen-specific immune response to hAFP137-145 (PLFQVPEPV), hAFP158-166 (FMNKFIYEI), hAFP325-334 (GLSPNLNRFL) and hAFP542-550 (GVALQTMKQ), emulsified with Montanide ISA-51, in peripheral blood of patients with liver cancer.</p> <p>Survival [ Time Frame: 1 month ]</p> <p>Determine the overall survival, disease-free survival or progression-free survival of patients with HCC vaccinated with hAFP137-145 (PLFQVPEPV), hAFP158-166 (FMNKFIYEI), hAFP325-334 (GLSPNLNRFL) and hAFP542-550 (GVALQTMKQ), emulsified with Montanide ISA-51.</p>	
Completed	<u>Vaccine Therapy Plus QS21 in Treating Women With Breast Cancer Who Have No Evidence of Disease</u>	
	Condition:	Breast Cancer
	Interventions:	Biological: GM2-KLH vaccine; Biological: QS21 1999
	Determine whether immunization with GM2-KLH vaccine plus the immunological adjuvant QS21 induces an antibody response against GM2 and cells expressing GM2 in disease free patients at high risk for recurrence of breast cancer.	
Completed	<u>Vaccine Therapy, Chemotherapy, and GM-CSF in Treating Patients With Advanced Pancreatic Cancer</u>	
	Condition:	Pancreatic Cancer
	Interventions:	Biological: allogeneic tumor cell vaccine; Biological: recombinant interferon alfa; Biological: sargramostim; Drug: cyclophosphamide 1999
	<p>Active intralymphatic immunotherapy with interferon-treated pancreas cancer tissue culture cells, GM-CSF, and low dose-CYCLOPHOSPHAMIDE</p>	
	<p>OBJECTIVES: I. Determine the feasibility, toxicity, and antitumor effects of active specific intralymphatic immunotherapy with allogeneic pancreatic cancer cells treated with interferon alfa plus low-dose adjuvant systemic sargramostim (GM-CSF) and cyclophosphamide in patients with incurable pancreatic adenocarcinoma. II. Assess the immunologic and biologic correlates of this treatment regimen in these patients.</p> <p>OUTLINE: Cultured allogeneic pancreatic cancer cells are incubated with interferon alfa for 72-96 hours. Autologous cell lines, if established, may be used as an alternative. The cells are irradiated immediately prior to use. Patients receive cyclophosphamide IV on day -3 and sargramostim (GM-CSF) subcutaneously on days 0-8. On day 0, patients receive viable tumor cells via dorsal pedal lymphatic cannulation. Treatment repeats every 2-4 weeks for a minimum of 8 weeks in the absence of disease progression or unacceptable toxicity. Patients are followed every 2-4 months.</p> <p>PROJECTED ACCRUAL: A total of 14 patients will be accrued for this study.</p>	

Recruiting	<u>Trial of Vaccine Therapy in Curative Resected Prostate Cancer Patients Using Autologous Dendritic Cells Loaded With mRNA</u>		
	Condition:	Prostate Cancer	
	Intervention:	Biological: Dendritic cell vaccine 2010	
	<p>Primary : Time to treatment failure defined by two different measurement of PSA levels &gt;0.5 µg/L with minimum of 4 weeks interval</p> <p>Secondary Outcome Measures: Safety and toxicity of vaccination. Evaluation of immunological response.</p>		
Completed	<u>Vaccine Therapy in Treating Patients With Breast Cancer</u>		Vaccination With MUC-1 (Glycosylated) Keyhole Limpet Hemocyanin Conjugates Plus the Immunological Adjuvant QS21
	Condition:	Breast Cancer	
	Intervention:	Biological: MUC1-KLH vaccine/QS21 1999	
	<p>OBJECTIVES: I. Determine if immunization with glycosylated MUC-1 antigen containing MUC-1(106) or MUC-1(33) with keyhole limpet hemocyanin conjugate plus immunological adjuvant QS21 induces an antibody, helper T cell and/or cytotoxic T cell response against MUC-1 in patients with high risk breast cancer (MUC-1+).</p> <p>OUTLINE: Patients receive glycosylated MUC-1 antigen containing MUC-1(106) or MUC-1(33) with keyhole limpet hemocyanin conjugate subcutaneously (SQ) plus immunological adjuvant QS21 SQ on weeks 1-3, 7, and 19 for a total of 5 vaccinations. Patients are followed every 3 months.</p>		
Active, not recruiting	<u>Vaccine Therapy in Treating Patients With Stage III or Stage IV Breast Cancer</u>		Vaccination With Multiple Synthetic Peptides in Participants With Advanced Breast Cancer
	Condition:	Breast Cancer	
	Intervention:	Biological: synthetic breast cancer peptides-tetanus toxoid-Montanide ISA-51 vaccine 2006	
	<p>Primary Outcome Measures: Safety of the 9-peptide mixture if fewer than 33% of patients experience a dose-limiting toxicity at day 36</p> <p>Secondary Outcome Measures: Frequency of immune responses by Elispot assay</p> <p>Determine the safety of a vaccine comprising multiple synthetic breast cancer-associated peptides and a tetanus toxoid helper peptide emulsified in Montanide ISA-51 in patients with stage III or IV adenocarcinoma of the breast.</p> <p>Determine, preliminarily, the frequency of immune responses against the 9 class I MHC-restricted peptides in patients treated with the vaccine.</p> <p>Determine, preliminarily, the cytotoxic responses of T-cells to allogeneic breast cancer cells and autologous breast cancer cells (when available).</p> <p>OUTLINE: This is an open-label study.</p>		
Completed	<u>HER-2 Protein Vaccine in Treating Women With Breast Cancer</u>		Intramuscular Injections Of HER-2 Protein AUTOVAC (PX104.1.6) In Patients With Breast Cancer
	Condition:	Breast Cancer	
	Intervention:	Biological: HER-2/neu peptide vaccine 2003	
	<p>Primary: Determine the safety of HER-2 protein AutoVac™ in women with breast cancer.</p> <p>Secondary: Determine the ability of this drug to bypass the tolerance to the HER-2 self-protein by raising HER-2 antibodies in these patients.</p> <p>Determine the kinetics of the immune response to HER-2/neu in patients treated with this drug.</p> <p>OUTLINE: This is an open-label, multicenter study.</p> <p>Patients receive HER-2 protein AutoVac™ intramuscularly at weeks 0, 2, 6, and 10 in the absence of unacceptable toxicity.</p> <p>Patients are followed for up to 6 weeks.</p>		
Recruiting	<u>Allogeneic Tumor Cell Vaccination in Patients With Solid Tumors</u>		Allogeneic Tumor Cell Vaccination in Patients With Solid Tumors
	Condition:	Metastatic Solid Tumors	
	Intervention:	Biological: Tumor Cell Vaccine 2005	
	<p>Primary Outcome: Investigate the feasibility of anti-tumor immune response by allogeneic tumor cell vaccine using tumor cells that share MHC determinants with the patient.</p> <p>Secondary Outcome: Investigate the feasibility of immune responses against cancer cells by combining allogeneic TCV with chemical drugs and rIL-2.</p>		

Active, not recruiting	<u>Vaccine Therapy in Treating Patients With Advanced Refractory or Recurrent Non-Small Cell Lung Cancer</u>		Antitumor Vaccination Using $\alpha$ (1,3) Galactosyltransferase Expressing Allogeneic Tumor Cells
	Condition:	Lung Cancer	
	Interventions:	Biological: alpha-1,3-galactosyltransferase-expressing allogeneic lung tumor cell vaccine; Genetic: protein analysis; Genetic: western blotting; Other: enzyme-linked immunosorbent assay; Other: immunohistochemistry staining method 2004	
	<p>Primary Outcome: Adverse effects, dose-limiting toxicity, and maximum tolerated dose as measured by CTCAE v.3 and RECIST criteria pre-treatment, during study treatment, and 6 months after completion of study treatment (phase I) /Tumor response rate as measured by CTCAE v.3 and RECIST criteria pre-treatment, during study treatment, and 6 months after completion of study treatment (phase II)</p> <p>Secondary Outcome Measures: Immunological response as measured by an assay of serum anti-alpha-gal titers and enzyme-linked immunospot assay for interferon-gamma and interleukin-5 pre-treatment and at 6 months after completion of study treatment</p> <p>Determine the survival distribution and duration of response in patients treated with this vaccine. (phase II)</p> <p>Primary: Determine the side effects, dose-limiting toxicity, and maximum tolerated dose of vaccination comprising <math>\alpha</math>-1,3-galactosyltransferase-expressing allogeneic tumor cells (HyperAcute™ Lung Cancer Vaccine) in patients with advanced refractory or recurrent non-small cell lung cancer. (phase I, completed 10/06/09)</p> <p>Determine tumor response rate in patients treated with this vaccine. (phase II)</p> <p>Secondary: Determine the immunological response (phase II). /Determine the survival distribution and duration of response in patients treated with this vaccine. (phase II) /Some patients undergo tumor tissue biopsies at baseline and after 3 vaccinations for cellular immune response by IHC assays. Blood samples are also collected at baseline and periodically during study for immune response by ELISA, total immunophenotyping by FACS, and Western Blot.</p> <p>Patients are followed monthly for 1 year, every 3 months for 2 years, and then annually for 15 years.</p>		
Completed	<u>Vaccine Therapy in Treating Patients With Metastatic Prostate Cancer</u>		RECOMBINANT VACCINIA VIRUS THAT EXPRESSES PSA IN PATIENTS WITH ADENOCARCINOMA OF THE PROSTATE
	Condition:	Prostate Cancer	
	Interventions:	Biological: recombinant viral vaccine therapy; Biological: sargramostim 1999	
	<p>OBJECTIVES: I. Assess the toxicity associated with repeated vaccination with recombinant vaccinia virus expressing prostate-specific antigen (rV-PSA) in patients with metastatic adenocarcinoma of the prostate. II. Determine the optimal dose of rV-PSA given at monthly intervals based on cellular and hormonal immunity. III. Determine whether vaccination with rV-PSA is associated with anti-tumor activity. IV. Determine whether granulocyte-macrophage colony-stimulating factor (GM-CSF) has an effect on cellular and humoral immunity different from rV-PSA, and whether the addition of GM-CSF has enhanced antitumor effect compared to rV-PSA alone.</p>		
Active, not recruiting	<u>Vaccine Therapy in Treating Patients With Gastric, Prostate, or Ovarian Cancer</u>		EGFRvIII Peptide Based Vaccine in Patients With EGFRvIII Expressing Cancers
	Conditions:	Brain and Central Nervous System Tumors; Gastric Cancer; Ovarian Cancer; Prostate Cancer	
	Interventions:	Biological: EGFR antisense DNA; Biological: keyhole limpet hemocyanin; Biological: sargramostim 2001	
	<p>OBJECTIVES: Determine the toxicity of EGFRvIII peptide vaccine with sargramostim (GM-CSF) or keyhole limpet hemocyanin (KLH) as adjuvant in patients with EGFRvIII-expressing cancer. /Determine the preexisting antibody and T-cell responses to EGFRvIII in these patients.</p> <p>Determine the antibody and T-cell responses to EGFRvIII peptide after immunization with this vaccine with GM-CSF or KLH as adjuvant.</p> <p>OUTLINE: Patients are assigned to one of two treatment arms.</p> <p>Arm I: Patients receive a vaccine containing EGFRvIII peptide admixed with sargramostim (GM-CSF) intradermally monthly.</p> <p>Arm II: Patients receive a vaccine containing EGFRvIII peptide admixed with keyhole limpet hemocyanin subcutaneously monthly.</p> <p>Treatment in both arms continues for 6 months in the absence of disease progression or unacceptable toxicity.</p> <p>Patients are followed every 3 months for 1 year.</p>		

Recruiting	<u>Vaccine Therapy in Treating Patients With Stage IIIB, Stage IV, or Recurrent Non-Small Cell Lung Cancer</u>		CCL21 Gene Modified Dendritic Cells In Non-Small Cell Lung Cancer
	Condition:	Lung Cancer	
	Interventions:	Biological: autologous dendritic cell-adenovirus CCL21 vaccine; Genetic: polymerase chain reaction; Genetic: reverse transcriptase-polymerase chain reaction; Other: flow cytometry; Other: immunoenzyme technique; Other: immunohistochemistry staining method 2008	
	<p>Primary Outcome: Safety. / Maximum tolerated dose / Toxicity as measured by NCI Common Toxicity Criteria</p> <p>Secondary Outcome: Disease status at days 28 and 56. / Immune response assessment by antigen-specific IFN<math>\gamma</math> ELISPOT assays on days 0, 28, and 56</p> <p>Primary: To determine the safety, toxicity, and maximum tolerated dose (MTD) of autologous dendritic cell-adenovirus CCL21 vaccine administered as an intratumoral injection in treating patients with stage IIIB, IV, or recurrent non-small cell lung cancer.</p> <p>Secondary: To determine the biologic and clinical responses to therapy. / To determine treatment-related toxicity using the NCI Common Toxicity Criteria. To identify the MTD. / To monitor patients for evidence of autologous dendritic cell-adenovirus CCL21 vaccine-induced cytokines and antigen-specific immune responses.</p> <p>To detect immune responses to tumor-associated antigens and vector. / To assess patients for objective signs of tumor regression (RECIST Criteria).</p> <p>OUTLINE: This is a dose-escalation study of autologous dendritic cell-adenovirus CCL21 vaccine.</p> <p>Tissue samples are analyzed for immune-modulating cytokines (i.e., IFN<math>\gamma</math>, CXCL9, and CXCL10) by quantitative RT-PCR; detection of tumor infiltrating leukocytes by immunohistochemistry; CD83+ DC, CXCR3, CCR7, CCL21 and CD3+ T-cells, CD4, and CD8 by flow cytometry; determination of tumor expression of tumor-</p>		
Active, not recruiting	<u>Chemotherapy, Vaccine Therapy, and Peripheral Stem Cell Transplantation in Treating Patients With Newly Diagnosed Multiple</u>		Vaccination In Peripheral Stem Cell Transplant Setting For Multiple Myeloma: The Use Of Autologous Tumor Cells/An Allo PSCT
	Condition:	Multiple Myeloma and Plasma Cell Neoplasm	
	Interventions:	Biological: autologous tumor cell vaccine; Drug: chemotherapy; Procedure: autologous hematopoietic stem cell transplantation; Procedure: peripheral blood stem cell transplantation 2001	
	<p>OBJECTIVES: Determine the efficacy of induction chemotherapy followed by autologous tumor cell vaccine and autologous peripheral blood stem cell transplantation in patients with multiple myeloma. / Determine the safety of this regimen in these patients.</p> <p>OUTLINE: Autologous tumor cells are harvested. The vaccine is prepared in vitro by mixing autologous tumor cells with a bystander cell expressing sargramostim (GM-CSF). Patients receive induction chemotherapy followed by autologous tumor cell vaccination (ATCV) once. Patients then undergo autologous peripheral blood stem cell transplantation. At 6 weeks after transplantation, patients receive additional ATCVs every 3 weeks for a total of 8 vaccinations.</p>		
Completed	<u>Vaccine Therapy in Treating Patients With Metastatic Prostate Cancer</u>		Active Immunotherapy in Patients With Metastatic Prostate Carcinoma Using Autologous Dendritic Cells Pulsed With RNA Encoding Prostate Specific Antigen, PSA
	Condition:	Prostate Cancer	
	Intervention:	Biological: PSA RNA-pulsed dendritic cell vaccine 1999	

	<p>OBJECTIVES: I. Determine the safety and feasibility of prostate specific antigen (PSA) RNA pulsed autologous dendritic cells in patients with metastatic prostate cancer. II. Evaluate the presence and magnitude of cellular immune responses against PSA as a surrogate target for immune activation in this patient population. III. Assess the presence, frequency, and activation status of peripheral cytotoxic T lymphocytes prior to and following immunotherapy with this regimen in these patients. IV. Evaluate humoral immune responses as evidenced on circulating peripheral PSA specific antibodies in this patient population. V. Evaluate delayed type hypersensitivity reactions to irradiated PSA RNA transfected dendritic cells and other standard recall antigens prior to and following immunotherapy in these patients. VI. Evaluate eventual clinical responses as evidenced on clinical and biochemical (PSA) response criteria.</p> <p>OUTLINE: This is a dose escalation study. Patients receive prostate specific antigen (PSA) RNA pulsed autologous dendritic cells IV over 2 minutes followed by PSA RNA dendritic cells intradermally on weeks 0, 2, and 4 for a total of 3 treatments. Cohorts of 3-6 patients receive escalating doses of PSA RNA pulsed autologous dendritic cells 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. Patients are followed weekly for 3 months, then every 3 months for 1 year, and then annually thereafter</p>	
Completed	<p><u>Vaccine Therapy in Treating Patients With Metastatic Cancer</u></p> <p>Conditions: Melanoma (Skin); Unspecified Adult Solid Tumor, Protocol Specific</p> <p>Interventions: Biological: aldesleukin; Biological: incomplete Freund's adjuvant; Biological: telomerase: 540-548 peptide vaccine 2001</p>	<p>Immunization of HLA-A*0201 Patients With Metastatic Cancer Using a Peptide Epitope From the Telomerase Antigen</p>
	<p>OBJECTIVES: Determine whether an immunologic response can be obtained in HLA*0201-expressing patients with metastatic cancer treated with telomerase: 540-548 peptide vaccine emulsified in Montanide ISA-51. /Determine which vaccine strategy (frequency, schedule, and dosing) is best for future studies in these patients.</p> <p>Determine the toxicity of this treatment in these patients. / Determine whether prior immunization with telomerase: 540-548 peptide vaccine results in increased clinical response to interleukin-2 in patients with melanoma.</p> <p>OUTLINE: This is a randomized study. Patients are stratified according to disease (metastatic cutaneous melanoma vs other tumor types). Patients are randomized to one of three treatment arms. /Arm I: Patients receive telomerase: 540-548 peptide vaccine emulsified in Montanide ISA-51 subcutaneously (SC) on day 1 of weeks 1-4 and 7-10. Patients also undergo leukapheresis over 3 hours at baseline and after each course of treatment. /Arm II: Patients receive telomerase: 540-548 peptide vaccine emulsified in Montanide ISA-51 SC on day 1 of weeks 1, 4, 7, and 10. Patients also undergo leukapheresis over 3 hours at baseline, after the vaccine on week 4, and after each course of treatment. /Arm III: Patients receive telomerase: 540-548 peptide vaccine emulsified in Montanide ISA-51 SC on days 1-4 of weeks 1, 4, 7, and 10. Patients undergo leukapheresis as in arm II.</p> <p>Treatment in all arms repeats every 13 weeks for 4-6 courses in the absence of disease progression or unacceptable toxicity. Patients with a complete response (CR) receive 1 additional course of treatment after achieving CR</p>	
Completed	<p><u>Vaccine Therapy in Treating Patients With Recurrent or Persistent Cervical Cancer</u></p> <p>Condition: Cervical Cancer</p> <p>Interventions: Biological: human papillomavirus 16 E7 peptide; Procedure: in vitro-treated peripheral blood stem cell transplantation 1999</p>	<p>Immunization With Alternating Human Papillomavirus E7 Lipopeptide Epitope Vaccine and Dendritic Cells Presenting the E7 Epitope for the Treatment of Recurrent or Persistent Cervical Cancer</p>
	<p>OBJECTIVES: Evaluate alternating vaccination with lipidated human papillomavirus 16 E7 peptide (HPV-16 E7) and autologous dendritic cells pulsed with immunogenic HPV-16 E7 in terms of toxicity, immunologic reactivity, and therapeutic efficacy in patients with recurrent or persistent cervical cancer.</p> <p>OUTLINE: This is a dose-escalation study of dendritic cell-human papillomavirus 16 E7 (HPV-16 E7) peptide vaccine.</p>	
Recruiting	<p><u>Vaccine Therapy in Treating Patients Who Have Undergone Autologous Stem Cell Transplant for High-Risk Lymphoma or</u></p>	<p>Immune Reconstitution After Autologous</p>



	<p>Conditions: Lymphoma; Multiple Myeloma and Plasma Cell Neoplasm; Small Intestine Cancer</p> <p>Interventions: Biological: pneumococcal polyvalent vaccine; Other: immunologic technique; Other: laboratory biomarker analysis; Procedure: quality-of-life assessment 2007</p>	<p>Immune Reconstitution After Autologous Hematopoietic Stem Cell Transplantation for High-Risk Lymphoma and Myeloma</p>
	<p>Primary Outcome Measures: Immune reconstitution</p> <p>Secondary Outcome Measures: Serial assessment of the absolute number of circulating regulatory T-cells and the function of these cells as measured by their expression of TGFβ and interleukin-10 (IL-10) /Quality of life, including functional status, fatigue, and depression /Correlation of quality of life with inflammatory cytokine production of peripheral blood monocytes. /Collection of baseline immune reconstitution and quality of life pilot data for comparison in future post-transplant immunotherapy trials</p> <p>Primary: Assess immune reconstitution as measured by response to pneumococcal polyvalent vaccine, NK-cell activity against autologous lymphoblastoid cell lines, and cytomegalovirus and Epstein-Barr virus tetramer responses in patients who have undergone autologous hematopoietic stem cell transplantation for high-risk lymphoma or multiple myeloma.</p> <p>Secondary: Assess the absolute number of circulating regulatory T-cells and the function of these cells as measured by their expression of TGFβ and interleukin-10 (IL-10). /Evaluate the effect of conditioning therapy on quality of life, including functional status, fatigue, and depression, in these patients. /Correlate quality of life with inflammatory cytokine production of peripheral blood monocytes at specified time points. /Provide baseline immune reconstitution and quality of life pilot data for comparison in future post-transplant immunotherapy trials</p>	
Completed	<p>Vaccine Therapy in Treating Patients With Stage III or Stage IV Kidney Cancer</p> <p>Condition: Kidney Cancer</p> <p>Interventions: Biological: HLA-A2, A3-restricted FGF-5 peptides/Montanide ISA-51 vaccine; Biological: aldesleukin; Procedure: adjuvant therapy 2004</p>	<p>Immunization for Renal Cancer Using HLA-A2 and HLA-A3-Binding Peptides From Fibroblast Growth Factor 5 (FGF-5)</p>
	<p>Primary Outcome Measures: Clinical response (cohorts A and B) /Immunological response (cohort C)</p> <p>Secondary Outcome Measures: Immunological response (cohorts A and B)</p> <p>Primary: Determine the overall response rates in patients with stage IV clear cell renal cell carcinoma treated with vaccine comprising HLA-A2- and HLA-A3-binding peptides from fibroblast growth factor-5 emulsified in Montanide ISA-51. (Cohorts A and B)</p> <p>Determine the effect of this vaccine on the response rate to high-dose interleukin-2 in these patients. (Cohorts A and B)</p> <p>Determine the immunologic response in patients with stage III clear cell renal cell carcinoma at high risk for relapse treated with this vaccine. (Cohort C)</p> <p>Determine the toxicity of this vaccine in these patients.</p> <p>Secondary: Determine the immunologic response in patients with stage IV disease treated with this vaccine. (Cohorts A and B)</p> <p>OUTLINE: Patients are stratified according to class I haplotype (HLA-A2 vs HLA-A3). Patients are assigned to 1 of 3 cohorts.</p> <p>Cohort A (no requirement for immediate interleukin-2 [IL-2] therapy): Patients receive vaccination comprising the HLA-appropriate binding peptide from fibroblast growth factor-5 (FGF-5) emulsified in Montanide ISA-51 subcutaneously (SC) once daily on days 1-4. Treatment repeats every 21 days for up to 1 year in the absence of disease progression or unacceptable toxicity.</p> <p>At the time of disease progression, patients eligible for IL-2 who have not yet received it have high-dose IL-2 added to their regimen. Patients continue to receive peptide vaccination on days 1-4 and receive high-dose IL-2 IV over 15 minutes every 8 hours on days 2-5 (12 doses). Treatment repeats every 15-19 days for up to 1 year of total treatment.</p> <p>Cohort B (requirement for immediate IL-2 therapy): Patients receive vaccination comprising the HLA-appropriate binding peptide from FGF-5 emulsified in Montanide ISA-51 SC once daily on days 1-4. Patients also receive high-dose IL-2 IV over 15 minutes every 8 hours on days 2-5 (12 doses). Treatment repeats every 15-19 days for up to 1 year in the absence of disease progression or unacceptable toxicity.</p> <p>Cohort C: Patients receive peptide vaccination as in cohort A. At the time of relapse, patients have high-dose IL-2 added to their regimen as in cohort A. Treatment repeats every 15-19 days for up to 6 months of total treatment.</p> <p>Patients are followed every 3-6 months (cohorts A and B) OR every 3 months for 1 year and then every 6-12 months thereafter (cohort C)</p>	

Active, not recruiting	<u>Vaccine Therapy in Treating Patients With Stage IIB, Stage III, or Stage IV Colorectal Cancer</u>		Immunogenicity of Vaccination With HER-2/Neu and CEA Derived Synthetic Peptides With GM-CSF-in-Adjuvant, in Patients With Stage IIB, III, or IV Colorectal Cancer
	Condition:	Colorectal Cancer	
	Intervention:	Biological: HER-2-neu, CEA peptides, GM-CSF, Montanide ISA-51 vaccine 2004	
	<p>Primary Outcome Measures: Safety of the 4-peptide mixture if fewer than 33% of patients experience a dose-limiting toxicity at day 22 /Immunogenicity of the peptide mixture by Elispot assay at day 22</p> <p>OBJECTIVES: Determine whether vaccination comprising HER-2-neu and carcinoembryonic antigen synthetic peptides, sargramostim (GM-CSF), and Montanide ISA-51 causes an immune response in patients with stage IIB, III, or IV colorectal cancer. /Determine the safety of this regimen in these patients.</p> <p>OUTLINE: Patients receive vaccination comprising HER-2-neu and carcinoembryonic antigen synthetic peptides, sargramostim (GM-CSF), and Montanide ISA-51 on days 1, 8, and 15. On day 22, patients undergo removal of the lymph node into which the vaccination site drains to determine whether the immune system is responding to the vaccine.</p>		
Completed	<u>Vaccine Therapy in Treating Patients at High Risk for Breast Cancer Recurrence</u>		Vaccination with Heptavalent Antigen - Keyhole Limpet Hemocyanin Conjugate Plus The Immunological Adjuvant QS21
	Condition:	Breast Cancer	
	Interventions:	Biological: Globo-H-GM2-Lewis-y-MUC1-32(aa)-sTn(c)-TF(c)-Tn(c)-KLH conjugate vaccine; Biological:	
	<p>OBJECTIVES: Determine whether immunization with multiple antigens comprising GM2, Globo-H, Lewis y, TF(c), sTn(c), Tn(c), and glycosylated MUC-1 32(aa) conjugated to keyhole limpet hemocyanin plus QS21 induces an antibody response against these individual antigens and breast cancer cells expressing these antigens in patients at high risk for breast cancer recurrence. /Determine the toxic effects of this regimen in these patients.</p> <p>OUTLINE: Patients receive Globo-H-GM2-Lewis-y-MUC1-32(aa)-sTn(c)-TF(c)-Tn(c)-KLH conjugate vaccine with QS21 adjuvant subcutaneously weekly on weeks 1, 2, 3, 7, and 19. Patients are followed every 3 months.</p>		
Recruiting	<u>Vaccine Therapy in Treating Patients With Stage II, Stage III, or Stage IV Ovarian Epithelial Cancer, Fallopian Tube Cancer, or</u>		ALVAC(2)-NY-ESO-1(M)/TRICOM for Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Carcinoma Express NY-ESO-1 or LAGE-1 Antigen
	Conditions:	Fallopian Tube Cancer; Ovarian Cancer; Peritoneal Cavity Cancer	
	Interventions:	Biological: ALVAC(2)-NY-ESO-1 (M)/TRICOM vaccine; Biological: sargramostim 2008	
	<p>Primary Outcome Measures: Safety and tolerability as assessed by NCI CTCAE v3.0</p> <p>Secondary Outcome Measures: Tumor response as assessed by RECIST criteria. /Immune response (humoral and cellular immunity)</p> <p>Primary: Determine the safety and tolerability of ALVAC(2)-NY-ESO-1(M)/TRICOM vaccine in patients with stage II-IV ovarian epithelial, fallopian tube, or primary peritoneal cavity cancer.</p> <p>Secondary: Determine the tumor response in patients treated with this regimen. /Determine the immune response in patients treated with this regimen.</p> <p>OUTLINE: This is a multicenter study. /Patients receive ALVAC(2)-NY-ESO-1(M)/TRICOM vaccine subcutaneously (SC) on day 1 and sargramostim (GM-CSF) SC on days 1-4. Treatment repeats every 28 days for up to 6 courses in the absence of disease progression or unacceptable toxicity</p>		
Recruiting	<u>A Study to Assess the Safety and Efficacy of MUC1 Peptide Vaccine and hGM-CSF in Patients With MUC1-positive Tumor</u>		
	Condition:	Multiple Myeloma	
	Intervention:	Biological: ImMucin, hGM-CSF 2008	

	<p>Primary Outcome: Safety of intradermal or subcutaneous administration of the ImMucin peptide [ Time Frame: 6 months ] /Determine the safety and initial feasibility of intradermal or subcutaneous administration of the ImMucin peptide combined with hGM-CSF for maximal stimulation of T cell response. The patients will receive six or twelve biweekly injections of Imucin (3 or 6 months). Post Treatment visit will be performed 4 weeks after administration of last vaccination. FU telephone calls will be made up to 6 months following the last vaccination in order to assess the status of the disease. Secondary Outcome: Assess efficacy of study treatment [ Time Frame: 6 months ] /Assessment of response to treatment during treatment period (3 or 6 months).Post Treatment visit will be performed 4 weeks after administration of last vaccination. FU telephone calls will be made up to 6 months following the last vaccination in order to assess the status of the disease.</p>	
Completed	<p><u>Vaccine Therapy in Treating Patients With Multiple Myeloma</u></p>	
	<p>Conditions: Stage II Multiple Myeloma; Stage III Multiple Myeloma; Refractory Plasma Cell Neoplasm</p>	<p>Autologous Myeloma-Derived Immunoglobulin Idiotypic Conjugated to Keyhole Limpet Hemocyanin Plus Sargramostim (GM-CSF) in Patients With Multiple Myeloma Undergoing</p>
	<p>Interventions: Drug: autologous tumor cell vaccine; Drug: keyhole limpet hemocyanin; Drug: melphalan; Drug:</p>	
	<p>OBJECTIVES: I. Determine whether autologous myeloma-derived immunoglobulin idiotype conjugated to keyhole limpet hemocyanin plus sargramostim (GM-CSF) can induce cellular and humoral immunity against the unique idiotype expressed on the surface of myeloma cells in patients with multiple myeloma undergoing second autologous peripheral blood stem cell transplantation. II. Determine the clinical efficacy and safety of this regimen in these patients. PROTOCOL OUTLINE: Within 6 months after the first autologous peripheral blood stem cell transplantation (APBSCT), patients receive melphalan IV over 30 minutes on day -2 and the second APBSCT on day 0. Sargramostim (GM-CSF) is administered subcutaneously (SC) beginning on day 1 and continuing until blood counts recover. Patients are also assigned to 1 of 3 vaccination groups. Group 1: Patients receive autologous myeloma-derived immunoglobulin idiotype conjugated to keyhole limpet hemocyanin (Id-KLH) SC on day 1 and GM-CSF SC on days 1-4 of months 2, 3, and 5 after the second APBSCT for a total of 3 vaccinations. Group 2: Patients receive Id-KLH SC on day 1 and GM-CSF SC on days 1-4 of months 2, 3, 4, 5, 6, and 8 after the second APBSCT for a total of 6 vaccinations. Group 3: Patients receive Id-KLH SC on day 1 and GM-CSF SC on days 1-4 of weeks -8, -6, and -2 before and months 2, 3, and 5 after the second APBSCT for a total of 6 vaccinations. Patients are followed within 3 months and then every 6 months.</p>	
Completed	<p><u>Chemotherapy and Vaccine Therapy Followed by Bone Marrow or Peripheral Stem Cell Transplantation and Interleukin-2 in</u></p>	
	<p>Condition: Brain and Central Nervous System Tumors</p>	<p>High Dose Cyclophosphamide, Cisplatin And Carmustine With Stem Cell Reconstitution Followed By Specific Cellular Therapy</p>
	<p>Interventions: Biological: aldesleukin; Biological: autologous tumor cell vaccine; Biological: filgrastim; Biological: sargramostim; Biological: therapeutic autologous lymphocytes; Drug: carmustine; Drug: cisplatin; Drug: cyclophosphamide; Drug: paclitaxel; Procedure: autologous bone marrow transplantation; Procedure: conventional surgery; Procedure: peripheral blood stem cell transplantation 2007</p>	

	<p><b>OBJECTIVES:</b> Determine the effectiveness of induction paclitaxel and cyclophosphamide followed by autologous tumor cell vaccine and sargramostim (GM-CSF) followed by high-dose chemotherapy with cisplatin, cyclophosphamide, and carmustine, autologous bone marrow or peripheral blood stem cell transplantation, and interleukin-2 in patients with recurrent or refractory primary high-grade brain tumors. Determine the safety and toxicity of this regimen in these patients. Determine if a specific quantitative cellular response can be elicited in patients treated with this regimen.</p> <p><b>OUTLINE:</b> After partial surgical resection of tumor, patients receive induction chemotherapy comprising paclitaxel IV over 3 hours and cyclophosphamide IV over 1 hour on day 1. Patients also receive filgrastim (G-CSF) subcutaneously (SC) daily beginning on day 3 and continuing until peripheral blood stem cell (PBSC) or bone marrow collection is completed. After the collection of PBSC or bone marrow, patients receive autologous tumor cell vaccine and sargramostim (GM-CSF) SC once every 2 weeks for up to 5 vaccinations. Two weeks after the last vaccination, patients undergo a second leukapheresis to collect lymphocytes. After completion of the second leukapheresis, patients receive high-dose chemotherapy comprising cisplatin IV continuously over 24 hours on day -5, cyclophosphamide IV over 1 hour on days -5, -4, and -3, and carmustine IV over 2 hours on day -2. Patients undergo autologous bone marrow or PBSC transplantation on day 0. Patients receive G-CSF IV daily beginning on day 0 and continuing until blood counts recover. Approximately 12 weeks after bone marrow or PBSC transplantation, patients receive autologous lymphocytes IV over 2-5 hours. Patients also receive interleukin-2 IV once every other day for 10 days. <i>Patients are followed at 18, 24, 36, 40, and 52 weeks.</i></p>		
Recruiting	<p><u>Vaccine Therapy in Treating Patients With Stage III or Stage IV Melanoma</u></p>		Immunization Against Melanoma Comparing Autologous Dendritic Cells Pulsed With gp100 Peptide to Autologous Dendritic Cells Fused With Autologous Tumor Cells
	Condition:	Melanoma (Skin)	
	Interventions:	Biological: autologous dendritic cell-tumor fusion vaccine; Biological: gp100 antigen; Biological: therapeutic autologous dendritic cells 2004	
	<p>Primary: Compare the tumor-specific immune response, in terms of the number of gp100-specific cytotoxic T-lymphocytes, T-cell production of interferon gamma, or T-cell proliferation in response to in vitro exposure to gp100 and tumor lysate, in patients with stage III or IV melanoma treated with autologous dendritic cells (DC) pulsed with gp100 antigen vs autologous DC fused with autologous tumor cells. Secondary: Compare the safety and toxicity of these regimens in these patients. /Compare the therapeutic effect of these regimens in these patients. OUTLINE: This is a randomized study. Patients are randomized to 1 of 2 treatment arms. All patients undergo leukapheresis. Peripheral blood mononuclear cells are cultured to generate dendritic cells (DC). Arm I: Patients undergo surgical harvesting of tumor cells for subsequent fusion. Patients receive vaccination comprising DC fused with autologous tumor cells subcutaneously on day 1. Treatment repeats every 21 days for 3 courses. Patients who achieve a partial (PR) or complete response (CR) may receive an additional 3 courses. /Arm II: Patients receive vaccination comprising DC pulsed with gp100 antigen IV on day 1. Treatment repeats every 21 days for 6 courses. Patients who achieve a PR or CR may receive an additional 6 courses. /In both arms, patients are followed monthly for 6 months.</p>		
Not yet recruiting	<p><u>Primary and Secondary Prevention of Human Papillomavirus (HPV) Disease in China</u></p>		Gardasil (VLP, HPV Quadrivalent prophylactic vaccine)
	Conditions:	HPV Infections; Precancerous Disease of the Cervix; Cervical Cancer; HPV Related Diseases	
	Intervention:	Biological: Gardasil (VLP, HPV Quadrivalent prophylactic vaccine)	
Recruiting	<p><u>A Phase II Study of an Anti-Tumor Immunotherapy Regimen Comprised of Pegylated Interferon-Alpha 2b and HyperAcute Melanoma Vaccine for Subjects With Advanced Melanoma</u></p>		Anti-Tumor Immunotherapy Regimen Comprised of Pegylated Interferon-Alpha 2b (PEG-Intron) and HyperAcute Melanoma Vaccine for Subjects With Advanced Melanoma
	Condition:	Melanoma	
	Interventions:	Biological: HyperAcute vaccine; Drug: Pegylated Interferon-Alpha 2b 2008	

	<p>Primary Outcome: To conduct scientific studies of patient tumor and peripheral blood samples to determine the mechanism of any observed anti-tumor effect involving the immune responses to the HyperAcute® vaccine alone &amp; combined with PEG-Intron [ Time Frame: 2 years ]</p> <p>Secondary Outcome: To determine the safety and response rate of the administration of the HyperAcute®-Melanoma Vaccine combined with PEG-Intron® into patients with recurrent, refractory, metastatic, or high risk of recurrence melanoma [ Time Frame: 2 years ]</p>		
Not yet recruiting	<p><u>A Study to Evaluate the Safety and Efficacy of Inactivated Varicella-zoster Vaccine (VZV) as a Preventative Treatment for</u></p>		<p>Study the Safety and Efficacy of V212 in Adult Patients With Solid Tumor or Hematologic Malignancy</p>
	Condition:	Herpes Zoster	
	Interventions:	Biological: V212; Biological: Placebo 2010	
	<p>Primary Outcome: The number of HZ cases per 1000 person-years of follow-up [ Time Frame: From study enrollment up to approximately 5 years ]</p> <p>The number of participants experiencing serious adverse events [ Time Frame: From vaccination day 1 through 28 days post vaccination dose 4 ]</p> <p>Secondary Outcome: The number of HZ cases per 1000 person-years of follow-up in the STM population [ Time Frame: From study enrollment up to approximately 5 years ] . /The number of HZ cases per 1000 person-years of follow-up in the HM population [ Time Frame: From study enrollment up to approximately 5 years ]</p> <p>Incidence of moderate to severe HZ-associated pain [ Time Frame: From HZ onset through the end of the 6 month HZ-follow-up period ]</p> <p>Moderate to severe HZ-associated pain is defined as 2 or more occurrences of a score of 3 or greater (0 to 10 scale) on the Zoster Brief Pain Inventory (ZBPI)</p> <p>Incidence of HZ complications [ Time Frame: Approximately 5 years ] [ Designated as safety issue: No ]</p> <p>HZ complications defined as the occurrence of any of the following during the study: hospitalization or prolongation of hospitalization due to HZ, disseminated HZ (including disseminated HZ rash or VZV viremia), visceral HZ, ophthalmic HZ, neurological impairment due to HZ, or administration of intravenous acyclovir therapy for treatment of HZ. /Incidence of postherpetic neuralgia (PHN) [ Time Frame: From HZ onset through the end of the 6 month HZ-follow-up period ]</p> <p>Postherpetic neuralgia (PHN) is defined as a worst pain score (in the last 24 hours) of 3 or greater (0 to 10 scale) on the Zoster Brief Pain Inventory (ZBPI) that persists or appears &gt;= 90 days after the onset of the HZ rash.</p>		
Recruiting	<p><u>Acceptability and Feasibility of Human Papilloma Virus Vaccine</u></p>		
	Condition:	Cervical Cancer	
	Intervention:	Behavioral: Health education	
Active, not recruiting	<p><u>Melanoma Vaccine With Peptides and Leuprolide</u></p>		<p>Modulatory Activity of an LHRH-Agonist (Leuprolide) on Melanoma Peptide Vaccines as Adjuvant Therapy</p>
	Condition:	Melanoma 2005	
	Interventions:	Drug: Leuprolide; Biological: GP100: 209-217(210M) Peptide; Biological: MAGE-3 Peptide	
	<p>vPrimary Outcome: To learn if the drug leuprolide will increase the level of immune cells in your body. [ Time Frame: 4 Years ]</p> <p>Secondary Outcome: To learn if this drug given together with melanoma vaccines (gp100 and MAGE-3) can improve the ability of tumor fighting immune cells (T cells) to fight melanoma cells. [ Time Frame: 4 Years ]</p>		
Recruiting	<p><u>Anti-MART-1 F5 Cells Plus ALVAC MART-1 Vaccine to Treat Advanced Melanoma</u></p>		<p>Metastatic Melanoma Using Lymphodepleting Conditioning Followed by Infusion of Anti-MART-1 F5 TCR-Gene Engineered Lymphocytes and ALVAC Virus</p>
	Conditions:	Metastatic Melanoma; Skin Cancer	
	Interventions:	Biological: autologous anti-MART-1 F5 T-cell receptor gene-engineered peripheral blood lymphocytes; Biological: ALVAC MART-1 Vaccine; Biological: aldesleukin; Drug: cyclophosphamide; 2008	

	<p>MART-1 is a gene present in melanoma cells.                  An experimental procedure developed for treating patients with melanoma uses the anti-MART-1 F5 gene and a type of virus to make special cells called anti-MART-1 F5 cells that are designed to destroy the patient's tumor. These cells are created in the laboratory using the patient's own tumor cells or blood cells. The treatment procedure also uses a vaccine called ALVAC MART-1, made from a virus that ordinarily infects canaries and is modified to carry a copy of the MART-1 gene. The virus cannot reproduce in mammals, so it cannot cause disease in humans. When the vaccine is injected into a patient, it stimulates cells in the immune system that may increase the efficiency of the anti-MART-1 F5 cells.  <b>Primary Outcome</b> Measures: Clinical tumor regression. [ Designated as safety issue: No ]  <b>Secondary Outcome</b> Measures: In vivo survival of T-cell receptor (TCR) gene-engineered cells. /Toxicity profile</p>	
Completed	<p><u>Peptide Vaccine to Prevent Recurrence of Nasopharyngeal Cancer</u></p> <p>Condition: Nasopharyngeal Neoplasms Drug: EBV-LMP-2 2004</p> <p>Intervention: Latent Membrane Protein (LMP) – 2 Immunization for the Assessment of the Natural History a</p>	
	<p>Nasopharyngeal tumors are caused by a common virus called Epstein-Barr virus, which produces a protein called LMP-2. Vaccination with specific pieces, or peptides, of the LMP-2 protein may boost the immune system's fight against the cancer. The vaccine injections are mixed with an oil-based substance called Montanide ISA-51, which is intended to increase the immune response to the peptide.                  Patients are screened with a physical examination and blood and urine tests. x-rays and other imaging studies are also done in patients who have not had these tests recently. All candidates are tested for HLA tissue type. Only patients with type HLA-A*1101 or HLA-A*2402 - the types on which the two vaccines in this study are based - receive vaccine therapy; others are offered standard medical treatment and observation.                  Participants are randomly assigned to receive injections of one of two different vaccines (LMP-2:340-349 or LMP-2:419-427) to determine which peptide may offer the best immunity. Each treatment course consists of weekly immunizations for 8 consecutive weeks. The injections are given under the skin of the thigh. After every other treatment course (about every 3 months), patients undergo a series of x-rays and scans to look for tumor.  <b>Detailed Description:</b> HLA-A*1101 and HLA-A*2402 positive patients with locally controlled anaplastic nasopharyngeal carcinoma at risk for loco-regional or distant recurrence will receive immunization with peptides representing HLA-restricted T cell epitopes of the Epstein-Barr virus encoded latent membrane protein-2 (LMP-2) emulsified in Montanide ISA-51. Patients will be allocated to treatment according to their HLA phenotype. The immunologic potential of the vaccine will be followed by enumerating the frequency of vaccines-specific CD8+ T cells in the peripheral blood using tetrameric HLA/peptide complexes. This study is designed to evaluate the immunologic effectiveness of peptide immunization in adjuvant settings in the context of anaplastic NPC.</p>	
Recruiting	<p><u>GP96 Heat Shock Protein-Peptide Complex Vaccine in Treating Patients With Recurrent or Progressive Glioma</u></p> <p>Condition: Brain and Central Nervous System Tumors</p> <p>Interventions: Biological: HSPPC-96; Procedure: conventional surgery 2006</p>	
	<p>Heat Shock Protein Peptide Complex-96 (HSPPC-96) Vaccine for Patients With Recurrent High Grade Glioma</p>	
	<p>Primary Outcome: Safety and maximum tolerated dose [survival]. /Frequency of gp96 heat shock protein-peptide complex vaccine (Phase I [closed to accrual as of 7/25/2007]) [survival] Toxicity (Phase I [closed to accrual as of 7/25/2007]) [survival] /Progression-free survival at 6 months (Phase II) [ Time Frame: 6 months ]                  Secondary Outcome: Immunological response (Phase I [closed to accrual as of 7/25/2007]) [last vaccine] /Safety (Phase II) [ Time Frame: survival ] /Tumor response as measured by neuro-imaging and neurologic exam (Phase II) [survival]. /Survival (Phase II) [survival]. /Immunological response (Phase II) [survival]</p>	
Completed	<p><u>Phase II Study of Lucanix™ in Patients With Stages II-IV Non-Small Cell Lung Cancer</u></p> <p>Conditions: Lung Neoplasm; Carcinoma, Bronchogenic</p>	
	<p>Lucanix™ (TGF-beta2 Antisense Gene Modified Allogeneic Tumor Cell Vaccine) in</p>	

	Intervention: Biological: Lucanix 2010	Patients With Stages II-IV Non-Small Cell
	<p>Primary Outcome Measures: Evaluate the ability of increasing doses of Lucanix™, a gene-modified tumor cell vaccine, to induce tumor response in patients with non-curable NSCLC [ Week 16, quarterly during treatment and first year of post-intervention follow-up ]</p> <p>Biological: Lucanix Monthly intradermal injections of four irradiated allogeneic TGF-beta2 antisense gene modified NSCLC cell lines. Patients are randomized to receive either 12,500,000, 25,000,000 or 50,000,000 cells per injection for up to 16 injections.</p>	
Recruiting	<u>Efficacy and Safety Study of the Therapeutic Vaccine PEP223 in Prostate Cancer Patients</u>	
	Condition: Prostate Cancer	Therapeutic Vaccine PEP-223/CoVaccine HT, to Hormone Treatment naïve, Immunocompetent Subjects With T1-3, N0-1/x, M0 Prostate Cancer, Eligible for Hormone Therapy
	Intervention: Biological: PEP-223/CoVaccine HT 2009	
	<p><b>Primary Outcome:</b> Testosterone suppression [ after 12 weeks ]</p> <p><b>Secondary Outcome:</b> The time course of testosterone suppression [ after 2, 4, 6, 8, 10 and 12 weeks. /Effects on LH and FSH levels [after 2, 4, 6, 8, 10 and 12 weeks]. /Effects on PSA levels [ after 2, 4, 6, 8, 10 and 12 weeks]. /Antibody response to PEP223/CoVaccine HT [ after 2, 4, 6, 8, 10 and 12 weeks] /</p> <p>Safety (adverse events, laboratory values, injection site reactions) [ Time Frame: as applicable ]</p>	
Recruiting	<u>Flu Vaccine in Preventing Influenza Infection in Healthy Volunteers and in Patients Who Have Undergone Stem Cell Transplant</u>	
	Conditions: Chronic Myeloproliferative Disorders; Leukemia; Lymphoma; Multiple Myeloma and Plasma Cell Neoplasm;	Influenza Specific Humoral and Cellular Immunity After Vaccination in Recipients of Allogeneic and Autologous Hematopoietic Stem Cell Transplantation
	Interventions: Biological: trivalent influenza vaccine; Other: immunoenzyme technique; Other: laboratory biomarker analysis 2009	
	<p><b>Primary Outcome:</b> Humoral and cellular memory immune responses in patients and healthy volunteers</p> <p><b>Secondary Outcome:</b> Incidence rate of influenza or respiratory incidence in patients after vaccination. /Impact of graft-vs-host disease on immune reconstitution and vaccine response. /Impact of age ≥ 60 years on immune reconstitution of after vaccination. /Differences between antibody and cytokine (CD8 and CD4) response</p>	
Active, not recruiting	<u>Vaccine Therapy and Interleukin-2 in Treating Young Patients With Relapsed or Refractory Ewing's Sarcoma or Neuroblastoma</u>	
	Conditions: Neuroblastoma; Sarcoma	Tumor Cell - B Lymphoblastoid Cell Line Vaccination in Pediatric Subjects With Relapsed Ewing's Sarcoma and Neuroblastoma
	Interventions: Biological: aldesleukin; Biological: autologous EBV-transformed B lymphoblastoid-tumor fusion cell vaccine; Biological: therapeutic autologous lymphocytes 2005	
	<p>OBJECTIVES: Determine the safety of vaccination comprising autologous tumor cells fused with Epstein-Barr virus-transformed B-lymphoblastoid cells followed by interleukin-2 (IL-2) in children with relapsed or refractory Ewing's sarcoma or neuroblastoma.</p> <p>Determine antitumor immunity by examining cell phenotype and function in patients treated with this vaccine and cytotoxic T lymphocytes (CTL).</p> <p>Determine the safety of CTL and IL-2 in these patients.</p>	
Active, not recruiting	<u>Vaccine Therapy in Treating Patients Who Are Undergoing Surgery for Ductal Carcinoma In Situ of the Breast</u>	
	Condition: Breast Cancer	A HER-2/Neu Pulsed DC1 Vaccine for Patients With DCIS
	Interventions: Biological: therapeutic autologous dendritic cells; Procedure: conventional surgery; Procedure: neoadjuvant therapy 2005	

	<p>Primary: Determine the feasibility and safety of neoadjuvant ultrasound-guided intranodal vaccine therapy comprising autologous dendritic cells pulsed with recombinant HER2/neu peptides in patients with ductal carcinoma in situ of the breast. /Determine the sensitization of CD4+ and CD8+ T cells to HER2/neu in patients treated with this vaccine. /Determine clinical response in patients treated with this vaccine.</p> <p>Secondary: Correlate post-vaccine sensitization of CD4+ and CD8+ T cells to HER2/neu with clinical response in patients treated with this vaccine.</p> <p>Patients undergo leukapheresis over 2-3 hours to obtain lymphocytes and monocytes. Monocytes are cultured with sargramostim (GM-CSF), interleukin-4, interferon gamma, and lipopolysaccharides for the production of dendritic cells (DC). DC are then pulsed with recombinant HER2/neu peptides to produce the dendritic cell vaccine. Approximately 2 days after leukapheresis, patients receive the vaccine intranodally (into 2 different lymph nodes) by ultrasound guidance once a week for 4 weeks in the absence of unacceptable toxicity. Patients then undergo a second leukapheresis to obtain T lymphocytes for immunologic analysis. Within 2-3 weeks after completion of vaccine therapy, patients undergo lumpectomy or mastectomy AND sentinel lymph node biopsy.</p> <p>After completion of study treatment, patients are followed every 6 months for 5 years and then annually thereafter</p>	
Completed	<p><u>Vaccine Biotherapy of Cancer: Autologous Tumor Cells and Dendritic Cells</u></p> <p>Condition: Metastatic Melanoma</p> <p>Interventions: Biological: Autologous tumor cells plus dendritic cells; Drug: GM-CSF 2009</p>	<p>Vaccine Biotherapy Of Cancer: Autologous Tumor Cells and Dendritic Cells as Active Specific Immunotherapy in Patients With Metastatic Melanoma</p>
	<p>Primary Outcome: event-free survival [death or disease progression] [ Time Frame: 5.5 years after treatment initiation ]</p> <p>Secondary Outcome: Overall survival [ Time Frame: 5.5 years after treatment initiation ]</p> <p>Patients were stratified by whether they had no measurable disease [NMD] at the time of treatment (usually because of surgical resection of metastases), or whether they had objectively measurable disease (OMD) by physical examination or radiologic scans per response evaluation criteria in solid tumors (RECIST criteria). Key endpoints were the results of delayed type hypersensitivity (DTH) skin testing to their own irradiated tumor cells, event-free survival [death or disease progression], overall survival, and objective tumor regression in patients who have measurable disease at the time vaccine therapy was initiated. This study was activated in the fall of 2000 and closed to accrual in June 2007</p>	
Completed	<p><u>Vaccine Therapy in Treating Patients With Stage IV Head and Neck Cancer</u></p> <p>Conditions: Head and Neck Cancer; Metastatic Cancer</p> <p>Intervention: Biological: recombinant fowlpox-TRICOM vaccine 2001</p>	<p>Intralesional Immunotherapy With A Recombinant Avipox Virus Engineered To Express A Triad Of Co-Stimulatory Molecules</p>
	<p>Determine the maximum tolerated dose and dose-limiting toxic effects of recombinant fowlpox-TRICOM vaccine in patients with advanced squamous cell carcinoma of the oral cavity or oropharynx or nodal or dermal metastases. /Determine the safety profile of this regimen in these patients. / Determine the clinical activity of this regimen, in terms of inflammation at injection site(s) and disease regression or stabilization, in these patients.</p>	
Recruiting	<p><u>Vaccine Therapy and GM-CSF in Treating Patients With Locally Advanced or Metastatic Pancreatic Cancer That Cannot Be</u></p> <p>Condition: Pancreatic Cancer</p> <p>Interventions: Biological: falimarev; Biological: inalimarev; Biological: sargramostim 2008</p>	<p>Intratumoral Recombinant Fowlpox PANVAC (PANVAC-F) Plus Subcutaneous Recombinant Vaccinia PANVAC (PANVAC-V) PANVAC-F and r-GM-CSF</p>
	<p>Primary Outcome: Maximum tolerated dose of intratumoral recombinant fowlpox PANVAC vaccine (PANVAC-F; falimarev) [ Time Frame: Pretreatment to day 71 ]</p> <p>Secondary Outcome: T-cell proliferation and cytokine production before and after treatment. [ Time Frame: Pretreatment to day 71 ]</p> <p>Beginning on day 71, patients with no irreversible or dose limiting toxicity , receive PANVAC-F vaccine SC (given on the day of and for 3 days after each PANVAC-F vaccination) monthly in the absence of disease progression or unacceptable toxicity.</p> <p>patients are followed every 3 months.</p>	
Completed	<p><u>A Study to Evaluate the Immune Response and Safety of GSK Biologicals' HPV-16/18 L1 VLP AS04 Vaccine/Cervarix TM</u></p>	<p>the Immunogenicity and Safety of</p>



Has Results	Conditions:	Human Papillomavirus (HPV) Infection; Associated Cervical Neoplasia; Papillomavirus Vaccines	GlaxoSmithKline Biologicals' HPV-16/18 L1 VLP AS04 Vaccine, Administered Intramuscularly in Healthy Female Subjects
	Interventions:	Biological: HPV-16/18 VLP/AS04 vaccine (Cervarix TM); Biological: Placebo	
Recruiting	<u>Gemcitabine With Peptide Vaccine Therapy in Treating Patients With Bile Duct Cancer</u>		Gemcitabine With Vaccine Therapy Targeting Tumor Antigen, URLC10, For Unresectable or Recurrent Bile Duct Cancer
	Condition:	Bile Duct Cancer	
	Interventions:	Biological: Peptide vaccine for URLC10; Drug: Gemcitabine 2008	
	<p>Primary Outcome: Safety (toxicities as assessed by NCI CTCAE version 3) [ Time Frame: 2 years ]</p> <p>Secondary Outcome: URLC10 peptide specific CTL induction in vitro [2 years ] /DTH to URLC10 peptide [2 years ]. /Changes in levels of regulatory T cells [ 2 years ]. /Objective response rate as assessed by RECIST criteria [ 2 years ]. /time to progression [2 years ]. /Survival rate [2 years ]</p> <p>Our previous studies have demonstrated that up-regulated lung cancer 10 (URLC10) has been identified as a new target of tumor associated antigen using cDNA microarray technique combined with the expression profiles of normal and cancer tissues. We have also found that 100% of tissue samples from bile duct cancer express URLC10. We have determined the HLA-A*2402 and HLA-A*0201 restricted epitope peptides derived from URLC10. These epitope peptides have shown to induce specific Cytotoxic T Lymphocytes (CTL) in vivo and in vitro. Furthermore, 60% and 20% of Japanese population have HLA-A*2402 and HLA-A*0201, respectively. Therefore, these peptides are suitable for clinical trial. On the other hand, gemcitabine is a drug approved against bile duct cancer. Recent studies has reported that gemcitabine has an additional ability to improve immune response. From these results, synergistic effect between vaccine therapy and chemotherapy using gemcitabine will be expected.</p>		
Active, not recruiting	<u>Cervical Intraepithelial Neoplasm (CIN) in Women (Gardasil)</u>		HPV 16/18-Related CIN2/3 or Worse of the Quadrivalent HPV (Types 6, 11, 16, 18,) L1 Virus-Like Particle (VLP) Vaccine (V501, Gardasil) in 16- to 23-Year Old Women
Has Results	Conditions:	Cervical Cancer; Genital Warts	
	Interventions:	Biological: Gardasil, human papillomavirus (type 6, 11, 16, 18) recombinant vaccine; Biological: Matching	
Completed	<u>Immunogenicity and Safety of a Commercially Available Vaccine Co-administered With GSK HPV Vaccine (580299)</u>		Immunogenicity and Safety of a Commercially Available Vaccine When Co-administered With GlaxoSmithKline
Has Results	Conditions:	Cervical Intraepithelial Neoplasia; Hepatitis B; Human Papillomavirus Infection	
	Interventions:	Biological: Subjects received 3 doses of GSK Biologicals' HPV vaccine (580299) (Cervarix™); Biological:	
Completed	<u>Vaccine Therapy in Treating Patients With Chronic Myelogenous Leukemia</u>		Vaccination of Patients With Chronic Myelogenous Leukemia With a Multivalent Tumor Specific Breakpoint Peptide Vaccine
	Condition:	Leukemia	
	Interventions:	Biological: QS21; Biological: bcr-abl peptide vaccine 1999	
	<p>Determine the safety and immunogenicity of a multivalent tumor-specific breakpoint peptide vaccine in patients with chronic myelogenous leukemia.</p> <p>Determine the antileukemic effects of vaccination with these peptides in these patients.</p>		
Active, not recruiting	<u>SGN-00101 Vaccine in Treating Human Papillomavirus in Patients Who Have Abnormal Cervical Cells</u>		of HPV 16 Vaccine on the Reduction of Viral Load in HPV 16 Positive Women With Persistent Viral Infection, But Low Grade
	Conditions:	Cervical Cancer; Precancerous Condition	
	Intervention:	Biological: HspE7 2004	
	<p>Compare the effectiveness of SGN-00101 vaccine vs placebo in reducing the human papillomavirus (HPV)-16 viral load in patients with atypical squamous cells of undetermined significance (ASCUS) or low-grade squamous intraepithelial lesions (LSIL) of the cervix with persistent HPV 16 infection who are at increased risk for developing a high-grade squamous intraepithelial lesion or invasive cervical cancer. /Compare the natural history of HPV-16 viral load in patients treated with these regimens. /Compare the effect of HPV-16 variants on viral load response in patients treated with these regimens. /Compare the relative effectiveness of these regimens on the regression of cervical cellular atypias (based on Pap test results), in terms of the regression of cytologic findings of LSIL and ASCUS to normal findings and resolution or regression of colposcopically defined cervicovaginal lesions, in these patients.</p>		

Completed	<u>Synthetic Vaccine in Patients With Chronic Myeloid Leukemia and Minimal Residual Disease</u>		Synthetic Tumor-Specific Breakpoint Peptide Vaccine in Patients With CML and Minimal Residual Disease
	Conditions:	Chronic Myeloid Leukemia; Minimal Residual Disease	
	Intervention:	Biological: Synthetic Tumor-Specific Breakpoint Peptide Vaccine	
Primary Outcome Measures: To evaluate the anti-leukemic effects of vaccination with CML breakpoint peptides as measured by a one-log decrease in circulating BCR-ABL transcripts using reverse transcription polymerase chain reaction (RT-PCR). [ Time Frame: September 2007 ]			
Terminated	<u>Docetaxel in Combination With GVAX ® Immunotherapy Versus Docetaxel and Prednisone in Prostate Cancer Patients</u>		Docetaxel in Combination With CG1940 and CG8711 Versus Docetaxel and Prednisone
	Condition:	Prostate Cancer	
	Interventions:	Biological: Immunotherapy allogeneic GM-CSF secreting cellular vaccine; Drug: Chemotherapy (docetaxel and prednisone) 2005	
Primary Outcome Measures: Survival [ Time Frame: 0 ] [ Designated as safety issue: No ] Secondary Outcome Measures: Time to disease progression. Time to pain progression. [ Time Frame: 0 ] [ Designated as safety issue: No ]			
Not yet recruiting	<u>An Intervention Study To Improve HPV Immunization in Haitian and African American Girls</u>		
	Condition:	Cervical Cancer	
	Intervention:	Behavioral: BNI-brief Negotiated Interview	
Recruiting	<u>Phase III Lucanix™ Vaccine Therapy in Advanced Non-small Cell Lung Cancer (NSCLC) Following Front-line Chemotherapy</u>		Lucanix™ (Belagenpumatucel-L) in Advanced Non-small Cell Lung Cancer:
	Conditions:	Lung Neoplasm; Carcinoma, Non-Small-Cell Lung: Stage IIIA (T3,N2 Only); Carcinoma, Non-Small-Cell Lung:	
	Interventions:	Biological: Lucanix™; Other: Placebo Comparator 2008	
<p><b>Primary Outcome:</b> Compare the overall survival of subjects with stage III or IV non-small cell lung cancer treated with belagenpumatucel-L (Lucanix™) vs placebo. [7 years ]</p> <p><b>Secondary Outcome:</b> Evaluate the progression free survival (PFS) of subjects treated with Lucanix™ compared to treatment within the Best Supportive Care control group. [3 years ] . /Evaluate the quality of life (QOL) as determined by the Lung Cancer Symptom Scale (LCSS) compared to treatment within the Best Supportive Care control group. [3 years ] . /Evaluate the time-to-progression of subjects treated with Lucanix™ compared to treatment within the Best Supportive Care control group. [3 years ] . /Evaluate the best overall tumor response in subjects treated with Lucanix™ compared to treatment in the Best Supportive Care control group. [3 years ] . /Evaluate the response duration in subjects treated with Lucanix™ compared to the Best Supportive Care control group. [3 years ] /Evaluate the rate of CNS metastases development in subjects treated with Lucanix™ as compared to the Best Supportive Care control group. [7 years ] /Adverse events of subjects treated with Lucanix™ will be compared to subjects in the Best Supportive Care control group. [ 7 years ]</p> <p><b>Blood samples</b> are collected and analyzed for routine chemistry, cytokines, chemokines, and some instances circulating tumor cells, including response to multiple lung cancer-associated antigens by IFN-γ ELISPOT CD8+ assay; CEA by CD4 class II assay; lung tumor-associated antigens by in vitro proliferation assays; regulatory T-cell (Treg) phenotype by flow cytometry; and Treg function.</p> <p>Subjects complete the Lung Cancer Symptom Scale quality of life questionnaire at baseline, on the days of treatment, 30 days after completion of study treatment, and then every 3 months for 1 year.</p> <p>After completion of study treatment, subjects are followed every 3 months for 1 year and then annually for 4 years</p>			
Active, not recruiting	<u>A Phase I/II Study With CEA(6D) VRP Vaccine in Patients With Advanced or Metastatic CEA-Expressing Malignancies</u>		Active Immunotherapy With CEA(6D)VRP Vaccine(AVX701) Advanced or Metastatic Malignancies Expressing CEA or Stage III Colon Cancer
	Conditions:	Colorectal Cancer; Breast Cancer; Lung Cancer; Pancreatic Cancer; Colon Cancer	
	Intervention:	Biological: AVX701	

	<p>CEA represents an attractive target antigen for immunotherapy since it is over expressed in nearly all colorectal cancers and pancreatic cancers, and is also expressed by some lung and breast cancers, and uncommon tumors such as medullary thyroid cancer, but is not expressed in other cells of the body except for low-level expression in gastrointestinal epithelium [1]. That CEA is a potential target for T cell mediated immune responses in humans is demonstrated by the observation that CEA contains epitopes that may be recognized in an MHC restricted fashion by T cells [2-11]. Specifically, there is support for the existence of human cytolytic T cells (CTLs) that recognize CEA epitopes that bind to MHC molecules HLA- A2, A3, and A24. For the most part, these T cells have been generated by in vitro cultures using antigen-presenting cells pulsed with the epitope of interest to stimulate peripheral blood mononuclear cells. In addition, T cell lines have been generated after stimulation with CEA latex beads, CEA protein-pulsed plastic adherent peripheral blood mononuclear cells, or DCs sensitized with CEA RNA. T cells have also been generated from patients immunized with a vaccinia vector encoding CEA immunogen (discussed below). Using high-performance liquid chromatography mass-spectrometry-based approaches, HLA A2-presented peptides from CEA have been identified in primary gastrointestinal tumors [12]. Of the HLA A2 restricted epitopes of CEA, CAP-1, a nine amino acid sequence, has been shown to stimulate CTLs from cancer patients immunized with vaccinia-CEA. Cap-1(6D) is a peptide analog of CAP-1. Its sequence includes a heteroclitic (nonanchor position) mutation, resulting in an amino acid change from Asn to Asp, to enhance recognition by the T-cell receptor without any change in binding to HLA A2. Compared with the non mutated CAP-1 epitope, Cap-1(6D) has been shown to enhance the sensitization of CTLs by 100 to 1,000 times [3, 5, 13]. CTL lines could be elicited from peripheral blood mononuclear cells of healthy volunteers by in vitro sensitization to the Cap-1(6D) peptide but not to the CAP-1 peptide. These cell lines can lyse human tumor cells expressing endogenous CEA. /evaluate CEA-specific immune response to immunizations [ Time Frame: 3 years ]</p>	
Recruiting	<p><u>Dendritic Cell Vaccine for Patients With Brain Tumors</u></p> <p>Conditions: Glioma; Anaplastic Astrocytoma; Anaplastic Astro-oligodendrogloma; Glioblastoma</p> <p>Intervention: Biological: autologous tumor lysate-pulsed DC vaccination 2010</p>	<p>Autologous Dendritic Cells Pulsed With Tumor Lysate Antigen +/- Toll-like Receptor Agonists for the Treatment of Malignant Glioma</p>
	<p>Tumor Lysate Antigen +/- Toll-like Receptor Agonists: Experimental                  Cohort #1 will receive autologous tumor lysate-pulsed DC vaccination alone. Cohort #2 will receive autologous tumor lysate-pulsed DC vaccination together with adjuvant 5% imiquimod (TLR7 agonist). Cohort #3 will receive autologous tumor lysate-pulsed DC vaccination together with adjuvant poly ICLC (TLR3 agonist).                  Intervention: Biological: autologous tumor lysate-pulsed DC vaccination                  目的: Dendritic cells (DC) (cells which "present" or "show" cell identifiers to the immune system) isolated from the subject's own blood will be treated with tumor-cell lysate isolated from tumor tissue taken from the same subject during surgery. This pulsing (combining) of antigen-presenting and tumor lysate will be done to try to stimulate the immune system to recognize and destroy the patient's intracranial brain tumor. These pulsed DCs will then be injected back into the patient intradermally as a vaccine. The investigators will also utilize adjuvant imiquimod or poly ICLC in some treatment cohorts. It is thought that the host immune system might be taught to "recognize" the malignant brain tumor cells as "foreign" to the body by effectively presenting unique tumor antigens to the host immune cells (T-</p>	
Recruiting	<p><u>Vaccine Therapy in Treating Patients Undergoing Surgery for Recurrent Glioblastoma Multiforme</u></p> <p>Condition: Brain and Central Nervous System Tumors</p> <p>Interventions: Biological: autologous CD133-positive BTSC mRNA-pulsed autologous dendritic cell vaccine; Procedure: adjuvant therapy; Procedure: therapeutic conventional surgery 2009</p>	<p>Recurrent GBM Stem Cell Tumor Amplified RNA Immunotherapy Trial</p>

	<p>Biological: autologous CD133-positive BTSC mRNA-pulsed autologous dendritic cell vaccine          An escalating total dose of mRNA-loaded DCs (<math>2 \times 10^6</math>, <math>5 \times 10^6</math>, and <math>2 \times 10^7</math> per vaccination) will be evaluated for purpose of establishing a MTD and a DLT          Primary Outcome: Feasibility and safety [12 months ]          Secondary Outcome: Humoral and cellular immune responses [12 months ]          Primary: To evaluate the feasibility and safety of an autologous brain tumor stem cell mRNA-loaded dendritic cell vaccine for recurrent glioblastoma multiforme.          Secondary: To assess humoral and cellular immune responses to vaccination. /To compare the proportion of vaccinated patients alive at 6 months from the time of surgery for recurrent tumor with matched historical cohorts.          Patients undergo surgical resection of tumor. Tumor tissue samples are collected to isolate brain tumor stem cells (BTSCs) and for extraction and amplification of BTSC-specific mRNA. Within 4 weeks after surgical resection, patients undergo leukapheresis over 4 hours to generate dendritic cells (DCs). Patients also undergo leukapheresis at 1 week after the third vaccination and then at least every 3 months as needed for generation of additional DCs.</p>	
Active, not recruiting	<u>Vaccine Therapy in Treating Patients With Malignant Glioma</u>	
	Condition:	Brain and Central Nervous System Tumors
	Intervention:	Biological: glioma-associated antigen peptide-pulsed autologous dendritic cell vaccine 2008
	Glioma-Associated Antigen (GAA) Peptide-pulsed Dendritic Cell Vaccination in Malignant Glioma Patients	
	<p>Primary Outcome: Dose-limiting toxicity and maximum tolerated dose of autologous dendritic cells pulsed with synthetic glioma-associated antigen (GAA) peptides /Survival. /Tumor progression. /Cellular immune response. Patients are followed every 2 months for 1 year.</p>	
Recruiting	<u>Vaccine Therapy and Monoclonal Antibody Therapy in Treating Patients With Stage III or Stage IV Melanoma That Cannot Be</u>	
	Condition:	Melanoma (Skin)
	Interventions:	Biological: MART-1:26-35(27L) peptide vaccine; Biological: NY-ESO-1 peptide vaccine; Biological: anti-PD-1 human monoclonal antibody MDX-1106; Biological: gp100:209-217(210M) peptide vaccine; Biological: gp100:280-288(288V) peptide vaccine; Drug: Montanide ISA 51 VG; Other: laboratory biomarker analysis; Other: pharmacological study 2010
	Vaccine Combining Multiple Class I Peptides and Montanide ISA 51 VG With Escalating Doses of Anti-PD-1 Antibody BMS-936558 for Patients With Unresectable Stages III/IV Melanoma	
	<p>Primary Outcome: Best overall response (complete or partial response, stable disease, or progressive disease). Adverse events          Secondary Outcome: Time to response. Duration of response.          Primary: To assess the safety and tolerability of multiple class I peptide vaccine comprising gp100:209-217(210M), MART-1:26-35(27L), gp100:280-288(288V), and NY-ESO-1 emulsified in Montanide ISA 51 VG and anti-PD-1 human monoclonal antibody MDX-1106 (BMS-936558) in HLA-A*0201-positive patients with unresectable stage III or IV malignant melanoma.          Secondary: To evaluate the immune response at week 12 in patients treated with these regimens compared to the immune response to peptide vaccine alone. /To assess the host immune response (immunogenicity) to BMS-936558. /To assess, preliminarily, the efficacy of these regimens in these patients.          OUTLINE: This is a dose-escalation study of anti-PD-1 human monoclonal antibody MDX-1106.          Blood samples are collected for pharmacokinetic and immunologic analysis. After completion of study therapy, patients are followed up periodically for 2 years.</p>	
Recruiting	<u>Tumor Lysate Pulsed Dendritic Cell Immunotherapy for Patients With Brain Tumors</u>	
	Condition:	Glioblastoma
	Interventions:	Biological: Dendritic Cell Immunotherapy; Biological: Dendritic Cell Vaccine 2007
	Tumor Lysate-Pulsed Dendritic Cell Immunotherapy for Patients With Atypical or Malignant, Primary or Metastatic Brain Tumors of the Central Nervous System	