	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. 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	
Completed	Vaccine Therapy in Treating Patients With Metastatic Cancer Conditions: Melanoma (Skin); Unspecified Adult Solid Tumor, Protocol Specific Interventions: Biological: aldesleukin; Biological: incomplete Freund's adjuvant; Biological: telomerase: 540–548 peptide vaccine 2001	Immunization of HLA–A*0201 Patients With Metastatic Cancer Using a Peptide Epitope From the Telomerase Antigen
	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. 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. 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. 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	
Completed	Vaccine Therapy in Treating Patients With Recurrent or Persistent Cervical Cancer Condition: Cervical Cancer Interventions: Biological: human papillomavirus 16 E7 peptide; Procedure: in vitro–treated peripheral blood stem cell transplantation 1999	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
	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. OUTLINE: This is a dose-escalation study of dendritic cell-human papillomavirus 16 E7 (HPV-16 E7) peptide vaccine.	
Recruiting	Vaccine Therapy in Treating Patients Who Have Undergone Autologous Stem Cell Transplant for High–Risk Lymphoma or	Immune Reconstitution After Autologous

	Conditions:	Lymphoma; Multiple Myeloma and Plasma Cell Neoplasm; Small Intestine Cancer	Immune Reconstitution After Autologous Hematopoietic Stem Cell Transplantation for High-Risk Lymphoma and Myeloma
	Interventions:	Biological: pneumococcal polyvalent vaccine; Other: immunologic technique; Other: laboratory biomarker analysis; Procedure: quality-of-life assessment 2007	
	Primary Outcome Measures: Immune reconstitution 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 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. 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		
Completed	Vaccine Therapy in Treating Patients With Stage III or Stage IV Kidney Cancer		Immunization for Renal Cancer Using HLA-A2 and HLA-A3-Binding Peptides From Fibroblast Growth Factor 5 (FGF-5)
	Condition:	Kidney Cancer	
	Interventions:	Biological: HLA-A2, A3-restricted FGF-5 peptides/Montanide ISA-51 vaccine; Biological: aldesleukin; Procedure: adjuvant therapy 2004	
	Primary Outcome Measures: Clinical response (cohorts A and B) /Immunological response (cohort C) Secondary Outcome Measures: Immunological response (cohorts A and B) 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) Determine the effect of this vaccine on the response rate to high-dose interleukin-2 in these patients. (Cohorts A and B) 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) Determine the toxicity of this vaccine in these patients. Secondary: Determine the immunologic response in patients with stage IV disease treated with this vaccine. (Cohorts A and B) OUTLINE: Patients are stratified according to class I haplotype (HLA-A2 vs HLA-A3). Patients are assigned to 1 of 3 cohorts. 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. 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. 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. 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. 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)		

Active, not recruiting	Vaccine Therapy in Treating Patients With Stage IIB, Stage III, or Stage IV Colorectal Cancer		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	
	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 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. 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.		
Completed	Vaccine Therapy in Treating Patients at High Risk for Breast Cancer Recurrence		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:	
	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. 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.		
Recruiting	Vaccine Therapy in Treating Patients With Stage II, Stage III, or Stage IV Ovarian Epithelial Cancer, Fallopian Tube Cancer, or		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	
	Primary Outcome Measures: Safety and tolerability as assessed by NCI CTCAE v3.0 Secondary Outcome Measures: Tumor response as assessed by RECIST criteria. /Immune response (humoral and cellular immunity) 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. Secondary: Determine the tumor response in patients treated with this regimen. /Determine the immune response in patients treated with this regimen. 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		
Recruiting	A Study to Assess the Safety and Efficacy of MUC1 Peptide Vaccine and hGM-CSF in Patients With MUC1-positive Tumor		
	Condition:	Multiple Myeloma	
	Intervention:	Biological: ImMucin, hGM-CSF 2008	

	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 respose 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.	
Completed	Vaccine Therapy in Treating Patients With Multiple Myeloma Conditions: Stage II Multiple Myeloma; Stage III Multiple Myeloma; Refractory Plasma Cell Neoplasm Interventions: Drug: autologous tumor cell vaccine; Drug: keyhole limpet hemocyanin; Drug: melphalan; Drug:	Autologous Myeloma-Derived Immunoglobulin Idiotype Conjugated to Keyhole Limpet Hemocyanin Plus Sargramostim (GM-CSF) in Patients With Multiple Myeloma Undergoing
	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.	
Completed	Chemotherapy and Vaccine Therapy Followed by Bone Marrow or Peripheral Stem Cell Transplantation and Interleukin-2 in Condition: Brain and Central Nervous System Tumors 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	High Dose Cyclophosphamide, Cisplatin And Carmustine With Stem Cell Reconstitution Followed By Specific Cellular Therapy

	OBJECTIVES: 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. OUTLINE: 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. Patients are followed at 18, 24, 36, 40, and 52 weeks.	
Recruiting	Vaccine Therapy in Treating Patients With Stage III or Stage IV Melanoma Condition: Melanoma (Skin) Interventions: Biological: autologous dendritic cell–tumor fusion vaccine; Biological: gp100 antigen; Biological: therapeutic autologous dendritic cells 2004	Immunization Against Melanoma Comparing Autologous Dendritic Cells Pulsed With gp100 Peptide to Autologous Dendritic Cells Fused With Autologous Tumor Cells
	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.	
Not yet recruiting	Primary and Secondary Prevention of Human Papillomavirus (HPV) Disease in China Conditions: HPV Infections; Precancerous Disease of the Cervix; Cervical Cancer; HPV Related Diseases Intervention: Biological: Gardasil (VLP, HPV Quadrivalent prophylactic vaccine)	Gardasil (VLP, HPV Quadrivalent prophylactic vaccine
Recruiting	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 Condition: Melanoma Interventions: Biological: HyperAcute vaccine; Drug: Pegylated Interferon-Alpha 2b 2008	Anti-Tumor Immunotherapy Regimen Comprised of Pegylated Interferon-Alpha 2b (PEG-Intron)and HyperAcute Melanoma Vaccine for Subjects With Advanced Melanoma

	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 & combined with PEG-Intron [Time Frame: 2 years] 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]	
Not yet recruiting	A Study to Evaluate the Safety and Efficacy of Inactivated Varicella-zoster Vaccine (VZV) as a Preventative Treatment for Condition: Herpes Zoster Interventions: Biological: V212; Biological: Placebo 2010	Study the Safety and Efficacy of V212 in Adult Patients With Solid Tumor or Hematologic Malignancy
	Primary Outcome: The number of HZ cases per 1000 person-years of follow-up [Time Frame: From study enrollment up to approximately 5 years] The number of participants experiencing serious adverse events [Time Frame: From vaccination day 1 through 28 days post vaccination dose 4] 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] Incidence of moderate to severe HZ-associated pain [Time Frame: From HZ onset through the end of the 6 month HZ-follow-up period] 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) Incidence of HZ complications [Time Frame: Approximately 5 years] [Designated as safety issue: No] 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] 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 >= 90 days after the onset of the HZ rash.	
Recruiting	Acceptability and Feasibility of Human Papilloma Virus Vaccine Condition: Cervical Cancer Intervention: Behavioral: Health education	
Active, not recruiting	Melanoma Vaccine With Peptides and Leuprolide Condition: Melanoma 2005 Interventions: Drug: Leuprolide; Biological: GP100: 209-217(210M) Peptide; Biological: MAGE-3 Peptide	Modulatory Activity of an LHRH-Agonist (Leuprolide) on Melanoma Peptide Vaccines as Adjuvant Therapy
	vPrimary Outcome: To learn if the drug leuprolide will increase the level of immune cells in your body. [Time Frame: 4 Years] 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]	
Recruiting	Anti-MART-1 F5 Cells Plus ALVAC MART-1 Vaccine to Treat Advanced Melanoma 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	Metastatic Melanoma Using Lymphodepleting Conditioning Followed by Infusion of Anti-MART-1 F5 TCR-Gene Engineered Lymphocytes and ALVAC Virus

	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. **Primary Outcome** Measures: Clinical tumor regression. [Designated as safety issue: No] **Secondary Outcome** Measures: In vivo survival of T-cell teceptor (TCR) gene-engineered cells. /Toxicity profile	
Completed	Peptide Vaccine to Prevent Recurrence of Nasopharyngeal Cancer Condition: Nasopharyngeal Neoplasms Drug: EBV-LMP-2 2004 Intervention: Latent Membrane Protein (LMP) - 2 Immunization for the Assessment of the Natural History a	
	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. **Detailed Description:** 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.	
Recruiting	GP96 Heat Shock Protein-Peptide Complex Vaccine in Treating Patients With Recurrent or Progressive Glioma Condition: Brain and Central Nervous System Tumors Interventions: Biological: HSPPC-96; Procedure: conventional surgery 2006	Heat Shock Protein Peptide Complex-96 (HSPPC-96) Vaccine for Patients With Recurrent High Grade Glioma
	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]	
Completed	Phase II Study of Lucanix™ in Patients With Stages II-IV Non-Small Cell Lung Cancer Conditions: Lung Neoplasm; Carcinoma, Bronchogenic	Lucanix™ (TGF-beta2 Antisense Gene Modified Allogeneic Tumor Cell Vaccine) in

	Intervention:	Biological: Lucanix 2010	Patients With Stages II–IV Non–Small Cell
	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] 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.		
Recruiting	Efficacy and Safety Study of the Therapeutic Vaccine PEP223 in Prostate Cancer Patients		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
	Condition:	Prostate Cancer	
	Intervention:	Biological: PEP–223/CoVaccine HT 2009	
	Primary Outcome: Testosterone suppression [after 12 weeks] **Secondary Outcome**: 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]. /ffects 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] / Safety (adverse events, laboratory values, injection site reactions) [Time Frame: as applicable]		
Recruiting	Flu Vaccine in Preventing Influenza Infection in Healthy Volunteers and in Patients Who Have Undergone Stem Cell Transplant		Influenza Specific Humoral and Cellular Immunity After Vaccination in Recipients of Allogeneic and Autologous Hematopoietic Stem Cell Transplantation
	Conditions:	Chronic Myeloproliferative Disorders; Leukemia; Lymphoma; Multiple Myeloma and Plasma Cell Neoplasm;	
	Interventions:	Biological: trivalent influenza vaccine; Other: immunoenzyme technique; Other: laboratory biomarker analysis 2009	
	Primary Outcome: Humoral and cellular memory immune responses in patients and healthy volunteers **Secondary Outcome**: *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		
Active, not recruiting	Vaccine Therapy and Interleukin–2 in Treating Young Patients With Relapsed or Refractory Ewing's Sarcoma or Neuroblastoma		Tumor Cell – B Lymphoblastoid Cell Line Vaccination in Pediatric Subjects With Relapsed Ewing's Sarcoma and Neuroblastoma
	Conditions:	Neuroblastoma; Sarcoma	
	Interventions:	Biological: aldesleukin; Biological: autologous EBV–transformed B lymphoblastoid–tumor fusion cell vaccine; Biological: therapeutic autologous lymphocytes 2005	
	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. Determine antitumor immunity by examining cell phenotype and function in patients treated with this vaccine and cytotoxic T lymphocytes (CTL). Determine the safety of CTL and IL-2 in these patients.		
Active, not recruiting	Vaccine Therapy in Treating Patients Who Are Undergoing Surgery for Ductal Carcinoma In Situ of the Breast		A HER–2/Neu Pulsed DC1 Vaccine for Patients With DCIS
	Condition:	Breast Cancer	
	Interventions:	Biological: therapeutic autologous dendritic cells; Procedure: conventional surgery; Procedure: neoadjuvant therapy 2005	

	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. Secondary: Correlate post-vaccine sensitization of CD4+ and CD8+ T cells to HER2/neu with clinical response in patients treated with this vaccine. 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. After completion of study treatment, patients are followed every 6 months for 5 years and then annually thereafter	
Completed	Vaccine Biotherapy of Cancer: Autologous Tumor Cells and Dendritic Cells Condition: Metastatic Melanoma Interventions: Biological: Autologous tumor cells plus dendritic cells; Drug: GM-CSF 2009	Vaccine Biotherapy Of Cancer: Autologous Tumor Cells and Dendritic Cells as Active Specific Immunotherapy in Patients With Metastatic Melanoma
	Primary Outcome: event-free survival [death or disease progression] [Time Frame: 5.5 years after treatment initation] Secondary Outcome: Overall survival [Time Frame: 5.5 years after treatment initation] 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	
Completed	Vaccine Therapy in Treating Patients With Stage IV Head and Neck Cancer Conditions: Head and Neck Cancer; Metastatic Cancer Intervention: Biological: recombinant fowlpox-TRICOM vaccine 2001	Intralesional Immunotherapy With A Recombinant Avipox Virus Engineered To Express A Triad Of Co-Stimulatory Molecules
	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.	
Recruiting	Vaccine Therapy and GM-CSF in Treating Patients With Locally Advanced or Metastatic Pancreatic Cancer That Cannot Be Condition: Pancreatic Cancer Interventions: Biological: falimarev; Biological: inalimarev; Biological: sargramostim 2008	Intratumoral Recombinant Fowlpox PANVAC (PANVAC-F) Plus Subcutaneous Recombinant Vaccinia PANVAC (PANVAC-V) PANVAC-F and r-GM-CSF
	Primary Outcome: Maximum tolerated dose of intratumoral recombinant fowlpox PANVAC vaccine (PANVAC-F; falimarev) [Time Frame: Pretreatment to day 71] Secondary Outcome: T-cell proliferation and cytokine production before and after treatment. [Time Frame: Pretreatment to day 71] 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. patients are followed every 3 months.	
Completed	A Study to Evaluate the Immune Response and Safety of GSK Biologicals' HPV-16/18 L1 VLP AS04 Vaccine/Cervarix TM	the Immunogenicity and Safety of

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	Gemcitabine With Peptide Vaccine Therapy in Treating Patients With Bile Duct Cancer		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	
	Primary Outcome: Safety (toxicities as assessed by NCI CTCAE version 3) [Time Frame: 2 years] 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] 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.		
Active, not recruiting	Cervical Intraepithelial Neoplasm (CIN) in Women (Gardasil)		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	Immunogenicity and Safety of a Commercially Available Vaccine Co-administered With GSK HPV Vaccine (580299)		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	Vaccine Therapy in Treating Patients With Chronic Myelogenous Leukemia		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	
	Determine the safety and immunogenicity of a multivalent tumor-specific breakpoint peptide vaccine in patients with chronic myelogenous leukemia. Determine the antileukemic effects of vaccination with these peptides in these patients.		
Active, not recruiting	SGN-00101 Vaccine in Treating Human Papillomavirus in Patients Who Have Abnormal Cervical Cells		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	
	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.		