Completed	p53 Vaccine for Ovarian Cancer	Tumor Specific p53 Peptides incomplete Freund's adjuvant + autologous dendritic cells (in vitro-treated peripheral blood stem cell transplantation):
	Condition: Ovarian Neoplasm 1999-2012	
	Interventions: Biological: aldesleukin; Biological: incomplete Freund's adjuvant; Biological: p53 peptide vaccine; Biological: sargramostim; Biological: therapeutic autologous dendritic cells; Procedure: in vitro-treated peripheral blood stem cell transplantation 1999	
	Cellular immunity as measured by Elispot assay + 51 Cr-release assay every 3 weeks This study will examine whether vaccination with a p53 peptide can boost an immune response to ovarian cancer and what the side effects are of the vaccine. Many patients with ovarian cancer have an altered (mutated) gene called p53 that causes the production of abnormal proteins found in their tumor cells. The body's immune system may try, unsuccessfully, to fight these abnormal proteins. In this study, ovarian cancer patients with a p53 abnormality will be vaccinated with a p53 peptide-a part of the same abnormal protein found in their tumor-to try to boost their body's immune response to the cancer. Patients will be divided into two groups. Group A will have four p53 peptide vaccinations three weeks apart, injected under the skin. The injection will include a drug called ISA-51, which increases the effect of the vaccine. This group will also receive two other drugs that boost the immune system, IL-2 and GM-CSF. Group B will have four p53 peptide vaccinations three weeks apart. The peptide will be mixed with the patient's own blood cells and infused into a vein. This group will also receive IL-2, but not GM-CSF. All study candidates will be tested to see if their cancer has a p53 abnormality and if their immune system mounted a defense against it. These tests may include a tumor biopsy (removal of a small part of the tumor for microscopic examination); lymphapheresis (a procedure to take blood, remove white blood cells called lymphocytes, and return the red cells); and an immune response test similar to a skin test for tuberculosis. During the study, patients will have additional skin tests	
Suspended	Trial of Two Versus Three Doses of Human Papillomavirus (HPV) Vaccine in India	Prophylactic quadrivalent HPV vaccine Merck. Serum neutralizing antibodies to HPV types (16/18/6/11) at 7, 12, 24, 36, 48 months. [5 years
	Conditions: Cervical Cancer; Cervical Precancerous Lesions	
	Intervention: Biological: Prophylactic quadrivalent HPV vaccine Merck (Gardasil®) 2009	
Completed	Safety and Effectiveness of a Vaccine for Prostate Cancer That Uses Each Patients' Own Immune Cells.	Polyvalent Vaccine-KLH Conjugate (NSC 748933) + OPT-821 Versus OPT-821(immunological adjuvant).
	Condition: Prostate Cancer	
	Intervention: Biological: autologous dendritic cell vaccine (DC/LNCaP) 2009	
	PFS + OS every 3 months for 2 years, every 6 months for 3 years by disease by CT scan of the abdomen and pelvis (lymph nodes). Outcome with antigen-specific immune titers: analyzed for IgM and IgG titers and antibody expression to antigens (e.g., Tn-MUC1-32mer, GM2, Globo-H, TF, sTn, and Tn) by ELISA. **Purpose** The purpose of this study is to assess the safety and activity of a type of vaccine as immune therapy for prostate cancer. This vaccine will be made for each participant's own immune cells (called dendritic cells) obtained by blood donation. Dendritic cells are immune cells, whose role is to identify foreign antigens (bacteria, viruses, or tumor cells, for example) in the body and to activate other cells of the immune system to mount an attack on that foreign antigen. Each participant will be randomized into either Arm 1 (experimental treatment only) or Arm 2 (placebo first, then the experimental treatment). Participants will be given the vaccine and three boosters as an injection. After the placebo phase, each participant in Arm 2 will crossover to the treatment phase so that all participants will eventually receive the experimental treatment.	
Completed	Vaccine Therapy in Treating Patients With Metastatic Solid Tumors	rec. fowlpox-B7.1 vaccine/ Rec. fowlpox-TRICOM vaccine
	Condition: Unspecified Adult Solid Tumor, Protocol Specific	

	Interventions:	Biological: recombinant fowlpox-B7.1 vaccine; Biological: recombinant fowlpox-TRICOM vaccine 2002	
	ELISPOT assay at 2 weeks following course 3 and at 3 months, Objective response rate by RECIST **OBJECTIVES:** Compare the feasibility of intratumoral administration of rF-B7.1 vaccine vs recombinant fowlpox-TRICOM vaccine in patients with cutaneous, subcutaneous, or lymph node metastatic solid tumors. Compare the feasibility of intratumoral administration of these vaccines in patients with visceral metastatic solid tumors. Compare the clinical toxicity of these vaccines in these patients. Determine the optimal dose of these vaccines in these patients. Compare the clinical response of patients treated with these vaccines. Compare the safety profiles of these vaccines in these patients. Determine the quality of life of patients treated with these vaccines. Determine the anti-tumor immune reactivity in patients treated with these vaccines. OUTLINE: This is a randomized study with dose-escalation component. Patients are stratified according to tumor location (cutaneous, subcutaneous, or lymph node metastases vs visceral metastases). Patients are randomized to 1 of 2 treatment arms. Arm I: Patients receive rF-B7.1 vaccine intratumorally on day 1. Arm II: Patients receive fowlpox-TRICOM vaccine intratumorally on day 1. Treatment in both arms repeats every 4 weeks for 3 courses in the absence of disease progression or unacceptable toxicity. Patients with stable or responding disease may receive additional courses. Three patients from the cutaneous disease (CD) stratum are treated at low-dose in each treatment arm. If no more than 1 of 6 patients experience dose-limiting toxicity (DLT), then 6 additional CD patients are randomized to high-dose treatment. If no more than 1 of these 6 patients experience DLT, then 12 patients from the visceral disease (VD) stratum are randomized to low-dose treatment. If no more than 2 of 12 VD patients experience DLT, then the next cohort of 12 VD patients is randomized to high-dose treatment. If 3 of the original 12 VD patients experience DLT, then 6 additional VD patients receive low-dose treatment. If no more than 3 of 18 patients experience DLT, then 12 VD patients receive high-dose treatment. Quality of life is assessed at baseline, monthly during therapy, and then at the end o	
Recruiting	OPT-821 With or Without Vaccine Therapy in Treating Patients With Ovarian Epithelial Cancer, Fallopian Tube Cancer, or Peritoneal Cancer in Second or Third Complete Remission		Polyvalent Vaccine-KLH Conjugate (NSC 748933) + OPT-821 Versus OPT-821(Adjuvant).
	Conditions:	Fallopian Tube Cancer; Ovarian Cancer; Peritoneal Cavity Cancer	
	Interventions:	Biological: immunological adjuvant OPT-821; Biological: polyvalent antigen-KLH conjugate vaccine 2009	
	OS + antigen-specific immune titers IgM and IgG titers and antibody expression to antigens (e.g., Tn-MUC1-32mer, GM2, Globo-H, TF, sTn, and Tn) by ELISA..progression or death compared to immunological adjuvant OPT-821 alone every 3 months for 2 years, every 6 months for 3 years. **OUTLINE:** This is a multicenter study. Patients are randomized to 1 of 2 treatment arms. Arm I: Patients receive polyvalent antigen-KLH conjugate vaccine and immunological adjuvant OPT-821 subcutaneously (SC) once in weeks 1, 2, 3, 7, 11, 23, 35, 47, 59, 71, and 83 in the absence of disease progression or unacceptable toxicity. Arm II: Patients receive immunological adjuvant OPT-821 SC as in arm I. Blood samples are collected at baseline and periodically during study for immunological laboratory studies. Samples are analyzed for IgM and IgG titers and antibody expression to antigens (e.g., Tn-MUC1-32mer, GM2, Globo-H, TF, sTn, and Tn) by ELISA.		
Completed	PSA Vaccine Therapy in Treating Patients With Advanced Prostate Cancer		fowlpox virus vaccine vector recombinant vaccinia prostate-specific antigen:
	Condition:	Prostate Cancer	
	Interventions:	Biological: fowlpox virus vaccine vector; Biological: recombinant vaccinia prostate-specific antigen vaccine 1999	

	Biochemical PSA progression. Evaluate the effects of these prime and boost treatment regimens on cellular immunity . RATIONALE: Vaccines may make the body build an immune response to kill tumor cells. PURPOSE: Randomized phase II trial to study the effectiveness of different regimens of PSA vaccines in treating patients who have advanced prostate cancer.		
Active, not recruiting	Combination Chemotherapy, Radiation Therapy, and Vaccine Therapy in Treating Patients With Limited-Stage Small Cell Lung Cancer		MoAb 11D10 anti-idiotype and MoAb GD2 anti-idiotype vaccine/cisplatin + etoposide/ radiation therapy
	Condition:	Lung Cancer	
	Interventions:	Biological: monoclonal antibody 11D10 anti-idiotype vaccine; Biological: monoclonal antibody GD2 anti-idiotype vaccine; Drug: cisplatin; Drug: etoposide; Radiation: radiation therapy 2002	
	Overall and progression-free survival. immune response to each of the 2 anti-idiotype. 3 months for 2 years and then every 6 months for 3 years. RATIONALE: Drugs used in chemotherapy use different ways to stop tumor cells from dividing so they stop growing or die. Radiation therapy uses high energy x-rays to damage tumor cells. Vaccines may make the body build an immune response to kill tumor cells. Combining chemotherapy and radiation therapy with vaccine therapy may kill more tumor cells. PURPOSE: Phase II trial to study the effectiveness of combining chemotherapy and radiation therapy with vaccine therapy in treating patients who have limited-stage small cell lung cancer		
Recruiting	Transfected Dendritic Cell Based Therapy for Patients With Breast Cancer or Malignant Melanoma		Dendritic Cells Transfected With Survivin, hTERT and p53 mRNA:
	Conditions:	Breast Cancer; Malignant Melanoma	
	Intervention:	Biological: DC vaccine 2009	
	Immune response [after 8 and 12 week]. clinical tumor response and the duration [after 12 weeks]. Phase I trial. Single center study; patients will be referred to the study center from other institutions in Denmark. 14 patients will be included in this phase I trial DC vaccination regime consists of primary 6 biweekly intradermal injections with transfected dendritic cells, followed by monthly injections until progression; **Cyclophosphamide** is used as vaccine adjuvant. Defined procedures are employed for generation of autologous dendritic cells for clinical application in a classified laboratory. Unmobilized leukapheresis will be used for isolation of large-scale mononuclear cells, and dendritic cells will be generated from monocytes by cytokine stimulation and transfected with mRNA encoding for hTERT, survivin and p53 if the tumour express p53. Frozen preparations of dendritic cells will be prepared using automated cryopreservation. Each patient will receive a minimum of 1x106 dendritic cells per treatment supplemented with Cyclophosphamide 50 mg twice a day every second week. Toxicity including autoimmunity will be evaluated using the Common Toxicity Criteria (CTC).		
Active, not recruiting	Vaccine Therapy in Treating Patients With Previously Treated Stage II or Stage III Breast Cancer		MUC1/HER-2/Neu Peptide Based Immunotherapeutic Vaccines (CpG oligodeoxynucleotide/HER-2/ neu peptide vaccine/ MUC-1 peptid) with incomplete Freund's adjuvant +GM-CSF:
	Condition:	Breast Cancer	
	Interventions:	Biological: CpG oligodeoxynucleotide; Biological: HER-2/neu peptide vaccine; Biological: MUC-1 peptide vaccine; Biological: incomplete Freund's adjuvant; Biological: sargramostim; Other: immunoenzyme technique; Other: immunologic technique 2008	

	Percentage of CD4+ T cells, CD8+ T cells, B cells, monocytes, and dendritic cells. peptide-specific IFN-gamma producing T cells and peptide-specific IL-5 producing T cells estimated by ELISPOT. Disease-free survival and OS. up to 2 years. In all arms, treatment repeats every 4 weeks for 6 courses in the absence of disease progression or unacceptable toxicity. Patients who complete 6 courses of treatment without disease recurrence or a second primary or intolerable toxicity will go to the observation phase of the study for up to 2 years. Patients who develop recurrent disease during the observational phase will go to the event monitoring phase for up to 2 years. Blood samples are collected periodically. Blood samples and tissue samples from the patient's most recent surgery are used for correlative studies including immune responses to T helper and CTL epitopes by Elispot and tetramer analysis; and antigenic profiling by expression analysis of class I HLA antigens, MUC1, and HER-2 in tumor tissue. After completion of study treatment, patients are followed periodically until disease recurrence or for up to 2 years	
Active, not recruiting	Vaccine Therapy of Prostate Cancer Patients With Recombinant Soluble Prostate-Specific Membrane Antigen (Rs-PSMA) Plus the Immunological Adjuvant Alhydrogel Condition: Prostate Cancer Intervention: Biological: rsPSMA protein plus Alhydrogel® vaccine 2008	Recombinant Soluble Prostate-Specific Membrane Antigen (Rs-PSMA) Plus the Immunological Adjuvant Alhydrogel:
	The immune response to increasing dose levels of rsPSMA protein. [Time: conclusion of study]. The pattern of change in PSA T. **Purpose** The purpose of this research is to help us study a vaccine treatment for patients with prostate cancer. A vaccine is a medicine that teaches the body to destroy harmful infections and other diseases, such as cancer. Your immune system is made up of many different types of cells which fight infection and disease in your body. A vaccine may stimulate the immune system to destroy the cancer cells. It may also help to slow the growth of the cancer. The vaccine is a solution given as an injection into or under the skin. It is made up of several parts. The first part is PSMA, a protein present in many cancers, especially prostate cancer. It is referred to as rsPSMA when made in a laboratory for this study and is mixed with a material called Alhydrogel® (aluminum hydroxide suspension) which helps the immune system to make more cancer fighting cells	
Recruiting	Phase I Trial of TGFB2-Antisense-GMCSF Gene Modified Autologous Tumor Cell (TAG) Vaccine for Advanced Cancer Condition: Advanced Metastatic Carcinoma Intervention:	TGFB2-Antisense-GMCSF Gene Modified Autologous Tumor Cell (TAG) Vaccine:
	Progression following the administration of TAG vaccine. [Time: survival] effect on immune stimulation. [baseline, Month 3, and Month 6]. Preliminary studies with a variety of vaccines suggest target accessibility (potential immunogenicity) in a variety of solid tumors to immune directed approaches. However, four primary factors limit the generation of effective immune mediated anticancer activity in therapeutic application: identifying and/or targeting cancer associated immunogen(s) in an individual patient insufficient or inhibited level of antigen presenting cell priming and/or presentation suboptimal T cell activation and proliferation cancer-induced inhibition of the anticancer immune response in both afferent and efferent limbs.	
Recruiting	Vaccine Therapy and Chemotherapy With or Without Tretinoin in Treating Patients With Extensive-Stage Small Cell Lung Cancer Condition: Lung Cancer Interventions: Biological: autologous dendritic cell-adenovirus p53 vaccine; Drug: tretinoin; Procedure: standard follow-up care 2008	Dendritic Cells Transduced With an Adenoviral Vector Containing the p53 Gene:

	Survival rate between all arms Tumor response rate/ survival of all patients. antigen-specific T-cell responses and reducing the number of immature myeloid cells in patients at least 30 days. **OUTLINE:** Standard first-line chemotherapy: Patients receive standard first-line chemotherapy comprising carboplatin IV over 1 hour on day 1 and etoposide IV over 1 hour on days 1-3. Treatment repeats every 21 days for up to 4 courses. Patients undergo restaging after completion of first-line chemotherapy. Patients with progressive disease do not receive any protocol treatment and are changed to second-line therapy. Adjuvant therapy: Patients with stable disease or better are then randomized to 1 of 3 arms of adjuvant therapy approximately 3 weeks after completion of first-line chemotherapy. Arm I (Observation only [standard care]): Patients undergo observation with serial CT scans. Arm II (Vaccine): Patients receive autologous dendritic cell-adenovirus p53 vaccine intradermally every 2 weeks for 3 doses. Patients with no sign of disease progression will undergo another leukapheresis and receive autologous dendritic cell-adenovirus p53 vaccine intradermally every 4 weeks for 3 doses. Arm III (Vaccine and tretinoin): Patients receive autologous dendritic cell-adenovirus p53 vaccine for up to 6 doses as in arm II. They also receive oral tretinoin for 3 days before receiving each dose of the vaccine. Patients who develops evidence of disease progression at any point proceed to second-line chemotherapy with paclitaxel once every 21 days in the absence of	
Active, not recruiting	HLA-A*0201 Restricted Peptide Vaccine Therapy With Gemcitabine With Gemcitabine in Patient Pancreatic Cancer (Phase1) Condition: Pancreatic Cancer Interventions: Biological: VEGFR1, VEGFR2; Drug: Gemcitabine 2010		HLA-A*0201 Restricted Antiangiogenic Peptide Vaccine Therapy Using Epitope Peptide Derived From VEGFR1 and VEGFR2 With Gemcitabine.
	Peptide specific CTL response/ CD8 population / level of regulatory T cells [3 months]. Response rate and OS [1 year] **Detailed Description:** The prognosis of pancreatic cancer is extremely poor even with extensive surgery, chemotherapy or radiation. It has been required development of new treatment modalities. Immunotherapy is one of the encouraging modalities for cancer patients. The investigators have to assess its toxicities and immune responsiveness		
Completed	Multivalent Conjugate Vaccine Trial for Patients With Biochem. Relapsed Prostate Cancer Conditions: Prostate; Cancer Intervention: Biological: QS21 2007		Multivalent Conjugate Vaccine (QS21):

	Overall antitumor assessment performed during weeks 19 and 3. monitored every 3 months with history, physical, performance status and bloodwork. Imaging studies every 6 mo. multivalent vaccine will consist of the lowest dose of synthetic glycoprotein and carbohydrate antigens shown to elicit high titer IgM and IgG antibodies. **Detailed Description:** This is a pilot trial designed to assess safety and immunogenicity of a multivalent conjugate vaccine for use in patients with biochemically relapsed prostate cancer. This trial is based on the results of eight dose-seeking phase I monovalent glycoprotein and carbohydrate conjugate vaccine trials in a patient population with minimal tumor burden despite a rising biomarker, PSA, who have failed primary therapy such as surgery or radiation. We know that a rising PSA is indicative of micrometastatic disease - a state to which the immune system may maximally respond. Based on these trials, we have identified three glycolipid antigens, Globo H, Lewisy and GM2 and three mucin antigens, glycosylated MUC-1, Tn(c), and TF(c) for inclusion into a multivalent trial. As a result of these vaccinations, most patients generated specific high titer IgM and IgG antibodies against the respective antigen-KLH conjugates. Our previous work has shown the monovalent vaccines to be safe with local erythema and edema but minimal systemic toxicities. Our data from approximately 160 men who participated in our earlier monovalent vaccine trials against the aforementioned antigens have shown that a treatment effect in the form of a decline in PSA log slopes compared with pretreatment values could be seen in patients with minimal tumor burden. The multivalent vaccine will consist of the lowest dose of synthetic glycoprotein and carbohydrate antigens shown to elicit high titer IgM and IgG antibodies in patients with biochemically relapsed prostate cancer. A phase III double blind randomized trial with two hundred forty patients is planned based on the safety and immunogenicity data accrued from this pilot trial. The primary endpoints of this study will be the safety of the vaccine and the humoral response to each of the antigens. The secondary endpoint will be to evaluate post-therapy changes in PSA.		
Recruiting	Mammaglobin-A DNA Vaccine for Metastatic Breast Cancer Condition: Metastatic Breast Cancer Intervention: Biological: Mammaglobin-A DNA vaccine 2008		Safety and Immunogenicity of a Mammaglobin-A DNA Vaccine:
	Immunogenicity of the mammaglobin-A DNA vaccine by ELISPOT analysis, a surrogate for CD8 T cell function. [52 weeks] , a naked plasmid DNA vaccine (WUSM-MGBA-01). **Detailed Description:** This is a phase I open-label study to evaluate the safety and immunogenicity of a plasmid mammaglobin-A DNA vaccine. The plasmid mammaglobin-A DNA vaccine will be formulated as a naked plasmid DNA vaccine (WUSM-MGBA-01). The hypothesis of this study is that the mammaglobin-A DNA vaccine will be safe for human administration and capable of generating measurable CD8 T cell responses to mammaglobin-A. The primary objective of this study is to demonstrate the safety of the mammaglobin-A DNA vaccine. The secondary objective is to evaluate the immunogenicity of the mammaglobin-A DNA vaccine as measured by ELISPOT analysis, a surrogate for CD8 T cell function.		
Recruiting	Phase II Study of Adenovirus/PSA Vaccine in Men With Hormone - Refractory Prostate Cancer Condition: Hormone Refractory Prostate Cancer Intervention: Biological: ADENOVIRUS/PSA VACCINE 2010		Adenovirus/PSA Vaccine: PSA doubling-time response [18 months]. · Serum PSA levels and Immune response

	Detailed Description: Subjects in this trial will be eligible if they have recent evidence of hormone refractory disease (D3) and either (a) have a positive bone scan or a positive CT scan (with obvious soft tissue metastasis or lymph nodes >1 cm), with a PSA doubling time of >/= 12 months, a total PSA of < 5 mg/ml, and are asymptomatic; or (b) have a negative bone scan with any PSA doubling time, are asymptomatic, and are not a candidate for chemotherapy. This is a virus vaccine in which the gene for prostate specific antigen (PSA) has been placed into a common cold virus termed adenovirus (Ad) to produce this Ad/PSA product. The purpose of this study is to determine whether vaccination with the Ad/PSA vaccine will induce an anti-PSA immunity that will result in the destruction of the remaining prostate cancer cells. Subjects will be vaccinated three times, each injection administered at 30-day intervals. Based upon our earlier clinical trial, the vaccine is considered safe and should not induce any major side effects. The investigators hope that vaccination with this PSA virus will cause the body to produce immunity to the PSA and that immunity will destroy any cell that produces PSA. Since the only cells left in the body that produce PSA will be the cancer cells, the investigators propose that the vaccination and ensuing anti-PSA immunity will kill the prostate cancer cells. Importantly, this treatment should not cause any major side effects as would treatment with anti-cancer drugs.		
Withdrawn	A Novel Vaccine for the Treatment of MUC1-expressing Tumor Malignancies		Peptide Vaccine (MUC-1) for MUC1-expressing Tumor Malignancies: anti-tumor response and immune response
	Conditions:	Multiple Myeloma; Tumors	
Completed	Safety & Activity of P501-AS15 Vaccine as a First-Line Treatment for Patients With Hormone-Sensitive Prostate Cancer Who Show Rising PSA		P501-AS15 vaccine CPC-P501 Protein Formulated With the Adjuvant AS15:
	Condition:	Prostate Cancer	
	Intervention:	Biological: P501-AS15 vaccine 2008	
	PSA response. Humoral immune response induced by P501-AS15 vaccine: Anti-CPC seropositivity. Anti-P501 seropositivity. Cellular immune response induced by P501-AS15 vaccine. Frequency of in vitro cellular immune response to CPC P501. This Phase I/II study will be conducted according to a multicenter, open-label, single-group design at approximately ten centers in Europe. At least 21 HSPC patients with rising PSA after primary tumor treatment will be enrolled in this study. All patients will be treated as out-patients and will receive the same treatment. The maximum dose will be 16 vaccinations. Follow-up: The patients' long-term safety and PSA status will be followed over a period of 48 weeks. The Protocol Posting has been updated in order to comply with the FDA Amendment Act. Sep 2007		
Recruiting	Phase II Study of Adenovirus/PSA Vaccine in Men With Recurrent Prostate Cancer After Local Therapy APP21		Adenovirus/PSA Vaccine: PSA doubling-time + ·Serum PSA levels and immune response [18 months].
	Condition:	Recurrent Prostate Cancer	
	Intervention:	Biological: Adenovirus/PSA Vaccine 2007	
Completed	Vaccine Therapy Plus Interleukin-2 in Treating Women With Stage IV, Recurrent, or Progressive Breast or Ovarian Cancer		aldesleukin/p53 peptide vaccine/in vitro-treated peripheral blood stem cell transplantation
	Conditions:	Breast Cancer; Ovarian Cancer	
	Interventions:	Biological: aldesleukin; Biological: p53 peptide vaccine; Procedure: in vitro-treated peripheral blood stem cell transplantation 2001-2009	

	•Cellular immunity as measured by Elipsot assay and 51 Cr-release assay every 3 weeks. Tumor response by CT scan every 3 months. **OBJECTIVES:** Determine whether endogenous cellular immunity to the p53 peptide vaccine is present in patients with stage IV, recurrent, or progressive breast or ovarian cancer and whether vaccination with these peptides and low-dose interleukin-2 can induce or boost the cellular immunity in these patients. Determine the type and characteristics of cellular immunity generated by this regimen in these patients. Determine the toxicity of this regimen in these patients. Correlate any immunologic response with any objective tumor response to this regimen in these patients. **OUTLINE:** This is a randomized, pilot study. Patients are randomized to 1 of 2 treatment arms. All patients undergo apheresis of autologous peripheral blood mononuclear cells, which are harvested and selected for monocytes on day -6. The monocyte fraction is cultured with sargramostim (GM-CSF) and interleukin-4 for 7 days and then pulsed with p53 peptide vaccine. Arm I: Patients receive p53 peptide vaccine subcutaneously (SC) on day 1. Arm II: Patients receive p53 peptide vaccine IV over 5 minutes on day 1. Treatment in both arms repeats every 3 weeks for a total of 4 vaccinations (4 courses). During courses 3 and 4, patients also receive low-dose interleukin-2 (IL-2) SC daily on days 3-7 and days 10-14. Patients with stable or responding disease may continue to receive vaccine and IL-2 treatment for up to 2 years. /Patients are followed at 1 month and then every 2-4 months for 2 years.	
Active, not recruiting	Vaccine Therapy and Interleukin-2 in Treating Patients With Stage IV Kidney Cancer Condition: Kidney Cancer Interventions: Biological: adenovirus B7-1; Biological: aldesleukin; Biological: autologous tumor cell vaccine; Procedure: conventional surgery 2002-2009	B7-1 Gene-Modified Autologous Tumor Cell Vaccine and Systemic IL-2: Reduction in tumor size. Immunogenicity, OS.
Completed	Vaccine Therapy Plus QS21 in Treating Patients With Prostate Cancer Condition: Prostate Cancer Interventions: Biological: MUC-2-Globo H-KLH conjugate vaccine; Biological: QS21 2002-2009	Bivalent MUC-2-Globo H-KLH conjugate vaccine/ QS21(Adjuvant):
	Antibody response. •Assess post-immunization changes in PSA levels and other objective parameters of disease (radionuclide bone scan) followed every 3 months for 1 year or until biochemical relapse. **OBJECTIVES:** Determine the safety of glycosylated MUC-2-Globo H-KLH conjugate vaccine with adjuvant QS21 in patients with prostate cancer. Determine the antibody response in patients treated with this vaccination therapy. Assess post-immunization changes in PSA levels and other objective parameters of disease (radionuclide bone scan) in patients treated with this vaccination therapy. OUTLINE: Patients receive glycosylated MUC-2-Globo H-KLH conjugate vaccine with adjuvant QS21 subcutaneously once weekly on weeks 0-2, 6, 14, and 26 in the absence of unacceptable toxicity. Patients whose antibody titers against Globo-H or MUC-2 antigens fall below 1/40 and who have no disease progression may receive a seventh vaccination after week 50. Patients are followed every 3 months for 1 year or until biochemical relapse or radiographic disease progression.	
Completed	Vaccine Therapy and GM-CSF in Treating Patients With Acute Myeloid Leukemia, Myelodysplastic Syndromes, Non-Small Cell Lung Cancer, or Mesothelioma Conditions: Leukemia; Lung Cancer; Malignant Mesothelioma; Myelodysplastic Syndromes; Peritoneal Cavity Cancer	WT-1 analog peptide vaccine/ incomplete Freund's adjuvant/GM-CSF PCR/flow cytometry/ immunoenzyme technique

	Interventions:	Biological: WT-1 analog peptide vaccine; Biological: incomplete Freund's adjuvant; Biological: sargramostim; Genetic: polymerase chain reaction; Other: flow cytometry; Other: immunoenzyme technique 2006	
	Immune response by T-cell proliferative response, DTH against WT-1 peptides, or ELISPOT. •Antileukemic effects. •Antitumor response as measured by CT scan based on RECIST criteria. Blood samples are collected at baseline, week 8, and week 14. Samples are examined by polymerase chain reaction (PCR) to measure levels of WT-1 and by T-cell proliferative response, delayed-type hypersensitivity against WT-1 peptides, or ELISPOT to measure immune response. **Primary** Determine the safety and immunogenicity of the Wilms tumor-1 analog peptide vaccine in patients with acute myeloid leukemia, myelodysplastic syndromes, non-small cell lung cancer, or mesothelioma. **Secondary:** Determine the antitumor effects of this vaccine in these patients. **OUTLINE:** This is a pilot study. Patients are stratified according to disease type (acute myeloid leukemia [AML] or myelodysplastic syndromes [MDS] vs non-small cell lung cancer or mesothelioma). **Patients** receive vaccine comprising Wilms-tumor 1 (WT-1) analog peptide emulsified in Montanide ISA-51 subcutaneously (SC) once in weeks 0, 4, 6, 8, 10, and 12 and sargramostim (GM-CSF) SC twice in weeks 0, 4, 6, 8, 10, and 12 (on the day of and 2 days prior to each vaccination). Patients who have an immunologic response and have no disease progression may receive up to 6 more vaccinations approximately 1 month apart. Blood samples are collected at baseline, week 8, and week 14. Samples are examined by polymerase chain reaction (PCR) to measure levels of WT-1 and by T-cell proliferative response, delayed-type hypersensitivity against WT-1 peptides, or ELISPOT to measure immune response. Bone marrow samples are collected from patients with AML or MDS at baseline and week 14. Samples are examined by PCR to measure levels of WT-1 and by multiparameter flow cytometry to measure residual disease. PROJECTED ACCRUAL: A total of 20 patients will be accrued for this study.	
Active, not recruiting	Vaccine To Prevent Cervical Intraepithelial Neoplasia or Cervical Cancer in Younger Healthy Participants		human papillomavirus 16/18 L1 virus-like particle/AS04 vaccine: HPV16/18 VLP Vaccine in the Prevention of Advanced Cervical Intraepithelial Neoplasia (CIN2, CIN3, Adenocarcinoma
	Conditions:	Cervical Cancer; Precancerous Condition	
	Intervention:	Biological: human papillomavirus 16/18 L1 virus-like particle/AS04 vaccine 2005	
Completed	Vaccine Therapy in Treating Women With Metastatic Breast Cancer		Detox-B adjuvant/ THERATOPE STn-KLH vaccine/KLH Measure the anti-STn, anti-OSM, and anti-KLH antibody titers
	Condition:	Breast Cancer	
	Interventions:	Biological: Detox-B adjuvant; Biological: THERATOPE STn-KLH vaccine; Biological: keyhole limpet hemocyanin; Drug: cyclophosphamide 1999	
Active, not recruiting	Vaccine Therapy and Interleukin-2 After Combination Chemotherapy in Treating Patients With Relapsed or De Novo Stage II, Stage III, or Stage IV Mantle Cell Lymphoma		Universal GM-CSF-Producing and CD40L-Expressing Bystander Cell Line (GM.CD40L) in the Formulation of Autologous Tumor Cell-Based Vaccines:
	Condition:	Lymphoma	
	Interventions:	Biological: GM.CD40L cell vaccine; Biological: aldesleukin; Biological: autologous tumor cell vaccine; Drug: CHOP regimen; Drug: cyclophosphamide; Drug: cytarabine; Drug: dexamethasone; Drug: doxorubicin hydrochloride; Drug: methotrexate; Drug: prednisone; Drug: vincristine sulfate 2005	

	Anti-tumor immune response by ELISPOT and DTH at 6 months. Tumor response rate and time to tumor progression by RECIST criteria at 6 months. • Disease-free and overall survival at 6, 9, and 12 months. DNA micro array analysis. **OUTLINE:** Patients undergo surgical resection of a malignant lymph node to collect autologous tumor cells for vaccine production. Vaccine is formulated by combining equal volumes of irradiated autologous tumor cells and irradiated cells from a cell line that produces sargramostim (GM-CSF) and expresses CD40L (GM.CD40L). Conventional chemotherapy: Patients receive conventional chemotherapy comprising 6 courses of cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) OR 3 courses of hyperfractionated cyclophosphamide, vincristine, doxorubicin, and dexamethasone alternating with high-dose methotrexate and cytarabine (hyper-CVAD) for patients who have relapsed after CHOP. Patients who achieve a partial or complete response after completion of chemotherapy proceed to vaccine therapy. Vaccine therapy: Patients receive vaccine comprising autologous tumor cells and GM.CD40L intradermally on day 1 and low-dose interleukin-2 (IL-2) subcutaneously twice daily on days 1-14. Treatment repeats every 28 days for 4 courses. Patients who have stable or responding disease at 12 months receive 4 additional courses of booster vaccine and low-dose IL-2 as above. Treatment continues in the absence of disease progression or unacceptable toxicity. Patients are followed every 3 months until disease progression and then annually thereafter.	
Recruiting	Multipeptide Vaccine for Advanced Breast Cancer Conditions: Breast Neoplasm; Breast Cancer; Cancer of the Breast; Carcinoma, Ductal Intervention: Biological: hTERT/Survivin Multi-Peptide Vaccine 2007	hTERT/Survivin Multi-Peptide Vaccine With Daclizumab (a-CD25) and Prevnar(augment T-helper cell immunity):
	•Immunologic response [After 4th vaccination, then after every 3-4 vaccinations, and then every 6 months]. **Target of daclizumab (a-CD25) including Treg cells, and inhibits its proliferation.** **[Detailed Description]:** Patients with advanced breast cancer may often fail standard of care treatments for metastatic disease. This research is studying a combinations of agents that impact the immune system. About >85% of all human cancers, including breast cancer, express telomerase (hTERT) activity. Targeting hTERT immunologically may also minimize immune escape due to antigen loss because mutation or deletion of hTERT may be incompatible with sustained tumor growth. hTERT Multi-Peptide Vaccine is made up of 1540 hTERT peptide and cryptic peptides selected for "low-affinity" binding to HLA-A2 in order to increase the likelihood that the host immune system would ignore them, and then they have been modified by changing the first amino acid of the peptides to tyrosine in order to increase HLA - A2 affinity. The two "heteroclitic" peptides are R572Y (YLFFYRKSV) and D988Y (YLQVNSLQTV), which bind HLA-A2 with high avidity and elicit specific CTL (cytotoxic T lymphocyte) responses using healthy donor mononuclear cells in vitro. In addition, in mouse models, these peptide vaccines elicit lytic CTL responses which are protective against tumor challenges using a TERT-expressing murine tumor. Subjects will also be immunized with a peptide vaccine derived from survivin, an important anti-apoptotic protein which is overexpressed in a broad range of malignancies including breast cancer. Survivin may be an ideal and "universal" tumor antigen since it is overexpressed in a wide variety of cancers yet terminally differentiated adult cells do not express the protein. CMV derived CTL epitopes will be used as positive control peptides. Daclizumab is a humanized anti-human CD25 monoclonal antibody that binds specifically to CD25 expressing cells, including Treg cells, and inhibits its proliferation. Prevnar is designed to augment T-helper cell immunity.	
Completed	Vaccine Therapy Plus Biological Therapy in Treating Patients With Relapsed Prostate Cancer Condition: Prostate Cancer	Multivalent Conjugate Vaccine (Globo H-GM2-Lewis-y-MUC1-32-mer-TF(c)-Tn(c)-