	Immunity results from either single injections or semi-continuous infusion [4-14 w], Detailed Description: Dendritic cell (DC)-based vaccination, usually administered by a traditional intradermal route, is a new treatment option for cancer patients. While the previous DC-based vaccination trials have shown the safety of this approach and its ability to induce objective clinical responses, the overall efficacy of DC-based vaccines is still disappointing (Rosenberg et al., 2004). We hypothesize that the two likely causes of such limited clinical activity are: A) suboptimal type of DCs used as a vaccine and B) suboptimal modes of use of such vaccines that do not allow the vaccinated patients to fully benefit from DC biology. We will conduct a pilot evaluation of the therapeutic vaccination with DC1s loaded with autologous tumor material, in patients with metastatic colorectal cancer that have been resected to no or minimal evidence of disease.The proposed evaluation of the novel intralymphatic route of DC-based vaccination will allow us to administer the vaccine in a way that is more physiologic with respect to the kinetics of antigen appearance to the lymph nodes and is feasible to be performed in repetitive fashion, without damaging local lymph nodes.	
Active, not recruiting	Vaccine Therapy in Treating Patients With Kidney Cancer		Autologous Tumor Cells And Dendritic Cells.
	Condition:	Kidney Cancer	
	Interventions:	Biological: autologous tumor cell vaccine; Biological: therapeutic autologous dendritic cells 2001	
	DTH, PR or CR as measured by RECIST at months 2 or 3 and 6. PFS as measured by RECIST at months 2 or 3 and 6. Event-free survival as measured by RECIST at months 2 or 3 and 6. OS. OUTLINE: Patients are stratified according to measurable disease at the time vaccine therapy is initiated (yes vs no). Patients undergo tumor cell harvest. Patients with multiple persistent sites of metastatic disease following harvest receive systemic therapy (biologic therapy and/or chemotherapy) during tumor cell line expansion. Over 2-4 months, the tumor cell line is expanded, treated with interferon gamma, and irradiated. Patients undergo leukapheresis to obtain peripheral blood mononuclear cells (PBMC). The PBMC are incubated over 7 days with sargramostim (GM-CSF) and interleukin-4 to produce dendritic cells (DC). The DC are incubated over 2-3 days with the irradiated tumor cells from the autologous tumor cell line for antigen loading of the DC. /Patients undergo delayed tumor hypersensitivity testing 1 week prior to vaccination and again at week 4. Patients receive vaccine therapy comprising autologous treated tumor cells and DC suspended in GM-CSF subcutaneously weekly for 3 weeks. Vaccine therapy continues monthly for 5 months in the absence of disease progression or unacceptable toxicity.		
Completed	Human Papilloma Virus (HPV) Vaccine Efficacy Trial Against Cervical Pre-cancer in Young Adults With GlaxoSmithKline (GSK) Biologicals HPV-16/18		GSK Bio HPV Vaccine (580299) vs Hepatitis A Vaccine as Control in Prevention of Persistent HPV-16/18 Cervical Infection & Cervical Neoplasia
Has Results	Conditions:	Human Papillomavirus (HPV) Infection; Papillomavirus Vaccines; Cervical Neoplasia	
	Interventions:	Biological: Cervarix™; Biological: Havrix™-based investigational formulation 2005	
	HPV DNA negative at Month 0 and Month 6 for the corresponding HPV-type and seronegative for HPV-16 and/or HPV-18 by ELISA		
Recruiting	153Sm-EDTMP With or Without a PSA/TRICOM Vaccine To Treat Men With Androgen-Insensitive Prostate Cancer		Recombinant vaccinia-TRICOM vaccine／Recombinant fowlpox-TRICOM vaccine contained genes for a protein(PSA) (PSA/TRICOM) :
	Condition:	Prostate Cancer	
	Interventions:	Radiation: Samarium Sm 153 lexidronam pentasodium; Biological: Sargramostim; Biological: Recombinant vaccinia-TRICOM vaccine; Biological: Recombinant fowlpox-TRICOM vaccine 2007	

	4-month PFS. PSA-specific antigen outcomes. Immunologic response. PFS + OS. **Background** No treatment is known to improve survival for prostate cancer patients who have not been helped by previous treatments with hormones and chemotherapy. An experimental vaccine called PSA/TRICOM contains genes for a protein produced by prostate cancer cells called prostate-specific antigen (PSA). The vaccine can trigger the immune system to make cells that may be able to recognize and attack the cancer cells that make PSA. GM-CSF is an approved drug that is usually given to increase a patient's white blood cell count or to stimulate the immune system. 153Sm-EDTMP is a radioactive drug that has been approved for many years to treat advanced prostate cancer. It is given through a vein and can be targeted directly to tumors in the bone where it can relieve pain caused by bone lesions. Radiation also increases the level of certain proteins inside the tumor, making it easier for the immune system to find and kill the tumor cells. When laboratory mice were given just vaccine, just radiation, or a combination of both, the combination was most effective in treating tumors. **Objectives:** -To determine if combined treatment with PSA/TRICOM vaccine and 153Sm-EDTMP radiation can delay progression of prostate cancer better than radiation alone. **Eligibility:** -Patients who have advanced prostate cancer that has worsened despite treatments with hormones, have two or more bone lesions related to their prostate cancer, and have had prior treatment with docetaxel chemotherapy. **Design:** Patients are randomly assigned to receive radiation alone (Arm A) or radiation with vaccine and sargramostim (Arm B). Arm A receives 153Sm-EDTMP radiation starting on study day 8 and repeated every 12 weeks. Arm B receives a priming vaccine on study day 1 and radiation on day 8. Radiation therapy is repeated every 12 weeks. Boosting vaccines are given on days 15 and 29 and then monthly. GM-CSF is given with each vaccination (on the day of the vaccination and for the next 3 days) to enhance the immune response. Vaccinations and GM-CSF are given as injections under the skin, usually in the thigh. Radiation therapy is given through a vein. Patients are monitored regularly with physical examinations, blood and urine tests, and scans to evaluate safety and treatment response. Patients who are HLA-A2 positive undergo apheresis, a procedure similar to donating blood, to obtain immune cells called lymphocytes to measure the immune	
Recruiting	p53 Synthetic Long Peptides Vaccine With Cyclophosphamide for Ovarian Cancer		p53 Synthetic Long Peptides Vaccine With Cyclophosphamide. Clinical Resp. by measurement of serum CA-125 levels and CT-scan[day 105 - 126]. p53-specific T cells by proliferation and IFN-γ ELISPOT {after fourth immunization}.
	Condition:	Ovarian Cancer	
	Interventions:	Drug: P53-SLP vaccine; Drug: Cyclophosphamide 2009	
Active, not recruiting	Vaccine Therapy in Treating Patients With Pancreatic Cancer That Has Been Removed by Surgery		Boosting With Lethally Irradiated Allogeneic Pancreatic Tumor Cells Transfected With the GM-CSF Gene:
	Conditions:	Anorexia; Fatigue; Pain; Pancreatic Cancer; Psychosocial Effects of Cancer and Its Treatment	
	Intervention:	Biological: sargramostim plasmid DNA pancreatic tumor cell vaccine 2006	

	PFS + OS. Immune response to prostate stem cell antigen, and mutated k-ras-specific T-cell responses, as measured by biopsy, histological analysis at 4 weeks post vaccination. GM-CSF serum level. 他多数 **Primary** Determine the safety of primary and boost vaccinations with lethally irradiated allogeneic pancreatic tumor cells transfected with sargramostim (GM-CSF) gene vaccine in patients with surgically resected adenocarcinoma of the head, neck, or uncinate of the pancreas. **Secondary** Correlate specific in vivo parameters of immune response (e.g., mesothelin, prostate stem cell antigen, and mutated k-ras-specific T-cell responses) with clinical response in patients treated with this regimen. Determine the efficacy, in terms of overall and recurrence-free survival, of this regimen in these patients. Correlate serum GM-CSF levels with longevity of an allogeneic vaccine after semi-annual boosting in these patients. Determine the psychosocial (e.g., demographics, quality of life, hope, trust, social support, decision control, and advanced directives) and symptom (e.g., pain, anorexia, fatigue, and mood state) profiles in these patients and explore changes over time. OUTLINE: This is a open-label study. Patients are stratified according to prior vaccination with allogeneic sargramostim (GM-CSF)-secreting pancreatic tumor cell vaccine (yes [stratum I] vs no [stratum II]). Stratum I: Patients receive booster vaccination comprising allogeneic GM-CSF plasmid DNA pancreatic tumor cell vaccine subcutaneously (SC). Treatment repeats every 6 months in the absence of disease progression or unacceptable toxicity. Stratum II: Patients receive priming vaccinations SC once a month for 3 months and then receive booster vaccinations as in stratum I. Patients complete self-reported psychosocial (including quality of life, hope, and trust) and symptom (including pain, fatigue, anorexia, and mood) questionnaires at day 0 and day 28. After completion of study treatment, patients are followed at day 28 and then annually for 15 years.	
Recruiting	MUC1 Vaccine for Triple-negative Breast Cancer Conditions: Breast Cancer; Inflammatory Breast Cancer; Stage I Breast Cancer; Stage II Breast Cancer; Stage IIIA Breast Cancer; Stage IIIB Breast Cancer; Stage IIIC Breast Cancer; Triple-negative Breast Cancer Interventions: Biological: MUC-1 peptide vaccine; Biological: poly ICLC; Biological: MUC1 peptide-poly-ICLC adjuvant vaccine; Other: laboratory biomarker analysis; Other: enzyme-linked immunosorbent assay; Other: flow	MUCI Peptide and Poly-ICLC Vaccine. Immunologic response [16 w following 4 injections] laboratory biomarker analysis by ELISA and flow-cytometry
	Primary: 1)Proportion of patients showing an immunologic response [Time Frame: At week 12 (2 weeks after the 3rd injection)]. 2) Defined as a >= 2-fold enhancement from baseline anti-MUC1 antibody immunity, or for subjects with no antibody to MUC1 at baseline, any detectable antibody immunity against MUC1. To test the hypothesis of a sufficient immunologic response, we will apply a Simon's optimum 2-stage design. The proportion of patients with an immunologic response will be calculated with a 95% confidence interval using method developed for multistage clinical trials. **Secondary**: •Safety and toxicity as assessed by NCI CTC [Time Frame: **Weeks 0, 2, 4, 10, 12, 52, and 54 and then for 30 days** after completion of study treatment] I. To evaluate the efficacy of MUC1 peptide-poly-ICLC adjuvant vaccine in boosting systemic immunity to MUC1 in women who have completed therapy for AJCC(American Joint Committee on Cancer) **stage I-III 'triple-negative' [i.e., ER(-) PR(-) HER2/neu(-)]** breast cancer. SECONDARY OBJECTIVES: I. To evaluate the safety and toxicity of the MUC1 peptide and poly-ICLC vaccine in this cohort of patients. **OUTLINE:** Patients receive **MUC-1 peptide vaccine subcutaneously (SC) and poly-ICLC vaccine SC** in **weeks 0, 2, and 10** in the absence of disease progression or unacceptable toxicity. **Some patients may receive a booster vaccine in week 52.** Patients will be followed for study-related Serious Adverse Events (SAEs) for a period of 30 days after their last vaccination. If a patient experiences a SAE while participating in this study, they will be followed until the resolution of the SAE. •AJCC stage I-III infiltrating adenocarcinoma of the breast who have completed standard adjuvant or neoadjuvant therapy (surgery, radiation, biologic therapy, chemotherapy) for TNBC (ER-, PR-, HER-2/neu-)	
Not yet	Measles Vaccine in Patients With Measles Virus-Positive, Advanced Non-Small Cell Lung Cancer	Measles Vaccine (attenuated measles) in

recruiting	Conditions:	Non-Small Cell Lung Cancer; Measles	Patients With Measles Virus-Positive, Stage 3B/4 Non-Small Cell Lung Cancer: (PFS) + (OS) [Time Frame: 2-years]
	Intervention:	Biological: attenuated measles vaccine 2009	
Recruiting	Vaccination of Patients With Ovarian Cancer With Dendritic Cell/Tumor Fusions With Granulocyte Macrophage Colony-stimulating Factor (GM-CSF) and Imiquimod		Dendritic Cell/Tumor Fusions With GM-CSF and Imiquimod (drug): Cellular immunity and clinical response [2 years]. Patient cellular immune function and phenotypic characteristics
	Conditions:	Ovarian Cancer; Primary Peritoneal Cancer; Fallopian Tube Cancer	
	Interventions:	Drug: GM-CSF; Biological: Dendritic Cell/Tumor Fusion Vaccine; Drug: imiquimod 2008	
Recruiting	Docetaxel and Prednisone With or Without Vaccine Therapy in Treating Patients With Metastatic Hormone-Resistant Prostate Cancer		PSA-TRICOM (fowlpox-PSA-TRICOM vaccine + vaccinia-PSA-TRICOM vaccine) Vaccine: Median overall survival. Radiographic progression. PSA response.Association between PSA-specific immune responses, time to progression, and overall survival. Evaluate the association of predicted survival (by Halabi nomogram)
	Condition:	Prostate Cancer	
	Interventions:	Biological: fowlpox-PSA-TRICOM vaccine; Biological: vaccinia-PSA-TRICOM vaccine; Drug: docetaxel; Drug: prednisone 2010	
Recruiting	Vaccination of Patients With Breast Cancer With Dendritic Cell/Tumor Fusions and IL-12		Dendritic Cell/Tumor Fusions and IL-12 To determine if cellular and humoral immunity and clinically measurable disease responses [3 years].
	Condition:	Breast Cancer	
	Interventions:	Biological: Dendritic Cell/Tumor Fusion Vaccine; Drug: Interleukin-12 2008	
Active, not recruiting	Vaccine Therapy and GM-CSF in Treating Patients With Prostate Cancer That Progressed After Surgery and/or Radiation Therapy		PROSTVAC-V (Vaccinia)/TRICOM and PROSTVAC-F (Fowlpox)/TRICOM With GM-CSF: Free of PSA progression before 6 months. Characterization of PSA velocity. PSA response on vaccine. T-cell immune response
	Condition:	Prostate Cancer	
	Interventions:	Biological: fowlpox-PSA-TRICOM vaccine; Biological: sargramostim; Biological: vaccinia-PSA-TRICOM vaccine; Drug: bicalutamide; Drug: goserelin 2005	
Recruiting	Tumor Cell Vaccines With ISCOMATRIX(Trademark) Adjuvant and Celecoxib in Patients Undergoing Resection of Lung and Esophageal Cancers and Malignant Pleural Mesotheliomas		Epigenetically-Modified Autologous Tumor Cell Vaccines With ISCOMATRIX(TM) Adjuvant and Oral Celecoxib: Immunologic response [3 years]
	Conditions:	Mesolthelioma; Esophageal Cancer; Lung Cancer	
	Interventions:	Drug: Celecoxib; Drug: ISCOMATRIX (TM) Adjuvant; Biological: Autologous Tumor Cell Vaccine 2010	
Not yet recruiting	Vaccine Therapy in Treating Patients With Colorectal, Stomach, or Pancreatic Cancer		
	Conditions:	Recurrent Colon Cancer; Recurrent Gastric Cancer; Recurrent Pancreatic Cancer; Recurrent Rectal Cancer; Stage III Colon Cancer; Stage III Gastric Cancer; Stage III Pancreatic Cancer; Stage III Rectal Cancer; Stage IV Colon Cancer; Stage IV Gastric Cancer; Stage IV Pancreatic Cancer; Stage IV Rectal	

	Interventions:	Other: laboratory biomarker analysis; Other: enzyme-linked immunosorbent assay; Other: flow cytometry; Other: immunoenzyme technique; Biological: modified vaccinia virus ankara vaccine expressing p53 2010	
	Modified vaccinia virus ankara vaccine expressing p53: Immunogenicity by using an ELISA assay for humoral response, lymphoproliferation for CD4+ T cell response and intracytoplasmic cytokine assays, and IFN-gamma and IL-4 by ELISPOT assays [1 years] PRIMARY OBJECTIVES:I. To establish whether 2 vaccine dose levels of MVAp53 vaccines are safe and well tolerated in patients with p53 over-expressing solid tumor malignancy.SECONDARY OBJECTIVES:I. To provide preliminary evidence of enhanced cellular and humoral immunity to p53.OUTLINE:This is a phase I, dose-escalation trial of modified vaccinia virus ankara vaccine expressing p53 (MVAp53).Patients receive MVAp53 subcutaneously (SC) on days 0, 21, and 42 in the absence of unacceptable toxicity. After completion of study treatment, patients are followed up annually for 5 years. •Patients with unresectable and chemotherapy resistant primary or recurrent carcinoma of colorectal, gastric or pancreatic origin •There must be pathologic evidence for malignancy with a soft tissue component of tumor evident on CT scan imaging or physical examinatior		
Active, not recruiting	Vaccine Therapy With Sargramostim (GM-CSF) in Treating Patients With Her-2 Positive Stage III-IV Breast Cancer or Ovarian Cancer		
	Conditions:	HER2-positive Breast Cancer; Stage III Ovarian Epithelial Cancer; Stage III Ovarian Germ Cell Tumor; Stage IIIA Breast Cancer; Stage IIIB Breast Cancer; Stage IIIC Breast Cancer; Stage IV Breast Cancer; Stage IV Ovarian Epithelial Cancer; Stage IV Ovarian Germ Cell Tumor	a
	Interventions:	Biological: pNGVL3-hICD vaccine; Biological: sargramostim; Other: flow cytometry; Other: immunologic technique; Other: immunoenzyme technique; Genetic: protein expression analysis; 2007	
	DNA Plasmid Based Vaccine Encoding the HER-2/Neu Intracellular Domain in Subjects With HER-2/Neu (HER2) Overexpressing Tumors: Dose on immunologic response [month 15]. Flow cytometry immunoenzyme technique Protein expression analysis Biopsy. Persistence of DNA at the injection site [: At 1 and 6 months after last vaccination] Biological: pNGVL3-hICD vaccine Plasmid-based DNA vaccine, given intradermally Biological: sargramostim, Given intradermally: Other Names: •GM-CSF, •granulocyte macrophage colony-stimulating factor, •Leukine, •Prokine, •rhu GM-CFS Other: flow cytometry Correlative studies Other: immunologic technique Correlative studies Other Names: •immunological laboratory methods, •laboratory methods, immunological Other: immunoenzyme technique 1) Undergo ELIspot (correlative studies), 2) Other Name: immunoenzyme techniques Genetic: protein expression analysis Undergo ELISA (correlative studies) Procedure: biopsy Undergo punch biopsy (correlative studies) Other Name: biopsies •Breast cancer: stage III or stage IV breast cancer with metastasis in remission and defined as NED (no evidence of disease); stable or healing bone disease by radiologic evaluation which may include, but is not limited to, bone scan, MRI, or PET scan documented within 90 days of enrollment to study and NED status for extraskeletal metastasis •Ovarian cancer: stage III or stage IV ovarian cancer in first complete remission with a normal AND stable CA-125; thus, two sequential normal CA-125 values will need to be documented; a minimum of 30 days between 2 sequential CA-125 values; the most recent will be within 2 weeks of enrollment into study •HER2 overexpression by immunohistochemistry (IHC) of 2+ or 3+ in their primary tumor or metastasis, and if overexpression is 2+ by IHC or in the absence of IHC, then patients must have documentation of HER2 gene amplification by FISH		
Recruiting	Autologous Tumor DRibble Vaccine in Patients With Non-Small Cell Lung Cancer		Autologous, unmodified tumor cells and DRibble Vaccine (highly immunogenic
	Condition:	Non Small Cell Lung Cancer	

	Intervention:	Biological: DRibble vaccine 2009	accumulated short-lived proteins).
	Ten patients will be enrolled. Study treatment is as follows: Docetaxel 75 mg/m2 will be given on day 1. Intradermal vaccinations of DRibbles from 5-20 x 106 cell equivalents per vaccine will begin 14 days after docetaxel. Immediately following vaccination, subcutaneous infusion of GM-CSF (50 micrograms/24 hrs) will be initiated. GM-CSF will be infused into the vaccination site for 6 days using the CADD-MS 3 pump. Immune response as measured by in vitro immune monitoring and by (DTH). [DTH on days 7-10 and days 77-80 and blood for immune monitoring (30-50 cc)]. Tumor response (RECIST criteria) [Week 12] A second docetaxel injection will be given at day 29 followed by a second vaccination 14 days later and 3 additional vaccines will be given at 2-week intervals. Following each vaccination, GM-CSF will again be infused over 6 days via the CADD-MS 3 pump. Peripheral blood will be obtained for immune monitoring at each vaccination. DTH to autologous tumor and to DRibble vaccine will be tested before the first and fifth vaccines. A second leukapheresis for immune monitoring will be obtained at 12 weeks. Clinical tumor response will be assessed after the fifth vaccination unless clinical evidence of tumor progression occurs sooner. Immune response will be assessed by DTH, T-cell function, T-cell migration into the vaccine sites and cytokine release assays. Sophisticated flow cytometry assays will be used to detect active T-cell subsets. Safety will be monitored by physical and laboratory exams at each vaccine visit and adverse events will be recorded and reported as appropriate. Clinical response will be assessed by tumor measurements by CT scan and/or physical exam at study entry and after 12 weeks. PFS and		
Recruiting	Prospective Trial of Vaccine Responses in Childhood Cancer Survivors		
	Conditions:	Childhood Cancer; Multiple Diseases 2007	I
	Interventions:	Biological: Immunization Schedule patients <7 years.; Biological: Immunization Schedule patients > or = to 7 years and <11 years of age; Biological: Immunization Schedule patients > or = to 11 years of age	
	Immunization Schedule patients > or = to 7 years and <11 years of age •Time 0 months: Hib #1, Prevnar 13 #1, Hepatitis B #1 •Time 1 month: Td#1, IPV #1(inactivated polio virus vaccine), Hepatitis B #2 •Time 2-3 months: Prevnar 13 #2, Hib #2 •Time 3-6 months: Td #2, Draw post vaccine titers Time 6-12 months: Administer Hepatitis #3 to patients not immunized prior to treatment for cancer, or with negative Hepatitis B titers after two immunizations		
Recruiting	Vaccine Therapy, Temozolomide, and Radiation Therapy in Treating Patients With Newly Diagnosed Glioblastoma Multiforme		IMA950 (A Novel Multi-Peptide Vaccine) Plus GM-CSF. glioblastoma multiform multi-antigen vaccine IMA950 and GM-CS..
	Condition:	Brain and Central Nervous System Tumors	
	Interventions:	Biological: glioblastoma multiform multi-antigen vaccine IMA950; Biological: sargramostim; Drug: temozolomide; Other: laboratory biomarker analysis; Other: pharmacological study; Procedure: adjuvant	
	T-cell responses against a single or multiple tumor-associated peptides (TUMAP) at one or more post-vaccination time points by HLA multimer analysis. (PSF) at 6 and 9 months post-surgery as assessed by the Macdonald criteria from conventional gadolinium-enhanced MRI and clinical assessment. Steroid levels and observed T-cell responses. O6-methyl-DNA-methyltransferase (MGMT) promoter methylation status in tumor tissue.•Kinetics of vaccine-induced TUMAP responses		
Recruiting	Evaluating the T Cell Response to a Peptide-based Vaccine in Patients With Breast Cancer		CD8+ T Cell Activation and Infiltration Into Primary Breast Tumors Following Administration of a Peptide Vaccine:
	Condition:	Breast Neoplasms	
	Intervention:	Biological: 9 Peptides from Her-2/neu, CEA, & CTA 2009	

	multi-peptide vaccine induces T cells that traffic to and penetrate into human primary breast cancers. (day22). Antigen specificT cell response to a peptide-based vaccine and the induction of differentiated effector cells, both in the peripheral blood and within the tumor microenvironment. [1 year] Just under 200,000 American women will be diagnosed with breast cancer this year. Standard breast cancer therapies have long included surgical resection, chemotherapy, radiation therapy, and hormonal therapy. However, other immune therapies are now being explored for the treatment of breast cancer, including peptide-based vaccines. In support of directed T cell therapies for breast cancer, antigenic epitopes from breast cancer-associated proteins such as Her-2/neu and the MAGE gene family have been identified, and vaccines containing peptides derived from these proteins have been shown to be safe and immunogenic in breast cancer patients. Results from successful immune therapy approaches, for various human and murine cancers, have shown that antitumor effects can be mediated by T cells, which is proof-of-principle that the immune system, and in particular, T cells, can reject tumor. Overall, however, the complete clinical response rate for T cell mediated immunotherapies has been low. There are at least two possibilities to explain why this may be the case. First, tumor reactive T cells may not traffic to tumors. Second, tumor reactive T cells may not have adequate effector function within the tumor microenvironment. Neither of these hypotheses has been adequately explored, though there are data suggesting that either or both may represent obstacles to successful immune therapy. In order to improve upon the clinical response rate with vaccines, we need to address the questions of whether vaccine-induced T cells traffic to tumor and exhibit effector function within the tumor. Specifically for breast cancer, there are opportunities for targeting T cells against primary tumors with the intent of providing immune protection early in the disease course. In the proposed clinical trial we will be administering a peptide-based vaccine and monitoring responses to the vaccine at the site of primary tumor. Peptide vaccines are unique in that they provide an opportunity to monitor directly the T cell response to defined antigens, enabling dissection of the immune response pre- and post-vaccination. The proposed analyses are designed to test the hypotheses that vaccination 1) enhances T cell infiltration into tumor and 2) induces T cells to become activated and fully differentiate into effector cells. The goals of this proposal are to define the extent to which these two processes occur following vaccination and to identify opportunities for improving tumor targeting and T cell effector function in human breast cancer.	
Active, not recruiting	Vaccine Therapy With Either Neoadjuvant or Adjuvant Chemotherapy and Adjuvant Radiation Therapy in Treating Women With p53-Overexpressing Stage III Breast Cancer Condition: Breast Cancer Intervention: Biological: autologous dendritic cell-adenovirus p53 vaccine 2004	Adenovirus p53 Infected DC Vaccine For Breast Cancer: Immune response, in terms of humoral and cellular response. antigen-specific immune

	OBJECTIVES: Determine the safety and toxicity of two different schedules of vaccination comprising p53-infected autologous dendritic cells in women with p53-overexpressing stage III breast cancer undergoing neoadjuvant or adjuvant chemotherapy and adjuvant radiotherapy. Determine the immune response, in terms of humoral and cellular response, in patients treated with these regimens. Determine antigen-specific immune responses in patients treated with these regimens. OUTLINE: This is a randomized, open-label study. Patients are randomized to 1 of 2 treatment arms. All patients undergo apheresis for the collection of peripheral blood monocytes that are cultured with interleukin-4 and sargramostim (GM-CSF) to produce dendritic cells. The dendritic cells are infected with a recombinant adenoviral vector containing the wild-type p53 gene. Patients receive doxorubicin IV and cyclophosphamide IV every 2 weeks for 8 weeks (4 courses) followed 2 weeks later by paclitaxel IV every 2 weeks for 8 weeks (4 courses). Patients with stage III disease then undergo surgery. Three weeks after completion of paclitaxel (or after surgery for patients with stage III disease), patients undergo radiotherapy once daily for 6.5 weeks. Patients are then receive vaccine therapy as per the arm to which they were randomized. Arm I: Patients receive vaccination comprising p53-infected autologous dendritic cells subcutaneously (SC) 1 week after completion of doxorubicin and cyclophosphamide, 1 week after completion of paclitaxel (or after surgery for patients with stage III disease), and at 6 and 12 weeks after completion of radiotherapy (for a total of 4 vaccinations). Arm II: Patients receive vaccination comprising p53-infected autologous dendritic cells SC at 6, 8, 10, and 12 weeks after completion of radiotherapy.	
Suspended	Alpha-Type 1 Dendritic Cell (DC)-Based Vaccines Loaded With Allogeneic Prostate Cell Lines in Combination With Androgen Ablation in Patients With Prostate Cancer Condition: Prostate Cancer Interventions: Biological: androgen ablation + dendritic cell vaccine; Biological: androgen ablation plus dendritic cell vaccine 2009	α-Type 1 Dendritic Cell-Based Vaccines Loaded With Allogeneic Prostate Cell Lines in Combination With Androgen Ablation:
	Evaluate the effect of the alpha-DC1 vaccine on time to PSA progression. Immune response to HLA-A2.1 restricted peptides derived from PAP and PSMA in patients who are A2.1 positive. Define the magnitude and cytokine production profiles of CD4+ and CD8+ T cell responses to the overlapping peptide libraries and individual peptides.	
Completed	Vaccine Therapy and Radiation Therapy in Treating Patients With Carcinoembryonic Antigen-Positive Solid Tumors That Have Metastasized to the Liver Conditions: Breast Cancer; Colorectal Cancer; Lung Cancer; Metastatic Cancer; Pancreatic Cancer; Unspecified Adult Solid Tumor, Protocol Specific Interventions: Biological: recombinant fowlpox GM-CSF vaccine adjuvant; Biological: recombinant fowlpox-CEA(6D)/TRICOM vaccine; Biological: recombinant vaccinia-CEA(6D)-TRICOM vaccine; Radiation: radiation	A CEA-Tricom Based Vaccine And Radiation To Liver Metastasis In Adults With CEA Positive Solid Tumors. Recombinant fowlpox GM-CSF vaccine/Recombinant fowlpox-CEA(6D)/TRICOM vaccine/ Recombinant vaccinia-CEA(6D)-TRICOM vaccine.
	Primary: Determine the clinical safety of vaccinia-CEA-TRICOM vaccine, fowlpox-CEA-TRICOM vaccine, recombinant fowlpox GM-CSF vaccine, and radiotherapy in patients with carcinoembryonic antigen (CEA)-positive solid tumors metastatic to the liver. Secondary: Determine the clinical response in patients receiving this regimen. Determine the immunological response, specifically the CEA-specific T-cell response, in patients receiving this regimen. Determine the effect of radiotherapy (before and after treatment) on FAS, major histocompatability complex, p53, and CEA in these patients. OUTLINE: Patients receive a priming vaccination of vaccinia (rV)-CEA-TRICOM and recombinant fowlpox GM-CSF (rF-GM-CSF) vaccine subcutaneously (SC) on day 1. Patients receive a booster vaccination of fowlpox (rF)-CEA-TRICOM and rF-GM-CSF SC on days 21, 35, 49, and 63. Patients undergo radiotherapy on days 22-25, 36-39, 50-53, and 64-67. Patients with stable disease or objective response after day 91 continue to receive rF-CEA-TRICOM and rF-GM-CSF SC every 28 days in the absence of disease progression or unacceptable toxicity. Patients are followed annually for 15 years.	

Active, not recruiting	Vaccine Therapy Combined With Interleukin-2 and Interferon Alfa in Treating Patients With Metastatic Renal Cell Carcinoma (Kidney Cancer) Condition: Kidney Cancer Interventions: Biological: aldesleukin; Biological: autologous tumor cell vaccine; Biological: recombinant interferon alfa; Biological: therapeutic autologous dendritic cells 2004	Autologous Tumor/DC Vaccine (DC Vaccine) Combined With IL-2 and IFN α-2a.
	Clinical response as measured by RECIST monthly and then every 2-3 months. T-cell and antibody responses to the tumor monthly for 5 months Primary: Determine the clinical response rate in patients with metastatic renal cell carcinoma treated with autologous dendritic cells (DC) loaded with autologous tumor lysate (DC vaccine) in combination with interleukin-2 and interferon-alfa. Determine the toxicity of this regimen in these patients. Secondary: Determine, within relevant immune pathways, the treatment-related, tumor-specific immune response in patients treated with this regimen. Correlate tumor-specific immune response with objective clinical response in patients treated with this regimen. OUTLINE: Induction therapy: Patients undergo leukapheresis on day -9. Patients receive autologous dendritic cells (DC) loaded with autologous tumor lysate (DC vaccine) by intranodal injection on days 0 and 14; interleukin-2 (IL-2) IV continuously on days 1-5 and 15-19; and interferon-alfa (IFN-α) subcutaneously (SC) once daily on days 1, 3, 5, 15, 17, and 19. Maintenance therapy: Patients undergo leukapheresis on days 33, 61, and 89. Patients receive DC vaccine by intranodal injection on days 42, 70, and 98; IL-2 IV continuously on days 43-47, 71-75, and 99-103; and IFN-α SC once daily on days 43, 45, 47, 71, 73, 75, 99, 101, and 103. Patients are followed every 3 months.	
Active, not recruiting	Vaccine Therapy in Treating Women With Previously Treated Metastatic Breast Cancer Condition: Breast Cancer Intervention: Biological: Ad-sig-hMUC-1/ecdCD40L vaccine 2008	Replication-Incompetent Adenoviral Vector Vaccine Used to Produce An Immune Response to MUC-1 Positive Epithelial Cancer Cells. Ad-sig-hMUC-1/ecdCD40L vaccine.
	Primary: Characterize the safety profile of Ad-sig-hMUC-1/ecdCD40L vaccine in women with metastatic breast cancer. Identify a tolerable, immunologically active dose level of this vaccine in these patients. Secondary: Evaluate the immune function in these patients before and after treatment with this vaccine. OUTLINE: Patients receive MUC-1 vector vaccine subcutaneously on day 0. After completion of study treatment, patients are followed monthly for 9 months.	
Suspended	DNP-Modified Autologous Tumor Cell Vaccine for Resectable Non-Small Cell Lung Cancer Condition: Non-Small Cell Lung Cancer - Completely Resectable Intervention: Biological: L-Vax: Autologous, DNP-Modified NSCLC Vaccine 2006	L-Vax: Autologous, DNP-Modified NSCLC Vaccine: Non-Small Cell Lung Cancer cell Cell-mediated immunity to autologous tumor cells [3 m].
	Biological: L-Vax: Autologous, DNP-Modified NSCLC Vaccine autologous, DNP-modified NSCLC cells in suspension dosage - depends on arm route - intradermal frequency - weekly x7, booster at 6 months Biological: L-Vax: Autologous, DNP-Modified NSCLC Vaccine autologous, DNP-modified NSCLC cells in suspension dosage - depends on arm route - intradermal frequency - weekly x7, booster at 6 months Biological: L-Vax: Autologous, DNP-Modified NSCLC Vaccine autologous, DNP-modified NSCLC cells in suspension dosage - depends on arm route - intradermal frequency - weekly x7, booster at 6 months	
Recruiting	A Study of a HER2/Neu Vaccine for Stage IIIB, IIIC and IV HER2/Neu Positive Breast Cancer Patients on Herceptin Condition: Breast Cancer	HER-2/Neu (HER2) Intracellular Domain (ICD) Peptide Based Vaccine

	Intervention:	Biological: HER2 Intracellular Domain Peptide-Based Vaccine 2006	(ICD) Peptide-Based Vaccine.
	Relapse free survival compared to historical control [4 years]. ELIspot. HER2 specific CD4+ and CD8+ T cell immunity by CFC. [18 months]. RFS to the generation of an immune response 2 years This is a phase II, single arm (no placebo, no randomization) study in patients who: Have HER2 overexpressing Stage IIIB, IIIC or IV breast cancer Have been treated with Herceptin; AND Show no evidence of disease or have stable bone only disease Patients will receive a monthly vaccination for 6 months with a HER2 vaccine and a total of 52 patients will be enrolled. Past studies have shown that vaccination elicits an immune response specific to HER2. This immunity has the potential for an anti-tumor effect		
Active, not recruiting	A Study of a Live Intranasal Influenza Vaccine in Children With Cancer		Flumist, a Live Attenuated Intranasal Influenza Vaccine, and Inactivated Influenza Vaccine in Children With Cancer.
	Condition:	Cancer	
	Interventions:	Biological: FluMist; Biological: Inactivated influenza vaccine 2009	
	Immune response of FluMist compared with inactivated influenza vaccine immunocompromised children with cancer. Viral Replication [1 year]. absolute neutrophil count, absolute lymphocyte count, serum IgA, IgG and IgM levels). Detailed Description: The secondary objectives of this study are to: Describe the safety of FluMist and inactivated influenza vaccine. Describe the incidence and duration of viral replication following immunization with FluMist. To examine the association between immunization response (seroconversion or seroprotection) and baseline clinical factors ().		
Recruiting	Immunogenicity of Fluzone HD,A High Dose Influenza Vaccine, In Children With Cancer or HIV		Immunogenicity of Fluzone (sanofi) HD,A High Dose Influenza Vaccine, In Children With Cancer or HIV.
	Conditions:	HIV; Cancer	
	Intervention:	Biological: Fluzone High Dose Vaccine Vs Fluzone 2010	
	The immunogenicity of 1 vs. 2 doses will be assessed by determining the rate of sero-conversion using the hemagglutinin-inhibition assay. [2 years]. lymphocyte numbers/function and robustness/durability of the immune response		
Completed	Radiation Therapy With or Without Vaccine Therapy in Treating Patients With Prostate Cancer		PSA-based Vaccine (Rec fowlpox-prostate specific antigen vaccine/Rec. vaccinia prostate-specific antigen vaccine/Rec. vaccinia-B7.1 vaccine.
	Condition:	Prostate Cancer	
	Interventions:	Biological: aldesleukin; Biological: recombinant fowlpox-prostate specific antigen vaccine; Biological: recombinant vaccinia prostate-specific antigen vaccine; Biological: recombinant vaccinia-B7.1 vaccine; Biological: sargramostim; Radiation: brachytherapy; Radiation: radiation therapy 2001	

	Prostate-specific antigen (PSA)-specific T-cell precursors. Followed every 3 months for 1 year, every 6 months for 1 year, and then annually for 13 yearsOBJECTIVES: Compare immunologic response, as measured by the increase in prostate-specific antigen (PSA)-specific T-cell precursors, in patients with localized prostate cancer treated with vaccine comprising recombinant vaccinia-PSA and rV-B7.1 plus recombinant fowlpox-PSA vaccine, sargramostim (GM-CSF), and low-dose interleukin-2 (IL-2) vs no vaccine regimen. Determine the safety and tolerability of this regimen in combination with radiotherapy in these patients. Compare the toxic effects of IL-2 in patients treated with these regimens. OUTLINE: This is a randomized study. Patients are stratified according to planned radiotherapy (irradiation alone vs irradiation and radioactive implant) and planned hormonal therapy (yes vs no). Patients are randomized to treatment arms I or II and, once accrual on these arms is complete, up to 20 patients (9-10 HLA-A2 positive) are accrued to arm III. Arm I: Patients receive vaccine comprising recombinant vaccinia-PSA admixed with rV-B7.1 subcutaneously (SC) on day 2. On days 30, 58, 86, 114, 142, 170, and 198, patients receive recombinant fowlpox-PSA vaccine SC. Beginning on day 86, patients undergo radiotherapy 5 days a week with total duration dependent upon whether patient undergoes radiotherapy alone or radiotherapy plus brachytherapy. Patients receive sargramostim (GM-CSF) SC on days 1-4, 29-32, 57-60, 85-88, 113-116, 141-144, 169-172, and 197-200. Patients receive low-dose interleukin-2 SC on days 8-12, 36-40, 64-68, 91-95, 120-124, 148-152, 176-180, and 204-208. Arm II: Patients undergo radiotherapy 5 days a week with total duration dependent upon whether patient undergoes radiotherapy alone or radiotherapy plus brachytherapy. Arm III: Patients undergo radiotherapy and receive recombinant vaccinia-PSA admixed with rV-B7.1 vaccine and GM-CSF as in arm I. Patients also receive a lower dose of IL-2 SC on days 8-21, 36-49, 64-77, 91-104, 120-133, 148-161, 176-189, and 204-217.		
Completed	Vaccine Therapy With or Without Sargramostim in Treating Patients With Advanced or Metastatic Cancer		Recombinant Fowl Pox Vaccine rF-CEA (6D)/TRICOM Alone or With GM-CSF(Rec. fowlpox GM-CSF vaccine adjuvant).
	Conditions:	Breast Cancer; Colorectal Cancer; Gallbladder Cancer; Gastric Cancer; Head and Neck Cancer; Liver Cancer; Ovarian Cancer; Pancreatic Cancer; Testicular Germ Cell Tumor	
	Interventions:	Biological: recombinant fowlpox GM-CSF vaccine adjuvant; Biological: recombinant fowlpox-CEA(6D)/TRICOM vaccine; Biological: sargramostim 2002	
	CEA-specific T-cell precursor frequency. Immunogenicity of GM-CSF. Inflammatory response and cytokine expression at the vaccination site. Correlate telomere length of leukocytes RATIONALE: Vaccines may make the body build an immune response to kill tumor cells. Colony-stimulating factors such as sargramostim may increase the number of immune cells found in bone marrow or peripheral blood. Combining vaccine therapy with sargramostim may make tumor cells more sensitive to the vaccine and may kill more tumor cells. PURPOSE: Phase I trial to study the effectiveness of vaccine therapy with or without sargramostim in treating patients who have advanced or metastatic cancer		
Recruiting	Dose Finding Study of a DNA Vaccine Delivered With Intradermal Electroporation in Patients With Prostate Cancer		pVAXrcPSAv53I (DNA encoding rhesus PSA) with DERMA VAX™ intradermal DNA delivery system (Electroporation).
	Condition:	Prostate Cancer	
	Interventions:	Biological: pVAXrcPSAv53I (DNA encoding rhesus PSA); Device: DERMA VAX™ intradermal DNA delivery system 2009	
	Primary Outcome Measures: Assess the feasibility and safety of escalating doses of pVAXrcPSAv53I DNA vaccine, administered intradermally in combination with electroporation in patients with relapse of prostate cancer. [Time Frame: From start of treatment to 30 days (safety) or up to 12 months] PSA-specific immune response induced by the vaccine. [30 days up to 12 months]. Anti-tumor effect [30 days up to 12 months] This study will assess the feasibility and safety of vaccination with increasing doses of xenogenic DNA administered intradermally in combination with electroporation in patients with relapse of prostate cancer. The DNA encodes prostate specific antigen (PSA) from Rhesus Macaque (Macaca mulatta), a protein that is 89% homologous to human PSA. The study will also assess the safety and functionality of the DERMA VAX™ (Cyto Pulse Sciences) DNA vaccine delivery system		

Completed	Vaccine Therapy, Chemotherapy, and Radiation Therapy in Treating Patients With Stage III Non-Small Cell Lung Cancer That Cannot Be Removed With Surgery		CEA/TRICOM-Based Vaccine (Rec. fowlpox GM-CSF vaccine adjuvant/Rec. fowlpox-CEA(6D)/TRICOM vaccine/Rec. vaccinia-CEA(6D)-TRICOM vaccine)
	Condition:	Lung Cancer	
	Interventions:	Biological: recombinant fowlpox GM-CSF vaccine adjuvant; Biological: recombinant fowlpox-CEA(6D)/TRICOM vaccine; Biological: recombinant vaccinia-CEA(6D)-TRICOM vaccine; Drug: carboplatin; Drug: paclitaxel; Radiation: radiation therapy 2004	
	Clinical response. Disease progression and overall median survival. Iimmunologic response		
Recruiting	Vaccine Therapy in Treating Patients With Progressive Stage D0 Prostate Cancer		Epitope-Enhanced TARP Peptide and TARP Peptide-Pulsed Dendritic Cells with GM-CSF (TARP 27-35 peptide +TARP 29-37-9V peptide):
	Condition:	Prostate Cancer	
	Interventions:	Biological: TARP 27-35 peptide vaccine; Biological: TARP 29-37-9V peptide vaccine; Biological: autologous TARP peptide-pulsed dendritic cell vaccine; Biological: incomplete Freund's adjuvant; Biological:	
	Immune response. Prostate-specific antigen doubling time response criteria. T-lymphocyte immune responses by tetramer staining, IFN-γ ELISPOT, and ^51Cr-release cytotoxic T-lymphocyte assays.. Serum prostate-specific antigen doubling time (PSADT). TARP tumor expression by in situ hybridization with immunologic reactivity Primary: Determine the safety and toxicity of TARP peptide vaccination vs TARP peptide-pulsed dendritic cell vaccination in patients with biochemically progressing stage D0 prostate cancer naïve to androgen-deprivation therapy. Determine the T-lymphocyte immune responses of these patients after treatment with TARP peptide vaccination with Montanide® ISA-51 VG and sargramostim vs autologous dendritic cells, as measured by tetramer staining, IFN-γ ELISPOT, and ^51Cr-release cytotoxic T-lymphocyte assays. Secondary: Determine the effect of TARP peptide vaccination on serum prostate-specific antigen doubling time (PSADT) in these patients. Correlate TARP tumor expression by in situ hybridization with immunologic reactivity. OUTLINE: Patients are randomized to 1 of 2 treatment arms. Arm I: Patients receive vaccine comprising wild-type and epitope-enhanced TARP peptides with Montanide® ISA-51 VG and sargramostim subcutaneously on weeks 3, 6, 9, 12, and 15*. Arm II: Patients receive vaccine comprising autologous, TARP peptide-pulsed dendritic cells intradermally on weeks 3, 6, 9, 12, and 15*. NOTE: *Patients that achieve PSA doubling time (PSADT) response at week 24 (i.e., ≥ 50% increase in calculated PSADT OR a PSADT > 15 months) may receive an additional dose of vaccine on week 36. All patients will receive a booster of vaccine at week 48.		
Active, not recruiting	Monoclonal Antibody Therapy and/or Vaccine Therapy in Treating Patients With Locally Advanced or Metastatic Colorectal Cancer		Anti-idiotype vaccine 別に
	Condition:	Colorectal Cancer	
	Interventions:	Biological: BCG vaccine; Biological: monoclonal antibody 105AD7 anti-idiotype vaccine; Drug: alum adjuvant	
Recruiting	Ovarian Dendritic Cell Vaccine Trial		CD4+CD25+ Immunoregulatory Treg-cells in Ovarian CancerPatients Who Receive Dendritic Cell Based.
	Condition:	Ovarian Cancer	
	Interventions:	Biological: Ontak DC; Biological: DC vaccination; Drug: Ontak 2008	

	Immunoregulatory T-cell inhibition by Ontak. [days 45 and 62 post vaccine]. in vitro and in vivo responses of Ontak [Days 46 and 62 post vaccine]Detailed Description: Patients with advanced ovarian carcinoma who have failed initial curative chemotherapy attempts will be evaluated at the time of relapse for tumor debulking surgery prior to the initiation of salvage chemotherapy. If appropriate, samples will be collected for tumor lysate preparation for vaccination as per the existing Loyola protocol. Lysates may also be produced by the collection of malignant effusions as performed for palliation of symptoms. Patients will then receive palliative chemotherapy to a maximum tumor cytoreduction. Patients from whom sufficient tumor cells have been collected for DC-based vaccine production will undergo a leukapheresis for DC cell production. Once completed, these patients will be randomly assigned one of two treatment groups: Cohort (Group) 1 - Administration of a single dose of Ontak at 18 μg/kg followed by DC vaccination with 1 x 106 tumor lysate and KLH-loaded immature DCs into inguinal nodes identified by ultrasound guidance for a total of three injections at two week intervals; or Cohort (Group) 2 - Identical DC vaccination as in Group 1 without Ontak pre-treatment. Patients for whom collection of tumor cells for lysate preparation is not possible will be assigned to Cohort (Group) 3, with administration of Ontak at the same dose without vaccination. In this pilot study we plan to treat 12 patients in each group over a two-year period of time. Therapy will begin four weeks after chemotherapy completion, given to achieve maximum cytoreduction prior to protocol therapy initiation	
Recruiting	Vaccine Therapy in Treating Patients With Stage IV Breast Cancer Conditions: Breast Cancer; HER2-positive Breast Cancer; Male Breast Cancer; Recurrent Breast Cancer; Stage IV Breast Cancer Interventions: Biological: HER-2/neu peptide vaccine; Procedure: leukapheresis; Biological: ex vivo-expanded HER2-specific T cells; Drug: cyclophosphamide; Other: laboratory biomarker analysis; Biological: sargramostim; Biological: trastuzumab; Other: flow cytometry; Other: immunoenzyme technique; Genetic: gene expression analysis; Genetic: polymerase chain reaction 2008	Adoptive T Cell Therapy Following In Vivo Priming With a HER-2/Neu (HER2) Intracellular Domain (ICD) Peptide-Based Vaccine (ex vivo-expanded HER2-specific T cells) + GM-CSF, trastuzumab.
	Response according to RECIST. T-cell immunity immunoenzyme technique gene expression analysis, PCR. skeletal or bone-only disease according to European Organization for Research and Treatment for Cancer (EORTC) PRIMARY OBJ.: I. To evaluate the safety of infusing escalating doses of HER2 specific T cells into patients with advanced HER2+ breast cancer using ex vivo expanded autologous T cells. SECONDARY OBJ.: I. To investigate to what extent HER2 specific T cell immunity can be boosted or generated in individuals after infusion of HER2 specific T cells. II. To evaluate how long T cell immune augmentation persists in vivo after adoptive transfer of HER2 specific T cells and subsequent booster immunizations. III. To determine the development of CD4+ and CD8+ epitope spreading after adoptive transfer of HER2 specific T cells. TERTIARY OBJECTIVE: I. To investigate the potential anti-tumor effects of HER2 specific T cells in patients with advanced HER2+ breast cancer. OUTLINE: This is a dose-escalation study of ex vivo-expanded HER2-specific autologous T cells followed by a phase II study. Patients receive HER2/neu peptide vaccine admixed with sargramostim (GM-CSF) intradermally on days 1, 8, and 15. Beginning 2 weeks later, patients undergo leukapheresis to isolate and collect peripheral blood mononuclear cells for T-cell expansion. Patients receive cyclophosphamide IV once on day -1 and autologous ex vivo-expanded HER2-specific T cell IV over 30 minutes on day 1. Treatment repeats every 7-10 days for a total of three immunizations. Patients receive a booster HER2/neu peptide vaccine 1 month after the final T-cell infusion, followed by 2 additional booster vaccines at 2-month intervals. Patients may continue trastuzumab IV weekly or every 3 weeks, except for 7 days before the cyclophosphamide dose.	
Not yet recruiting	Ex Vivo-Expanded HER2-Specific T Cells and Cyclophosphamide After Vaccine Therapy in Treating Patients With HER2-Positive Stage IV Breast Cancer Conditions: HER2-positive Breast Cancer; Male Breast Cancer; Stage IV Breast Cancer	

	Interventions:	Biological: HER-2/neu peptide vaccine; Drug: cyclophosphamide; Biological: ex vivo-expanded HER2-specific T cells; Other: laboratory biomarker analysis; Other: flow cytometry; Other: immunoenzyme technique 2010	
	Adoptive T-Cell Therapy With HER-2/Neu (HER-2)-Specific Memory CD8+ T Lymphocytes Obtained Following In Vivo Priming With a Peptide Vaccine. expand HER-2-specific T cells ex vivo from memory T cell subsets. quantitative assessment of HER-2-specific CD8+ T cells assessed by cytokine flow cytometry (CFC), Elispot, and tetramer staining [10, 20, 28, 35, 49, 63, then monthly for one year.] . HER-2-specific central memory T cells and effector memory T cells. Anti-tumor effects as assessed by RECIST criteria [Day 63		
Recruiting	An Open Label Phase I Study to Eval the Safety and Tolerability of a Vaccine (GI-6207) Consisting of Whole, Heat-killed Recombinant Saccharomyces Cerevisiae (Yeast) Genetically Modified to Express CEA Protein in Adults With Metastatic CEA-		Vaccine (GI-6207) Consisting of Whole, Heat-Killed Recombinant Saccharomyces Cerevisiae Genetically Modified to Express CEA Protein.
	Conditions:	Prostate Cancer; Breast Cancer; Lung Cancer; Colorectal Cancer; Head and Neck Cancer	
	Interventions:	Biological: GI-6207 [Recombinant Saccharomyces Cerevisia; Drug: (Yeast CEA Vaccine)(GI-6207[Recombinant Sarrcharomyces Cerevusua-CEA (610D)]) 2009	
	To evaluate CD4 and CD8 immunologic response. To evaluate humoral immune response to yeast antigen. To evaluate evidence of clinical benefit such as PFS, OR, & decreases in circulating tumor cells & tumor markers Objectives: •To find out the maximum tolerated dose of the GI-6207 vaccine (the highest dose that does not cause unacceptable side effects), and to evaluate any side effects. •To see if GI-6207 has any effect on patients' tumors. •To learn how the vaccine causes immune responses against the cancer. Eligibility: •Patients 18 years of age and older who have been diagnosed with a cancer that has not responded to standard treatments. Patients must not be allergic to yeast or yeast products. Design: •Initial physical examination, blood and tissue sampling, computed tomography (CT) scan, and skin test to determine eligibility for the procedure. •Treatment with GI-6027 in seven 14-day cycles as follows: •Vaccine administered on days 1, 15, 29, 43, 57, 71, and 85. •Vaccine given at four sites around the body: right and left chest area below the armpit, and right and left upper thigh in the pelvic region. (These areas drain into parts of your body that contain large numbers of lymph nodes. The lymph nodes contain immune cells that may be activated by the vaccine to target cancer cells.) •Clinic visits for physical examinations to check vital signs, take additional blood and urine samples, and perform other tests needed for the study. •After day 85 (about 3 months), patients will continue to receive vaccine monthly (or every 28 days) as long as the vaccine is not producing harmful effects or side effects and the cancer is either stable or reducing. Patients who do well on the vaccine may continue to receive it for as long as it is available.		
Active, not recruiting	Vaccine Therapy, MDX-010, and GM-CSF in Treating Patients With Metastatic Prostate Cancer		PSA Based Vaccine and an Anti-CTLA-4 Antibody (fowlpox-PSA-TRICOM vaccine/vaccinia-PSA-TRICOM vaccine, ipilimumab, GM-CS):
	Condition:	Prostate Cancer	
	Interventions:	Biological: fowlpox-PSA-TRICOM vaccine; Biological: ipilimumab; Biological: sargramostim; Biological: vaccinia-PSA-TRICOM vaccine 2005-2012	

	Objective responses by **RECIST every 2 months**. Prostate-specific antigen **(PSA) response by monthly serum PSA** Immunologic responses by ELISPOT at day 99 This study will evaluate the side effects of a fixed dose of vaccine and GM-CSF with increasing doses of**anti-CTLA-4 antibody** in patients with advanced prostate cancer. The vaccine consists of a "priming vaccine" called **PROSTVAC/TRICOM**, made from vaccinia virus, and a "boosting vaccine" called PROSTVAC-F/TRICOM, made from fowlpox virus. GM-CSF is a chemical that boosts the immune system, and anti-CTLA-4 antibody is a protein that may improve anti-tumor activity and the response to the vaccines. DNA is inserted into the priming and boosting vaccine viruses to cause production of proteins that enhance immune activity and also to produce prostate specific antigen (PSA)-a protein that is normally produced by the patient's tumor cells. Patients 18 years of age and older with androgen-insensitive prostate cancer that has spread beyond the original site may be eligible for this 7-month study. Candidates must have disease that has worsened despite treatments with hormones and up to one chemotherapy regimen. Their tumor must produce PSA, and they must have no history of allergy to eggs or egg products Candidates are screened with a medical history and physical examination, blood and urine tests, electrocardiogram, pathological confirmation of the diagnosis and presence of the PSA marker, chest x-rays, imaging studies to assess the extent of tumor, and, if clinically indicated, a cardiologic evaluation. Participants receive the priming vaccination on study day 1. After 2 weeks and then again every 4 weeks while on the study, they receive a boosting vaccine. All vaccines are injected under the skin. On the day of each vaccination and daily for the next 3 days, patients receive an injection of GM-CSF to increase the number of immune cells at the vaccination site. On the day of the first six boosting vaccinations, they receive anti-CTLA-4 antibody as an infusion through a vein over 90 minutes. Patients are monitored for safety and treatment response with the following tests and procedures: •Blood and urine tests monthly, or more often if needed, to monitor liver, kidney, and other organ function. •Imaging studies to assess the tumor before starting treatment, again around study days 99 and 183, and then every 3 months after that while on study. •Apheresis (a procedure for collecting immune cells called lymphocytes) to measure the immune response to treatment. Apheresis is done three times: before starting the study and again around study days 99 and 183. For this procedure, blood is collected through a needle in an arm vein. The blood circulates through a machine that separates it into its components by spinning, and the lymphocytes are extracted. The rest of the blood is returned to the patient through the same needle. This will only be done in participants who have the tissue marker HLA-A2 (about 50% of patients)	
Completed	Vaccine Therapy in Treating Patients With Colorectal Cancer Metastatic to the Liver		Anti-Idiotype Monoclonal Antibody Vaccine CeaVac and TriAb (MoAb 11D10 anti-idiotype vaccineMoAb 3H1 anti-idiotype vaccine):
	Conditions:	Colorectal Cancer; Metastatic Cancer	
	Interventions:	Biological: monoclonal antibody 11D10 anti-idiotype vaccine; Biological: monoclonal antibody 3H1 anti-idiotype vaccine; Procedure: adjuvant therapy 2002	

	2-year recurrence-free survival Primary •Determine the 2-year recurrence-free survival of patients with minimal metastatic colorectal cancer after hepatic resection when treated with adjuvant monoclonal antibody 3H1 anti-idiotype vaccine and monoclonal antibody 11D10 anti-idiotype vaccine. Secondary •Determine the toxicity of this regimen in these patients. OUTLINE: This is a multicenter study. Beginning 6-12 weeks after curative hepatic resection, patients receive monoclonal antibody 3H1 anti-idiotype vaccine and monoclonal antibody 11D10 anti-idiotype vaccine intracutaneously at separate sites on days 1, 15, 29, and 45, then subcutaneously monthly for 4 months. PROJECTED ACCRUAL: A total of 63 patients will be accrued for this study within 9 months. Biological: monoclonal antibody 11D10 anti-idiotype 2 mg intradermal injection q 14 days for 4 doses, then sub Q monthly for 4 months, following a 6-12 wk rest period after curative hepatic resection Other Name: TriAb Biological: monoclonal antibody 3H1 Alu Gel 2 mg intradermal injection q 14 days for 4 doses, then sub Q monthly for 4 months, following a 6-12 wk rest period after curative hepatic resection Other Name: CeaVac	
Not yet recruiting	Vaccine Therapy and OPT-821 or OPT-821 Alone in Treating Patients With Ovarian Epithelial Cancer, Fallopian Tube Cancer, or Primary Peritoneal Cancer in Complete Remission Conditions: Fallopian Tube Cancer; Ovarian Cancer; Peritoneal Cavity Cancer 2008 Interventions: Biological: immunological adjuvant OPT-821; Biological: polyvalent antigen-KLH conjugate vaccine	Polyvalent Vaccine-KLH Conjugate + OPT-821 Versus OPT-821(as adjuvant): polyvalent antigen-KLH conjugate vaccine (GM2-KLH, Globo-H-KLH, Tn-MUC1-32mer-KLH, TF-KLH, and sTn-KLH) with OPT-821 vs OPT-821 alone.
	Progression-free survival. Overall survival. Antigen-specific immune titers (by ELISA) in a limited sampling. Primary: To compare the progression-free survival of patients with ovarian epithelial, fallopian tube, or primary peritoneal cancer in second or third complete clinical remission treated with a polyvalent antigen-KLH conjugate vaccine (GM2-KLH, Globo-H-KLH, Tn-MUC1-32mer-KLH, TF-KLH, and sTn-KLH) in combination with OPT-821 vs OPT-821 alone. Secondary: To compare the incidence of toxicities in patients treated with these regimens. /To compare the overall survival of patients treated with these regimens. To characterize the immune response (by ELISA) in a limited sampling of patients, in order to determine if the outcome correlates with antigen-specific immune titers. OUTLINE: This is a multicenter study. Patients are randomized to 1 of 2 treatment arms. / Arm I: Patients receive polyvalent antigen-KLH conjugate vaccine in combination with OPT-821 subcutaneously (SC) once in weeks 1, 2, 3, 7, 15, 27, 39, 51, 63, 75, and 87. /Arm II: Patients receive OPT-821 SC once in weeks 1, 2, 3, 7, 15, 27, 39, 51, 63, 75, and 87.	
Completed	Vaccine Therapy in Treating Patients With Stage IIIB or Stage IV Non-Small Cell Lung Cancer Who Have Finished First-Line Chemotherapy Condition: Lung Cancer Interventions: Biological: Allogeneic B7.1/HLA-A1 transfected tumor cell vaccine; Other: Placebo 2007	Allogeneic B7.1/HLA-A1 transfected tumor cell vaccine

	Progression-free survival (Phase II). Adaptive immune response: the Relationship of CD8 response in B7-vaccinated patients with progression-free survival. nalyzed for CD8, CD4, and NK response and PBL and TH1/TH2 bias, including levels of IL-1β, IL-2, IL-4, IL-5, IL-6, IL-13, IFN-γ, TNF-α via ELISA. every 3 months for 2 years, every 6 months for 4 years		
Recruiting	To Immunize Pts w Extensive Stage SCLC Combined w Chemo w or w/oAll Trans Retinoic Acid		Dendritic Cells Transduced With an Adenoviral Vector Containing the p53 Gene to Immunize Patients.
	Condition:	Small Cell Lung Cancer	
	Interventions:	Other: Observation; Biological: Drug: Ad.p53-DC vaccines; Drug: Ad.p53-DC vaccines + ATRA 2008	
	estimate tumor response rate for each treatment group. [24 months]. Survival of all patients [24 months]		
Completed	Vaccine Therapy in Treating Patients With Progressive or Locally Recurrent Prostate Cancer		Intraprostatic PSA-Based Vaccine (fowlpox-PSA-TRICOM vaccine/fowlpox GM-CSF vaccine adjuvant / vaccinia-PSA-TRICOM vaccine)
	Condition:	Prostate Cancer	
	Interventions:	Biological: fowlpox-PSA-TRICOM vaccine; Biological: recombinant fowlpox GM-CSF vaccine adjuvant; Biological: vaccinia-PSA-TRICOM vaccine 2006-2012 Gene therapy	
	immunologic response by ELISPOT at baseline and at day 113. (PSA) changes by monthly serum PSA Background: •Pox viral vectors can induce a PSA-specific T-cell responses and clinical responses in patients with advanced prostate cancer. •Intratumoral vaccines of recombinant fowlpox vectors appear to be more potent in inducing antitumor effects than the s.c. route of administration, especially when the recombinant rF-vector given intratumorally is preceded by a rV-recombinant given s.c. This may be due to: •Making the tumor cell an antigen presenting cell via upregulation of both antigen (signal 1) and costimulatory molecules (signal 2). •Making the tumor cell more susceptible to killing via upregulation of ICAM. •The increased expression of perforin in peptide-specific T cells that came into contact with the TRICOM-infected targets. •Potentially allowing the immune system to select for other tumor encoded antigens to generate a polyvalent immune response. Objectives: •1: Safety and feasibility of an intraprostatic vaccine strategy. •2: To assess the change in PSA-specific T-cell response as measured by ELISPOT assay. •2: To evaluate T-cell infiltration histologically in patients who have pre- and post-vaccine prostate biopsies. Eligibility: •Must have either a) biopsy proven, locally recurrent prostate cancer following local radiation as defined by the ASTRO consensus criteria as 3 consecutively rising PSA levels or b) have refused or not be candidates for local definitive therapy (surgery or radiation therapy) and have clinically progressive disease on androgen deprivation therapy (eg. three increases in PSA over nadir, separated by at least one week). For patients with previous RT, the biopsy confirming local recurrence must be done at least 18 months after the completion of RT. •Since this may also generate a systemic immune response, patients with minimal extraprostatic disease may be enrolled. •Hepatic function: Bilirubin < 1.5 mg/dl, AST and ALT< 2.5 times upper limit of normal Design: •Dose escalation Phase I design. Each cohort will consist of 3-6 patients, with cohorts 4 & 5 restricted to include only HLA-A2 + patients; maximum accrual is 30 •Patients in all cohorts receive initial priming with rV- PSA(L155)/TRICOM and rF-GM-CSF s.c. •The first two cohorts utilize a booster intraprostatic with dose escalation of rF-PSA(L155)/TRICOM. •Third and fourth cohorts add dose escalations of rF-GM-CSF along with the highest dose of rF-PSA(L155)/TRICOM		

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	