	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)	Autologous Tumor/DC Vaccine (DC Vaccine) Combined With IL-2 and IFN α-2a.
	Condition: Kidney Cancer	
	Interventions: Biological: aldesleukin; Biological: autologous tumor cell vaccine; Biological: recombinant interferon alfa; Biological: therapeutic autologous dendritic cells 2004	
	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	Replication-Incompetent Adenoviral Vector Vaccine Used to Produce An Immune Response to MUC-1 Positive Epithelial Cancer Cells. Ad-sig-hMUC-1/ecdCD40L vaccine.
	Condition: Breast Cancer	
	Intervention: Biological: Ad-sig-hMUC-1/ecdCD40L vaccine 2008	
	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	L-Vax: Autologous, DNP-Modified NSCLC Vaccine: Non-Small Cell Lung Cancer cell Cell-mediated immunity to autologous tumor cells [3 m].
	Condition: Non-Small Cell Lung Cancer - Completely Resectable	
	Intervention: Biological: L-Vax: Autologous, DNP-Modified NSCLC Vaccine 2006	
	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	HER-2/Neu (HER2) Intracellular Domain (ICD) Peptide Based Vaccine
	Condition: Breast Cancer	

	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 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	Recombinant Fowl Pox Vaccine rF-CEA (6D)/TRICOM Alone or With GM-CSF(Rec. fowlpox GM-CSF vaccine adjuvant).
	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 Condition: Prostate Cancer Interventions: Biological: pVAXrcPSAv53l (DNA encoding rhesus PSA); Device: DERMA VAX™ intradermal DNA delivery system 2009	pVAXrcPSAv53l (DNA encoding rhesus PSA) with DERMA VAX™ intradermal DNA delivery system (Electroporation).
	Primary Outcome Measures: Assess the feasibility and safety of escalating doses of pVAXrcPSAv53l 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	