

	<p>Primary: Number of patients with adverse events as a measure of safety and tolerability of repeat doses. [Time Frame: Date of first dose until 30 days after off-study, or until resolution of related AEs]. /Humoral and cellular response as determinants of the optimal biological dose/recommended dose [Time Frame: Starting from first dose, samples taken within 72hrs of the 1st, 3rd, and 5th doses of each cycle until off-study]. /Humoral response (NY-ESO-1 antibody titre) and cellular response (NY-ESO-1 specific CD4 and CD8 T-cell) will be measured to determine the optimal biologic dose/recommended dose</p> <p>[Secondary]: Tumor response using RECIST 1.1 [Time Frame: Each cycle at weeks 7 and 11 (appx.)] [Designated as safety issue: Yes]</p> <p>Scans will be performed each cycle after the 4th and 6th injections (approximately Weeks 7 and 11). Scans will be performed; or, for patients with prostate cancer, response will be based on PSA levels. /Humoral and cellular immune response as indication of IMF-001 biologic activity [Time Frame: Starting from first dose, samples taken within 72hrs of the 1st, 3rd, and 5th doses of each cycle until off-study]. /Humoral response (NY-ESO-1 antibody titre) Cellular response (NY-ESO-1 specific CD4 and CD8 T-cells)</p> <p>NY-ESO-1 was isolated by serological analysis of recombinant cDNA expression libraries (SEREX), using tumor mRNA and autologous serum from an esophageal cancer patient. Reverse transcription-polymerase chain reaction (RT-PCR) analysis showed that NY-ESO-1 displayed the typical expression pattern of cancer testis antigens (CT antigens). NY-ESO-1 mRNA was expressed only in testis of normal tissues tested and in various types of cancer, including lung cancer, breast cancer, malignant melanoma and bladder cancer. /IMF-001 is a CHP-NY-ESO-1 complex consisting of recombinant NY-ESO-1 protein and cholesteryl hydrophobized pullulan (CHP). CHP forms colloiddally stable nanoparticles in water and complexes with substrate such as NY-ESO-1 protein.</p> <p>It is well known that exogenous antigen proteins can induce specific CD4+ T cells but not specific CD8+ T cell. Dendritic cells pulsed with IMF-001 induced NY-ESO-1 specific CD8+ T cells in blood samples of 4 healthy volunteers. These data suggest that immunization of patients with IMF-001 can evoke not only specific CD4+ T cells responses but also specific CD8+ T cell response to NY-ESO-1 more effectively than NY-ESO-1 protein alone. Similar results for both cellular and humoral immunity in response to NY-ESO-1 protein were observed in previous clinical investigational studies with IMF-001.</p>		
Completed	<p><u>Provenge® (Sipuleucel-T) Active Cellular Immunotherapy Treatment of Metastatic Prostate Cancer After Failing Hormone Therapy</u></p>		
Has Results	Condition:	Prostate Cancer	
	Interventions:	Biological: Sipuleucel-T; Biological: APC-Placebo	
	<p>To qualify for this trial, you must have ALL of the following: Histologically documented adenocarcinoma of the prostate. Cancer that has progressed while on adequate hormone therapy. This state of the disease is androgen independent prostate cancer (AIPC). Cancer that has spread outside the prostate (metastatic) to lymph nodes or bone. Please note that if your cancer has spread to organs (e.g., liver, lung, brain), you are not eligible for the study. The absence of or minimal current cancer-related pain. Please note that there are additional eligibility criteria. The study center will determine if you meet all of the criteria. Study personnel will explain the trial in detail and answer any questions you may have if you do qualify for the study. You can then decide whether or not you wish to participate. If you do not qualify for the trial, study personnel will explain the reasons</p>		<p>Sipuleucel-T: a minimum of 50 million autologous CD54+ cells activated with a PAP-GM-CSF. .</p>
Active, not recruiting	<p><u>Vaccine Therapy, Paclitaxel, and Carboplatin in Treating Patients Who Are Undergoing Surgery for Stage III or Stage IV Ovarian Cancer, Primary Peritoneal Cancer, or Fallopian Tube Cancer</u></p>		<p>MAGE-A1, Her-2/neu, FBP peptides ovarian cancer vaccine + tetanus toxoid helper peptide. Pepitde-specific Cytotoxic T-cell response</p>
	Conditions:	Fallopian Tube Cancer; Ovarian Cancer; Peritoneal Cavity Cancer	
	Interventions:	Biological: MAGE-A1, Her-2/neu, FBP peptides ovarian cancer vaccine; Biological: tetanus toxoid helper peptide; Drug: carboplatin; Drug: paclitaxel; Procedure: conventional surgery 2006	

	<p>Primary: Cytotoxic T-cell response to vaccine therapy comprising 5 synthetic ovarian cancer-associated peptides, as assessed using peripheral blood during course 1</p> <p>Secondary: Cytotoxic T-cell response to vaccine therapy comprising synthetic ovarian cancer-associated peptides, as assessed using peripheral blood during chemotherapy and during course 2. /Cytotoxic T-cell response against autologous and/or major histocompatibility complex-matched allogeneic tumor cells pre- and post-treatment</p> <p>[Purpose]: RATIONALE: Vaccines made from peptides may help the body build an effective immune response to kill tumor cells. Drugs used in chemotherapy, such as paclitaxel and carboplatin, work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. Giving chemotherapy before surgery may make the tumor smaller and reduce the amount of normal tissue that needs to be removed. Giving vaccine therapy and chemotherapy after surgery may kill any tumor cells that remain after surgery.</p> <p>PURPOSE: This phase II trial is studying how well giving vaccine therapy together with paclitaxel and carboplatin works in treating patients who are undergoing surgery for stage III or stage IV ovarian cancer, primary peritoneal cancer, or fallopian tube cancer.</p>	
Recruiting	<p><u>IMA901 in Patients Receiving Sunitinib for Advanced/Metastatic Renal Cell Carcinoma</u></p> <p>Condition: Metastatic Renal Cell Carcinoma</p> <p>Interventions: Drug: Sunitinib; Biological: IMA901 plus GM-CSF 2010</p>	<p>Sunitinib + IMA901 (IMA901 Muropeptide) plus GM-CSF</p> <p>OS, PFS Cellular immunomonitoring</p>
	<p>Primary: Overall survival [Time Frame: 2014 (estimated)]</p> <p>Secondary: Overall survival in biomarker-defined subgroup [2014 (estimated)]. /Progression-free survival [Time Frame: 2013 (estimated)]. /Best tumor response [Time Frame: 2013 (estimated)]. /Safety and tolerability [Time Frame: continuously] /Cellular immunomonitoring [Time Frame: 2014 (estimated)]</p> <p>This is a multicenter, open-label, randomized phase III study to investigate whether therapeutic vaccination with IMA901, a mult-peptide cancer vaccine (TUMAP), can prolong overall survival in patients with metastatic and/or locally advanced RCC when added to standard first-line therapy with sunitinib (primary endpoint). Secondary endpoints include a subgroup analysis of overall survival in patients who are positive for a prospectively defined primary biomarker signature (identified as being predictive for improved clinical outcome in IMA901-vaccinated patients in the previous phase II study), progression-free survival (PFS), best overall response, cellular immunomonitoring in a subset of patients, and safety. Safety analysis will be based on adverse events (AEs), physical examinations, vital signs, hematology, clinical chemistry, urinalysis and ECG changes.</p>	
Recruiting	<p><u>The Development of Human Papillomavirus Type 16 E7-Specific Human Immunologic Assays in Non-HLA2 Type Human Being</u></p> <p>Condition: Cervical Cancer</p> <p>Intervention:</p>	<p>major histocompatibility complex (MHC) class I restricted CD8+ T cytotoxic cell.</p>
Active, not recruiting	<p><u>Vaccine Therapy in Treating Patients With Stage D0 Prostate Cancer</u></p> <p>Condition: Prostate Cancer</p> <p>Interventions: Biological: BCG vaccine; Biological: prostate cancer vaccine ONY-P1; Other: placebo 2007</p>	<p>BCG vaccine + prostate cancer vaccine ONY-P1. PD: ELISPOT assay PSA kinetics. ONY-P1 vaccine with BCG 次にONY-P1のみ</p>

	<p>Primary: Time to PSA progression [Designated as safety issue: No]</p> <p>Secondary: Toxicity. /Immunologic response as assessed by ELISPOT assay. /PSA kinetics (doubling time/velocity) of treatment. /Time to testosterone recovery</p> <p>Primary To determine whether ONY-P1 vaccine can increase the time to PSA-defined progression in patients with androgen-dependent stage D0 prostate cancer.</p> <p>Secondary To evaluate all toxicities related to ONY-P1 vaccine. /To compare the immunologic response in patients treated with ONY-P1 vaccine vs placebo. To evaluate PSA kinetics (doubling time/velocity) of treatment. /To evaluate time to testosterone recovery following limited androgen ablation.</p> <p>OUTLINE: Patients are stratified according to estimated PSA doubling time (< 12 months vs ≥ 12 months). Patients receive goserelin subcutaneously once. Approximately 3 months later, patients are randomized to 1 of 2 treatment arms. Arm I: Patients receive ONY-P1 vaccine with BCG intradermally on days 1 and 15. Patients then receive ONY-P1 vaccine alone on day 29 and then every 4 weeks for up to 12 months in the absence of disease progression or unacceptable toxicity.</p>				
Not yet recruiting	<u>Vaccine Therapy in Treating Patients With Persistent or Recurrent Cervical Cancer</u>				
	<table border="1"> <tr> <td>Condition:</td> <td>Cervical Cancer</td> </tr> <tr> <td>Interventions:</td> <td>Biological: live-attenuated Listeria monocytogenes cancer vaccine ADXS11-001; Other: laboratory biomarker analysis 2010</td> </tr> </table>	Condition:	Cervical Cancer	Interventions:	Biological: live-attenuated Listeria monocytogenes cancer vaccine ADXS11-001; Other: laboratory biomarker analysis 2010
Condition:	Cervical Cancer				
Interventions:	Biological: live-attenuated Listeria monocytogenes cancer vaccine ADXS11-001; Other: laboratory biomarker analysis 2010				
	<p>Primary] To evaluate the tolerability, safety, and nature and degree of toxicity of ADX11-001 by the numbers of patients with dose-limiting toxicities (DLTs) and adverse events as assessed by the CTCAE v4.0. /To assess the activity of ADXS11-001 for patients with persistent or recurrent carcinoma of the cervix with the frequency of patients who survive for at least 12 months after initiating therapy.</p> <p>Secondary] To characterize the distribution of progression-free survival and overall survival. /To examine the proportion of patients with objective tumor response.</p> <p>Tertiary]: To assess changes in clinical immunology based upon serum cytokines and to correlate any observed changes with clinical response including progression-free survival, overall survival, tumor response, DLTs, and adverse effects. (Exploratory). /To examine associations between presence and type of high-risk human papillomavirus (H-HPV) and measures of clinical response and serum cytokine levels. (Exploratory)</p> <p>OUTLINE: This is a multicenter study. Patients receive live-attenuated Listeria monocytogenes cancer vaccine ADXS11-001 IV over 15 minutes on day 1. Treatment repeats every 28 days for 3 courses in the absence of disease progression or unacceptable toxicity. Tumor tissue and serum samples may be collected periodically for translational research. After completion of study treatment, patients are followed up every 3 months for 2 years and then every 6 months for 3 years.</p>				
Completed	<u>Oregovomab With or Without Cyclophosphamide in Treating Patients With Stage III or Stage IV Ovarian Epithelial Cancer, Fallopian Tube Cancer, or Primary Peritoneal Cancer That Responded to Second-Line Chemotherapy</u>				
	<table border="1"> <tr> <td>Conditions:</td> <td>Fallopian Tube Cancer; Ovarian Cancer; Peritoneal Cavity Cancer</td> </tr> <tr> <td>Interventions:</td> <td>Biological: oregovomab; Drug: cyclophosphamide; Other: immunoenzyme technique; Other: laboratory biomarker analysis; Procedure: adjuvant therapy 2007</td> </tr> </table>	Conditions:	Fallopian Tube Cancer; Ovarian Cancer; Peritoneal Cavity Cancer	Interventions:	Biological: oregovomab; Drug: cyclophosphamide; Other: immunoenzyme technique; Other: laboratory biomarker analysis; Procedure: adjuvant therapy 2007
Conditions:	Fallopian Tube Cancer; Ovarian Cancer; Peritoneal Cavity Cancer				
Interventions:	Biological: oregovomab; Drug: cyclophosphamide; Other: immunoenzyme technique; Other: laboratory biomarker analysis; Procedure: adjuvant therapy 2007				

	<p>Primary Outcome: Serum human anti-murine antibodies (HAMA) as assessed by enzyme-linked immunosorbent assay (ELISA) at approximately 14 weeks after initial treatment. /Frequency and severity of adverse events as assessed by NCI CTCAE v3.0 [Designated as safety issue: Yes]</p> <p>Secondary Outcome: Serum HAMA and anti-idiotypic antibodies as assessed by ELISA over the course of treatment /Frequency and magnitude of patients who have a delayed-type hypersensitivity (DTH) response to oregovomab, tetanus, mumps, and Candida as assessed by DTH skin testing /Duration of time from first response to first recurrence. /Duration of time from second response to second recurrence</p> <p>RATIONALE: Monoclonal antibodies, such as oregovomab, can block tumor growth in different ways. Some block the ability of tumor cells to grow and spread. Others find tumor cells and help kill them or carry tumor-killing substances to them. Drugs used in chemotherapy, such as cyclophosphamide, work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. It is not yet known whether oregovomab is more effective when given together with or without cyclophosphamide in treating patients with stage III or stage IV ovarian epithelial cancer, fallopian tube cancer, or primary peritoneal cancer.</p>	
Recruiting	<p><u>Active Immunotherapy CEA Vaccine in Patients With Malignancies Expressing CEA</u></p> <p>Conditions: Colon Cancer; Lung Cancer; Breast Cancer</p> <p>Intervention: Biological: AD5 CEA Vaccine 2010</p>	<p>AD5 CEA Vaccine: Immunotherapy With Ad5[E1-,E2b-]-CEA Vaccine Expressing CEA. CEA-specific immune responses</p>
	<p>Primary: The primary objective of this protocol is to determine the safety of immunization with Ad5 [E1-, E2B-]-CEA(6D), in patients with advanced or metastatic CEA-expressing malignancies, including Maximum Tolerated Dose (MTD). [Time Frame: 1 Year]</p> <p>Secondary: The secondary objectives of this protocol are to evaluate CEA-specific immune responses to the immunizations and to obtain preliminary data on clinical response rate. [Time Frame: 1 Year]</p> <p>Detailed: This is a phase I/II study with the primary purpose to determine the safety of immunization with Ad5 [E1-, E2B-]-CEA(6D), in patients with advanced or metastatic CEA-expressing malignancies. The secondary objectives are to evaluate CEA-specific immune responses to the immunizations and to obtain preliminary data on clinical response rate. The study population consists of patients with a histologically confirmed diagnosis of metastatic malignancy that is CEA positive who were previously treated with standard therapy known to have a possible survival benefit or refused such therapy. The study will determine the safety of three dosage levels of Ad5 [E1-, E2B-]-CEA(6D) vaccine (phase I component), and the maximally tolerated dose of Ad5 [E1-, E2B-]-CEA(6D) vaccine (phase II component). The study drug is Ad5 [E1-, E2B-]-CEA(6D) given by subcutaneous (SQ) injection every 3 weeks for 3 immunizations. We will evaluate safety in each cohort at least 3 weeks after the last patient in the previous cohort has received their first injection. A dosing scheme will be considered safe if <33% of patients treated at a dosage level experience DLT (e.g. 0 of 3, <1 of 6, <3 of 12, or <5 of 18 patients).</p>	
Recruiting	<p><u>Ipilimumab +/- Vaccine Therapy in Treating Patients With Locally Advanced, Unresectable or Metastatic Pancreatic Cancer</u></p> <p>Condition: Pancreatic Cancer 2009</p> <p>Interventions: Drug: Ipilimumab; Biological: PANC 10.05 pcDNA-1/GM-Neo and PANC 6.03 pcDNA-1 neo vaccine</p>	<p>Ipilimumab + PANC 10.05 pcDNA-1/GM-Neo and PANC 6.03 pcDNA-1 neo vaccine OS, PFS, tumor marker kinetics (CA 19-9) in patients</p>
	<p>Purpose] Research Hypothesis: Ipilimumab (an antibody that blocks negative signals to T cells) administered alone or in combination with a pancreatic cancer vaccine (allogeneic pancreatic tumor cells transfected with a GM-CSF gene), has an acceptable safety profile in subjects with locally advanced, unresectable or metastatic pancreatic adenocarcinoma.</p> <p>Primary] Objective: To determine the safety profile of ipilimumab alone or in combination with a pancreatic cancer vaccine in subjects with locally advanced, unresectable or metastatic pancreatic adenocarcinoma.</p> <p>Secondary Objectives: To estimate overall survival (OS) which will serve as the primary efficacy signal. To explore an association of T cell responses and immunological responses with OS in patients receiving treatment. To estimate overall response rate (ORR), immune related best overall response rate (irBOR), progression free survival (PFS), and duration of response in patients receiving treatment. /To explore an association between immune-related adverse events (IRAEs) and ORR. To measure tumor marker kinetics (CA 19-9) in patients receiving treatment.</p>	

Recruiting	<u>Vaccination With Dendritic Cell/Tumor Fusions With Autologous Stem Cell Transplants in Patients With Multiple Myeloma</u>		Dendritic Cell Tumor Fusion: dendritic cell/myeloma fusions and GM-CSF
	Condition:	Multiple Myeloma	
	Intervention:	Biological: Dendritic Cell Tumor Fusion 2007	
	<p>Primary: To assess the toxicity associated with vaccination of multiple myeloma patients with dendritic cell/myeloma fusions and GM-CSF prior to stem cell mobilization and following high dose chemotherapy with stem cell rescue. [Time Frame: 5 years]</p> <p>Secondary: To determine whether tumor specific cellular and humoral immunity can be induced by serial vaccination with DC/tumor cell fusions in conjunction with high dose chemotherapy with stem cell rescue [Time Frame: 5 years]. /To determine if vaccination with DC/tumor cell fusions results in clinical disease response in patients with evidence of residual disease post-transplant [Time Frame: 5 years]. /To determine the time to disease progression in this participant population.</p> <p>Detailed Description:</p> <p>The first group of participants on this study will receive up to 3 monthly doses of the study vaccine beginning about 1 month following the autologous transplant. If this is found to be safe, the next group will receive one additional study vaccine prior to the transplant and then up to 3 doses after the transplant.</p> <p>If the screening tests determine that the participant is eligible for the study, they will undergo dendritic cell collection by a procedure called leukapheresis. Leukapheresis involves the collection of white blood cells from the blood. Dendritic cells are grown from these white blood cells in the laboratory. Tumor cells will also be collected from the bone marrow through a bone marrow aspirate/biopsy.</p> <p>After cells have been collected for study vaccine generation, the participant may receive standard therapy to reduce the number of multiple myeloma cells in the body. The specific regimen will be determined by the participants multiple myeloma physician.</p> <p>Prior to the autologous stem cell transplant, we will harvest stem cells from the participants blood that will be used for the transplant later. G-CSF will be given as a daily injection beginning the day after the chemotherapy and GM-CSF injections will be started seven days after the chemotherapy. These injections will continue until after the stem cells are collected. Approximately 10 days after the chemotherapy, participants will undergo a leukapheresis procedure to collect the stem cells. Within a few weeks of successful stem cell collection, the participant will be admitted for high dose chemotherapy with autologous stem cell transplantation.</p>		
Recruiting	<u>A Pilot Study of Vaccination With Epitope-Enhanced TARP Peptide and TARP Peptide-Pulsed Dendritic Cells in the Treatment of Stage D0 Prostate Cancer</u>		TARP 29-35 Peptide (Native) + TARP 29-37-9V Peptide Epitope Enhanced Peptide: vTARP peptide and TARP peptide-pulsed dendritic cell vaccination.
	Conditions:	Prostatic Neoplasms; Prostate Specific Antigens 2009	
	Interventions:	Drug: TARP 29-35 Peptide (Native Peptide); Drug: TARP 29-37-9V Peptide Epitope Enhanced Peptide	

	<p>Background: PSA (prostate specific antigen) is a protein found on normal and cancerous prostate cells. Levels of this protein are used to identify men who are at risk for prostate cancer and to monitor responses to treatment in men who have been diagnosed with prostate cancer. Research has shown that men who continue to have an elevated PSA level following primary treatment for prostate cancer are at increased risk for cancer progression. Studies have shown that the change in PSA levels over time, or PSA doubling time (PSADT), can be accurate in predicting how quickly the cancer is likely to progress. Individuals with a PSADT of less than 3 months are at extremely high risk for disease progression and death from prostate cancer. Individuals with a PSADT of greater than 15 months have a very low risk of death from prostate cancer.</p> <p>TARP is a protein that is found in about 95% of prostate cancers and is known to stimulate the immune system. The TARP prostate cancer vaccine is made from pieces of the TARP protein called peptides and includes peptides that have been modified to make them more effective at stimulating immunity. Although these TARP peptides have been shown to stimulate the immune systems of mice, information is needed to determine if they also stimulate the immune system in humans. Since it is unclear what is the best way to give peptide vaccines, the TARP peptides will be given with substances known to stimulate the immune system or in a vaccine made with the patient's own cells.</p> <p>Objectives: To determine the immune system's response to vaccination with TARP peptides. /To determine the safety and toxicity of TARP peptide vaccination. To determine if vaccination with the TARP prostate cancer vaccine can slow down PSADT in men with an intermediate PSADT of 3 to 15 months. /Eligibility: Males 18 years of age and older who have completed their primary treatment for prostate cancer, have stage D0 disease, are HLA A*0201 positive and who have a PSADT greater than 3 and less than 15 months.</p> <p>Design: Patients will be randomized to one of two treatment arms: /Arm A will receive the TARP vaccine with other substances that stimulate the immune system. Arm B will receive the TARP vaccine that includes a patient's own white blood cells. /First week of study, after screening for eligibility has been completed: Day 1: Apheresis procedure to extract white blood cells..</p>	
Recruiting	<p><u>Long Term Follow Up Of Patients Who Have Received Gene Therapy Or Gene Marked Products</u></p> <p>Conditions: Severe Combined Immunodeficiency; Malignancy, Hematologic; Neuroblastoma; Neoplasm;</p> <p>Intervention: Procedure: Venipuncture 2008</p>	Venipuncture: follow-up study Gene Therapy Or Gene Marked Products
	<p>Primary: Obtain histories for detection of significant delayed medical events including hematologic, malignant, autoimmune, and neurologic events in research participants who have received an integrating vector based gene therapy/gene marked product at SJCRH. [Time Frame: 30 years]</p> <p>This protocol serves as an umbrella protocol for long-term follow-up (LTFU) for recipients of gene therapy/gene marked (GT/GM) products at St. Jude Children's Research Hospital. The FDA has recommended methods to assess the risk of delayed adverse events after GT/GM and has provided specific requirements regarding the duration and design of LTFU observations. This protocol is intended to provide LTFU in accordance with the FDA guidelines for those who received a GT/GM product as part of a St. Jude-sponsored clinical trial or compassionate use treatment plan. The protocol calls for a physical examination or general health evaluation and collection of required blood samples annually for up to 15 years after the last receipt of a GT/GM product.</p>	
Completed	<p><u>Vaccine Therapy in Treating Patients With Stage III or Stage IV Ovarian Epithelial Cancer</u></p> <p>Condition: Ovarian Cancer 1999</p> <p>Interventions: Biological: BCG vaccine; Biological: autologous tumor cell vaccine; Drug: carboplatin; Drug: cisplatin; Drug: cyclophosphamide; Drug: paclitaxel; Other: dinitrophenyl; Procedure: surgical procedure</p>	autologous tumor cell vaccine with BCG/paclitaxel/cisplatin/cyclophosphamide

	<p>OBJECTIVES: I. Determine whether patients with surgically debulked ovarian epithelial cancer develop delayed-type hypersensitivity to dinitrophenyl-modified autologous tumor vaccine. II. Assess the toxic effects of this regimen in these patients. III. Determine the feasibility of conducting a group wide vaccine study.</p> <p>OUTLINE: Patients undergo a standard debulking procedure with the tumor tissue being sent to Thomas Jefferson University. Patients then receive six courses of combination chemotherapy consisting of either paclitaxel and cisplatin or paclitaxel and carboplatin. Vaccine therapy must commence within 4-12 weeks of completion of chemotherapy. Patients are tested for delayed-type hypersensitivity (DTH) on day -7. Cyclophosphamide IV is administered on day 0. Dinitrophenyl (DNP)-modified autologous ovarian epithelial cell vaccine and BCG adjuvant are injected once a week beginning on day 3 and continuing for 6 weeks. DTH testing is repeated at week 8. Booster vaccine injections are administered at 6 and 12 months if patient is disease free. Patients are followed every 3 months for 2 years, every 6 months for 3 years, and then annually thereafter.</p>	
Active, not recruiting	<u>Phase I/II Clinical Trial Combining hTERT Tumor Vaccine & Autologous T Cells in Patients With Advanced Myeloma</u>	
	Condition:	Multiple Myeloma 2008
	Interventions:	Biological: Telomerase (hTERT vaccine + pneumoccal conjugate vaccine (PCV)); Biological: PCV vaccine
	<p>Primary: Does combination therapy delay hematopoietic recovery or induce other autoimmune events. [Time Frame: 2 yrs] [Designated as safety issue: Yes]</p> <p>Secondary: Does combination therapy generate cytotoxic T-cell responses to autologous myeloma cells in-vivo. [Time Frame: 2 yrs]</p> <p>This protocol proposes to combine two different investigational products to test the hypothesis that autologous T cell therapy can augment the potency of a putative tumor vaccine post- stem cell transplant, and lead to a myeloma-directed T-cell mediated "graft vs. myeloma" effect in patients with advance myeloma. The hope is that this combination therapy approach will result in a more rapid recovery of acquired immunity and consequently increased cure rates and better clinical outcomes. The two investigational products to be evaluated in this Phase I/II study include:</p> <p>hTERT Vaccine (the putative tumor vaccine)- a multi-peptide vaccine consisting of 3 peptides against the catalytic subunit of telomerase (hTERT D988Y, I540, and R572Y), 1 survivin peptide (Sur1M2- an antiapoptotic protein), and 1 CMV (cytopeptide (N495).</p> <p>T cell therapy- T-cells isolated from the patient and activated/expanded ex vivo by antiCD3/28 beads.</p> <p>This is a two-site study at the University of Pennsylvania and University of Maryland to recruit a total of fifty-six study patients. The key eligibility criteria are patients who have systemic or multifocal myeloma requiring autologous stem cell transplantation. After enrollment, patients will be divided into two arms (A and B) according to their HLA A2 status (A = HLA A2 +, B = HLA A2-). Patients in ARM A will be initially immunized with the hTERT vaccine along with a pneumoccal conjugate vaccine (PCV); patients in ARM B will be initially immunized and given boosters of PCV only. All patients will undergo T-cell harvest, stem cell mobilization and</p>	
Completed	<u>Safety and Efficacy Study of HER2/Neu (E75) Vaccine in Node-Positive Breast Cancer Patients</u>	
	Condition:	Breast Cancer
	Intervention:	Biological: E75 + GM-CSF vaccine
Recruiting	<u>Pilot Study of Allogeneic Tumor Cell Vaccine With Metronomic Oral Cyclophosphamide and Celecoxib in Patients Undergoing Resection of Lung and Esophageal Cancers, Thymic Neoplasms, and Malignant Pleural Mesotheliomas</u>	
	Conditions:	Lung Cancer; Esophageal Cancer; Malignant Pleural Mesothelioma; Thymoma; Thymic Carcinoma
	Interventions:	Biological: Allogeneic Tumor Cell Vaccine (K562); Drug: Celecoxib; Drug: cyclophosphamide 2010
	<p>Allogeneic Tumor Cell Vaccine (K562): Tumor Cell Vaccine With Metronomic Oral Cyclophosphamide and Celecoxib as Adjuvant Therapy.</p>	

	<p>CP and celecoxib reduce the number, percentage and function of CD4+ CD25+ Fox P3+ regulatory T cells (T reg) in peripheral blood .</p> <p>Background: - Certain types of lung, esophageal, or thymic cancers and mesotheliomas have specific antigens (protein molecules) on their surfaces. Research studies have shown that giving a vaccine that contains antigens similar to these may cause an immune response, which may keep tumors from growing. Researchers are also interested in determining whether the chemotherapy drug cyclophosphamide and the anti-inflammatory drug celecoxib may help the vaccine work better, particularly in patients with lung cancer.</p> <p>Objectives:- To evaluate the safety and effectiveness of tumor cell vaccines in combination with cyclophosphamide and celecoxib in patients with cancers (chest).</p> <p>Eligibility: - Individuals at least 18 years of age who have had surgery for small cell or non-small cell lung cancer, esophageal cancer, thymoma or thymic carcinoma, and malignant pleural mesothelioma.</p> <p>Design: Following recovery from surgery, chemotherapy, or radiation, participants will have leukapheresis to collect lymphocytes (white blood cells) for testing. Participants will receive celecoxib and cyclophosphamide to take twice a day at home, 7 days before the vaccine. Participants will have the vaccine in the clinical center (one or two shots per month for 6 months), and will stay in the clinic for about 4 hours after the vaccine. Participants will keep a diary at home of any side effects from the vaccine, and will continue to take cyclophosphamide and celecoxib. One month after the sixth vaccine, participants will provide another blood sample for testing, and if the tests are satisfactory will return to the clinic every 3 months for 2 additional vaccines. Participants will return to clinic for follow-up physical examinations, lab tests, and scans every 3 months for 2 years and then every 6 months for up to 3 years.</p>	
Recruiting	<p>A Study of the CDX-1307 Vaccine Regimen in Patients With Newly Diagnosed Muscle-Invasive Bladder Cancer (The "N-ABLE" Study)</p> <p>Condition: Bladder Cancer</p> <p>Interventions: Drug: Gemcitabine + Cisplatin; Biological: CDX-1307 Vaccine Regimen 2010</p>	<p>CDX-1307 Vaccine Regimen: CDX-1307 vaccine co-administered with immune adjuvants (GM-CSF, Poly-ICLC and Resiquimod).</p>
	<p>Primary] : 2 year Recurrence-Free Survival Rate [Time Frame: 2 years following randomization] /The 2-year recurrence-free survival rate will be estimated for each treatment arm based on the proportion of patients who are classified as alive and without documented disease recurrence at this time point. Duration of Recurrence-Free Survival [Time Frame: Up-to 4 years after bladder removal surgery (cystectomy)] [Designated as safety issue: No] The duration of recurrence-free survival is defined as the number of months from randomization to the earlier of disease recurrence or death (whatever the cause).</p> <p>Secondary]: Tumor response to neoadjuvant chemotherapy [about 4 months post-randomization)] /The tumor response to neoadjuvant chemotherapy will be evaluated as the proportion of patients who achieve a radiographic response as defined by the Response Evaluation Criteria for Solid Tumors (RECIST 1.1) or a pathologic complete response at cystectomy. /Overall survival [Time Frame: Up-to 4 years following bladder removal surgery (cystectomy)] Overall survival is defined as the number of months from randomization to the date of death (whatever the cause).</p> <p>Safety / Tolerability [about 1 year post-resection)] The number and percentage of patients experiencing one or more adverse events will be summarized by treatment arm, relationship to study drug, and severity. Separate tabulations will be provided for the neoadjuvant and adjuvant treatment phases</p> <p>CDX-1307 is an experimental vaccine that is designed to generate an immune response against a protein called human chorionic gonadotropin-beta (hCGβ). hCG-β is made by several types of cancers, including bladder cancer, and has been shown to be associated with shorter times to development of metastases and reduced survival in bladder cancer. In this study, it is hoped that administering the CDX-1307 vaccine will cause the body's immune system to attack bladder cancer cells in order to kill them or otherwise keep them from spreading or coming back..</p>	

Recruiting	<u>Vaccine Therapy in Treating Patients With Non-Small Cell Lung Cancer (NSCLC) Stages IIIB/IV</u>		Recombinant Human rEGF-P64K/Montanide Vaccine:
	Condition:	Non-Small-Cell Lung Cancer (NSCLC) Stage IIIB/IV	
	Intervention:	Biological: Recombinant Human rEGF-P64K/Montanide Vaccine 2007	
	Purpose The purpose of this study is to determine whether the recombinant human EGF-rP64K/Montanide ISA 51 vaccine is safe, immunogenic and effective in the treatment of stage IIIB/IV non-small-cell lung cancer (NSCLC).		
Completed	<u>Phase I Study of CDX-1307, hCG-B Vaccine, for Patients With Incurable, Locally Advanced or Metastatic Breast, Colorectal, Pancreatic, Bladder or Ovarian Cancer</u>		CDX-1307: CDX1307 alone and with adjuvant. 2 years or until progression
	Conditions:	Breast Cancer; Colorectal Cancer; Pancreatic Cancer; Bladder Cancer; Ovarian Cancer	
	Intervention:	Biological: CDX-1307 2007	
	Protocol CDX1307-02: CDX-1307 is an investigational drug that is being tested to see if it can stimulate the immune system (the cells and substances that protect the body from infection and foreign matter) of people with certain kinds of cancer. It is believed that the body's immune system can attack tumor cells and kill them. It is thought that immune cells recognize special proteins on the surface of tumors as a signal to fight the cancer. One of these proteins is called human chorionic gonadotropin-beta (hCG-β) and is found on several types of cancers including breast, colorectal, pancreatic, bladder and ovarian. The study drug, CDX-1307, is given as an intravenous infusion (administered in a vein in the arm or through a port-a-catheter). In addition, the study includes combination therapies which are thought to stimulate the immune response against tumor cells. In addition, the study includes combination therapies which are thought to stimulate the immune response against tumor cells.		
Active, not recruiting	<u>GM-CSF Vaccinations After Allogeneic Blood Stem Cell Transplantation in Patients With Advanced Myeloid Malignancies</u>		GM-CSF secreting leukemia vaccine: GVAX vaccination as measured by grade III-IV acute GVHD, and CTC. disease free and overall survival
	Conditions:	Myelodysplastic Syndrome RAEB-I or RAEB-II; Refractory Acute Myeloid Leukemia; Refractory CML Myeloid Blast Crisis	
	Intervention:	Biological: GM-CSF secreting leukemia vaccine 2007	

	<p>This trial can be divided into three phases: 1) Pre-transplant phase; 2) Reduced intensity transplant phase; 3) Vaccination phase.</p> <p>Pre-transplant phase: Once a suitable donor has been identified, the participant will undergo a battery of standard pre-transplant tests and procedure to collect their leukemia cells for vaccine generation. Blood tests, heart function test, pulmonary function test, tuberculosis test, bone marrow aspirate and biopsy, and leukemia cell collection through leukapheresis.</p> <p>Allogeneic reduced intensity stem cell transplant phase: The transplant phase of the study will begin when the participant is admitted to the hospital to receive the chemotherapy and stem cell transplant. The minimum duration of hospitalization for the procedure is approximately 8 days. In the week before the participant receives the stem cells, they will be treated with chemotherapy through a central line. The goal of chemotherapy is to both control the cancer and suppress the immune system so that the body will not reject the donor stem cells.</p> <p>Just prior to and immediately following the infusion of stem cells, participants will receive medications to help prevent graft-versus-host disease (GVHD), a common complication of transplant where the donor's immune cells attack the body. After the transplant, participants will also take antibiotic medication to help prevent possible infections.</p> <p>Sargramostim (GM-CSF, leukine), a white blood cell growth factor, will be given daily subcutaneously starting the day after the stem cell transplant until blood counts have recovered.</p> <p>After the stem cell infusion, participants will be examined and have blood tests weekly for 1 month. Between 30-45 days after the transplant, a bone marrow biopsy will be performed to assess the status of the disease and to look for evidence of the donor's cells in the bone marrow.</p> <p>Vaccination Phase: After the bone marrow biopsy 30-45 days after the transplant, the participant will begin to receive the vaccinations. The vaccine will be administered subcutaneously and intradermally on the arm, leg, or abdomen 6 times over a period of 9 weeks. The first 3 vaccinations will occur once a week for 3 consecutive weeks, and the last 3 vaccines will be given once every other week over 6 weeks. All vaccinations may be given as an outpatient in the clinic. During this period of time, participants will be closely monitored on a weekly basis to monitor for side effects. Before the first and after the fifth and sixth vaccinations, a small amount of the participants leukemia cells will be injected under the skin to see if the immune system will react against it and cause redness and swelling.</p> <p>About 4 weeks after the last vaccination (6th), a bone marrow aspirate and biopsy will be performed to assess the status of the disease.</p> <p>After the 1st and 5th vaccinations, a skin biopsy will be performed to assess for response at the vaccine site. These biopsies are relatively simple outpatient procedures.</p>	
Terminated	<p><u>A Study of Stimuvax® in Combination With Hormonal Treatment Versus Hormonal Treatment Alone for First-line Therapy of Endocrine-sensitive Advanced Breast Cancer</u></p> <p>Condition: Breast Cancer</p> <p>Interventions: Biological: Stimuvax (L-BLP 25 or BLP25 liposome vaccine) and Hormonal Treatment; Biological: Placebo of Stimuvax (L-BLP 25 or BLP25 liposome vaccine) and Hormonal Treatment; Drug: cyclophosphamide; Drug: sodium chloride 2009</p>	<p>Stimuvax (L-BLP 25 or BLP25 liposome vaccine) vs. Placebo of Stimuvax (L-BLP 25 or BLP25 liposome vaccine): PFS</p>
	<p>Primary: Progression-Free Survival (PFS) time will be analyzed as the main measure of treatment outcome. PFS time is defined as the the duration from randomization to first observation of PD by the independent radiologic review or death. [Time Frame: first assessment (of PFS) after 15 month; then on an ongoing basis]</p> <p>Secondary: Measurement Response Evaluation Criteria in Solid Tumours (RECIST) [every 8 weeks The purpose of the study is to determine whether the addition of the experimental cancer vaccine Stimuvax to hormonal treatment is effective in prolonging progression-free survival in postmenopausal women with endocrine-sensitive inoperable locally advanced, recurrent or metastatic breast cancer.</p>	
Active, not recruiting	<p><u>Study of NY-ESO-1 ISCOMATRIX® in Patients With Measurable Stage III or IV Melanoma</u></p> <p>Condition: Melanoma</p> <p>Interventions: Biological: NY-ESO-1 ISCOMATRIX® vaccine; Drug: Cyclophosphamide 2007</p>	<p>NY-ESO-1 ISCOMATRIX® vaccine: (100 microgram of NY-ESO-1 protein formulated with 120 microgram of ISCOMATRIX® adjuvant)</p>

	<p>Objective tumor response (RECIST criteria). DTH skin reactions, antibodies and T cell responses against NY-ESO-1.</p> <p>Detailed Description: This clinical trial cohort tests the combination of NY-ESO-1 ISCOMATRIX® vaccine given after low dose cyclophosphamide in patients with advanced melanoma. NY-ESO-1 protein is an immune target found in many cancers including melanoma. ISCOMATRIX® adjuvant enhances immune responses. Low dose cyclophosphamide has been shown to suppress a population of lymphocytes called "regulatory T cells". Regulatory T cells can interfere with immune responses in patients with cancer. The rationale for treating this new cohort of patients in the study is to use a small dose of cyclophosphamide to suppress the regulatory T cells and thus try to increase patient responses to the NY-ESO-1 ISCOMATRIX® vaccine. Eligible patients will receive three intramuscular injections of NY-ESO-1 ISCOM® vaccine at approximately four-week intervals (week 1, week 5, week 9). Low dose cyclophosphamide will be administered by intravenous infusion one day prior to the each NY-ESO-1 ISCOM® vaccine. Tumor evaluations (CT scans and physical evaluations), safety evaluation (blood tests and medical reviews) and immunological testing (special DTH skin tests and blood immunology tests) will be performed before, during and at the end of the 11 week treatment cycle. Treatment may continue for further cycles unless there is a reason to remove the patient from study</p>					
Completed	<p><u>A Study of CDX-1307, in Patients With Incurable Breast, Colorectal, Pancreatic, Ovarian or Bladder Cancer (CDX 1307-01)</u></p> <table border="1"> <tr> <td>Conditions:</td> <td>Breast Cancer; Colorectal Cancer; Pancreatic Cancer; Bladder Cancer; Ovarian Cancer</td> </tr> <tr> <td>Intervention:</td> <td>Biological: CDX1307 2008</td> </tr> </table>	Conditions:	Breast Cancer; Colorectal Cancer; Pancreatic Cancer; Bladder Cancer; Ovarian Cancer	Intervention:	Biological: CDX1307 2008	<p>CDX1307: Mannose Receptor-Targeted hCG-β Vaccine. utilizes fully human monoclonal antibodies to directly target specialized types of immune system cells, known as antigen presenting cells. APC Targeting Technology</p>
Conditions:	Breast Cancer; Colorectal Cancer; Pancreatic Cancer; Bladder Cancer; Ovarian Cancer					
Intervention:	Biological: CDX1307 2008					
	<p>Protocol CDX1307-01: CDX-1307 is an investigational drug that is being tested to see if it can stimulate the immune system (the cells and substances that protect the body from infection and foreign matter) of people with certain kinds of cancer. It is believed that the body's immune system can attack tumor cells and kill them. It is thought that immune cells recognize special proteins on the surface of tumors as a signal to fight the cancer. One of these proteins is called human chorionic gonadotropin-beta (hCG-β) and is found on several types of cancers including breast, colorectal, pancreatic, bladder and ovarian. The study drug will be given as an injection under the skin (an intradermal or intracutaneous injection). In addition, the study includes combination with TLR agonists, which are thought to stimulate the immune response against tumor cells.</p>					
Active, not recruiting	<p><u>Study of NY-ESO-1 ISCOMATRIX® in Patients With High-Risk, Resected Melanoma</u></p> <table border="1"> <tr> <td>Condition:</td> <td>Melanoma</td> </tr> <tr> <td>Interventions:</td> <td>Biological: NY-ESO-1 ISCOMATRIX®; Biological: ISCOMATRIX® adjuvant 2005</td> </tr> </table>	Condition:	Melanoma	Interventions:	Biological: NY-ESO-1 ISCOMATRIX®; Biological: ISCOMATRIX® adjuvant 2005	<p>NY-ESO-1(protein) ISCOMATRIX® with ISCOMATRIX® adjuvant: Relapse-free Survival. NY-ESO-1 immunity</p>
Condition:	Melanoma					
Interventions:	Biological: NY-ESO-1 ISCOMATRIX®; Biological: ISCOMATRIX® adjuvant 2005					
	<p>Primary: - Rate of Relapse-free Survival at 18 months. [Time Frame: 18 months] Secondary : Safety [Time Frame: 18 months] /NY-ESO-1 immunity [Time Frame: 18 months] /Relapse-free Survival and Overall Survival</p> <p>Detailed Description: NY-ESO-1 protein is an immune target found in many cancers including melanoma. ISCOMATRIX® adjuvant enhances immune responses. This trial compares NY-ESO-1 ISCOMATRIX® vaccine with ISCOMATRIX® adjuvant alone to assess whether treatment with NY-ESO-1 ISCOMATRIX® vaccine improves outcomes for participants with Malignant Melanoma which has been removed, but is at high risk of recurrence. Eligible participants are randomly allocated to a treatment arm. Treatment involves four intramuscular (into a muscle) injections (1 injection every 4 weeks x 3, plus 1 injection at 6 months). Participants are assessed for recurrence of melanoma, safety and immune responses (by blood test) over the 18 month study period. Off study, their own doctor will</p>					

Completed	<u>Phase II Feasibility Study of Dendritic Cell Vaccination for Newly Diagnosed Glioblastoma Multiforme</u>		Autologous Dendritic Cell: Adjuvant Intra-nodal Autologous Dendritic Cell Vaccination. Outcomes: measurable tumor-specific cytotoxic T-cell response + Time Frame: MRI OS, PFS
	Condition:	Glioblastoma Multiforme	
	Interventions:	Biological: Autologous Dendritic Cell; Drug: Temozolomide; Procedure: Radiotherapy; Biological: Dendritic Cell Vaccine. 2006	
	<p>Primary: To determine whether intranodal injection of an autologous glioma lysate-derived dendritic cell vaccine will result in a measurable tumor-specific cytotoxic T-cell response. /</p> <p>Secondary: To determine feasibility and toxicity profile of intra-nodal DC/tumor lysate vaccination in this context /To compare the progression free survival and overall survival with prognostic matched historical controls [Time Frame: PFS will be assessed for each patient as the time from surgery until the patient reaches objective disease progression by MRI]. /To correlate the immunological parameters with PFS and overall survival [Time Frame: Evaluable patients for immunologic parameters are those who have completed 3 vaccines]. /To assess radiological response when there is residual enhancing tumor at baseline MRI</p>		
Completed	<u>Safety Study of NY-ESO-1 Protein Vaccine to Treat Cancer Expressing NY-ESO-1</u>		protein vaccination: Immunization With Complex of NY-ESO-1 Protein and Cholesterol-bearing Hydrophobized Pullulan NY-ESO-1-specific immune responses
	Condition:	Neoplasms	
	Intervention:	Biological: protein vaccination 2005	
	<p>NY-ESO-1 was isolated by serological analysis of recombinant cDNA expression libraries (SEREX), using tumor mRNA and autologous serum from an esophageal cancer patient. Reverse transcription-polymerase chain reaction (RT-PCR) analysis showed that NY-ESO-1 displayed the typical expression pattern of CT antigens. NY-ESO-1 mRNA was expressed only in testis of normal tissues tested and in various types of cancer, including lung cancer, breast cancer, malignant melanoma and bladder cancer. LAGE-1 was identified by the representational difference analysis and revealed to display 84% amino acid homology with NY-ESO-1. In most cases, expression of LAGE-1 parallels the expression of NY-ESO-1. Since testis is an immune privileged organ where HLA molecules are not expressed, these antigens can be considered tumor-specific.</p> <p>Because of frequent NY-ESO-1 mRNA expression and high immunogenicity in advanced cancer, NY-ESO-1 is an attractive target molecule for a cancer vaccine. Current therapies against advanced cancer have limited effectiveness. The idea of vaccination with NY-ESO-1 protein in cancer patients with tumors expressing NY-ESO-1 mRNA is based on two findings: 1) the number of CD8+ T cell epitopes identified in NY-ESO-1 molecule are limited to those binding to HLA-A0201, A31, Cw3 and Cw6. These HLA subtypes are carried by a minor Japanese population; 2) CD8+ T cell responses specific to NY-ESO-1 are polyclonal. Protein vaccination may induce immune response more effectively against tumors expressing NY-ESO-1 than peptide immunization</p>		
Completed	<u>Dendritic Cell Based Therapy of Malignant Melanoma</u>		tumor antigen loaded autologous dendritic cells: Autologous Dendritic Cells Pulsed With Tumor Antigens. immune response and clinical response
	Condition:	Advanced Melanoma	
	Intervention:	Biological: tumor antigen loaded autologous dendritic cells 2005	
	<p>Eligible patients receive vaccination with tumor antigen pulsed autologous monocyte-derived mature dendritic cells with a fixed interval. The dendritic cells are generated from leukapheresis products and frozen after antigen loading.</p> <p>HLA A2 positive patients are treated with PADRE and oncopeptide pulsed DC; p53, survivin and telomerase peptides. HLA A2 negative patients are treated with KLH and tumorlysate pulsed DC; autologous or allogeneic. Each patient is given 6 immunizations with at least 5x10⁶ peptide/lysate pulsed autologous DC. Vaccination 1-4 is given weekly and 4-6 at 2-week intervals. Those patients who exhibit stable disease, partial response or complete response after 6 injections will be given 4 more vaccinations at 2-week interval. The vaccine is applied by intradermal injection near the inguinal region.</p> <p>IL-2 2 MIU s.c. day 2-6, Cyclophosphamide (Sendoxan®, Baxter A/S) 50 mg twice a day bi-weekly and 200 mg Celecoxib (Celebra®, Pfizer) daily are used. Scans and re-staging tests are performed at scheduled intervals throughout the study</p>		
Active, not recruiting	<u>Immunotherapy With TG4010 in Patients With Advanced Non-Small Cell Lung Cancer</u>		MVA-MUC1-IL2: Vaccine TG4010(MVA-MUC1-IL 2) as an Adjuvant to Standard
	Condition:	Carcinoma, Non-Small-Cell Lung	

	<p>Intervention: Biological: MVA-MUC1-IL2:: a cancer vaccine based on a modified vaccinia virus expressing MUC1 (108 pfu) and interleukin-2, in combination with cytokines, PFS, OS 2006</p>	<p>MUC1-IL2 as an Adjuvant to Standard Chemotherapy.</p>
	<p>In the experimental arm patients receive subcutaneous injections of TG4010 at the dose of 108 pfu in combination with chemotherapy treatment whereas patients in the control arm receive chemotherapy alone. The chemotherapy associates cisplatin and gemcitabine and is given for up to 6 cycles or progressive disease, whichever occurs first. TG4010 is administered once per week for 6 weeks, then once every 3 weeks in combination with chemotherapy and thereafter as monotherapy until documentation of progressive disease. Tumor response will be evaluated every 6 weeks by a CT-scan and results will be available before starting an additional treatment period of 6 weeks. The tumor response taken into account will be for each patient the best overall response obtained during the study. The endpoint of the study is based on Progression Free Survival (PFS) at 6 months</p>	
<p>Active, not recruiting</p>	<p><u>A Phase I Study of NY-ESO-1 Overlapping Peptides (OLP4) Immunoadjuvants Montanide and Poly-ICLC Vaccination of Epithelial Ovarian Cancer (EOC), Fallopian Tube, or Primary Peritoneal Cancer Patients in Second or Third Remission</u></p> <p>Conditions: Epithelial Ovarian Cancer; Fallopian Tube Cancer; Primary Peritoneal Cancer</p> <p>Interventions: Biological: NY-ESO-1 OLP4; Biological: NY-ESO-1 OLP4 + Montanide; Biological: NY-ESO-1 OLP4 + Montanide + Poly-ICLC 2008</p>	<p>NY-ESO-1 OLP4 / NY-ESO-1 OLP4 + Montanide / NY-ESO-1 OLP4 + Montanide + Poly-ICLC :NY-ESO-1 Overlapping Peptides (OLP4) With or Without Immunoadjuvants Montanide and Poly-ICLC Vaccination</p>
	<p>Immune response (NY-ESO-1 antibody, CD4+ and CD8+ cells) Cohort I (n=3) will receive NY-ESO-1 OLP4 by subcutaneous injection once every 3 weeks (weeks 1, 4, 7, 10, and 13) for a total of 5 vaccinations. At week 16 patients will return for final toxicity and immunologic assessments. If 0/3 DLT's are seen in Cohort I, this arm will be considered safe and accrual for this arm will stop. If 1/3 patients experience a DLT (as defined in section 11), then 3 further patients will be accrued. If 1/6 experience a DLT this arm will be considered safe. If >1/6 patients in this arm experience a DLT then this arm will not be considered safe, and accrual for the study will stop. If this arm is considered safe we will proceed to Cohort II. Cohort II (n=3 + 6) will receive NY-ESO-1 OLP in combination with Montanide immune adjuvant by subcutaneous injections, once every 3 weeks (weeks 1, 4, 7, 10, and 13) for a total of 5 vaccinations. At week 16 patients will return for final toxicity and immunologic assessments. If 0/3 initial patients experience a DLT we will add 6 further patients to this arm at the same dose and schedule described above, for a total of 9 patients. If 1/3 patients have a DLT, we will accrue 3 further patients at this dose and schedule. If 1/6 have a DLT this arm will be considered safe, and 3 further patients will be tested. Cohort III will begin accrual after 6 patients in cohort II have received all 5 vaccinations with no more than one DLT observed (this criterion has already been met in the study). Cohort III (n=3 + 6) will receive NY-ESO-1 OLP mixed with Poly-ICLC immunoadjuvant emulsified in Montanide by subcutaneous injections, once every 3 weeks (weeks 1, 4, 7, 10, and 13) for a total of 5 vaccinations. At week 16, patients will return for final toxicity and immunologic assessments. If 0/3 initial patients in Cohort III experience a DLT, 6 more patients will added to this for a total of 9 evaluable patients. If 1/3 initial patients have a DLT, then 3 more patients will be accrued in cohort III. If 1/6 patients have a DLT, then this arm will be considered safe, and 3 further patients will be accrued. Patient's vital signs will be monitored for one hour following each vaccination, The three cohorts will be accrued sequentially. Cohort I will be accrued directly. Cohort II will begin accrual when at least one patient in cohort I has received all 5 vaccinations. Cohort III will begin accrual after 6 patients in cohort II have received all 5 vaccinations with no more than one DLT observed (this criterion has already been met in the study).</p>	
<p>Active, not recruiting</p>	<p><u>Open Label Study of Sipuleucel-T</u></p> <p>Condition: Prostate Cancer</p> <p>Intervention: Drug: Sipuleucel-T Dendreon Comp. 2009</p>	<p>Sipuleucel-T: consists of autologous peripheral blood mononuclear cells (PBMCs), including antigen presenting cells (APCs), that have been activated in vitro with a recombinant fusion protein.</p>

	<p>Magnitude of immune responses</p> <p>Detailed Description: Subjects will receive the investigational product, sipuleucel-T, at approximately 2-week intervals, for a total of 3 infusions. The study will evaluate the safety of and magnitude of the immune responses to treatment with sipuleucel-T. All subjects will be followed for 30 days following the last infusion of sipuleucel-T. The study is also available to placebo subjects who participated in the D9902B study</p>	
Recruiting	<p><u>To Evaluate Sipuleucel-T Manufactured With Different Concentrations of PA2024 Antigen</u></p> <p>Condition: Prostate Cancer</p> <p>Intervention: Biological: Sipuleucel-T</p>	<p>Sipuleucel-T: Evaluate Sipuleucel-T Manufactured With Different Concentrations of PA2024 Antigen.</p>
	<p>CD54 upregulation ratio between each of the cohorts. magnitude of the immune response in each of the cohorts. OS.</p> <p>This is a multicenter, single blind, Phase 2 study. Subjects will receive the investigational product, sipuleucel-T, manufactured with 1 of 3 different concentrations of PA2024 antigen. The purpose of this study is to compare the changes in CD54 upregulation between each of these 3 groups of subjects. The study will also evaluate the levels of immune response, the length of survival, the role of circulating tumor cell levels in the blood, and changes in quality of life in each of the 3 groups of subjects. All subjects will be blinded to their cohort assignment to ensure unbiased completion of the quality of life (QOL) questionnaires. All subjects will be followed for this study for the remainder of their lives</p>	
Completed	<p><u>A Study of ZYC300 Administered With Cyclophosphamide Pre-Dosing</u></p> <p>Conditions: Breast Cancer; Ovarian Cancer; Prostate Cancer; Colon Cancer; Renal Cancer</p> <p>Intervention: Drug: Cyclophosphamide & ZYC300 (ZYC300 with cyclophosphamide pre-dosing) 2006 Eisai Comp.</p>	<p>Cyclophosphamide & ZYC300 (ZYC300 with cyclophosphamide pre-dosing): a plasmid encoding an inactivated form of the CYP1B1 DNA..</p>
	<p>Outcome: T reg number and function. generation of CYP1B1-specific immun.</p> <p>This is an open-label study of ZYC300 in the treatment of advanced stage malignancy of the kidney in patients who have not had previous immune-based therapies or treatment of advanced stage malignancies (cancerous growths) of the ovary, breast, colon, or hormone-refractory prostate in patients who have failed at least one but no more than two prior regimens of chemotherapy. Patients who meet all entry criteria will be administered 600 mg/m² cyclophosphamide intravenously 3 days before each dose of ZYC300. ZYC300 will be administered at 400 micrograms DNA/total dose every two weeks for a maximum of six doses (6 cycles). ZYC300 is a plasmid DNA formulated within biodegradable microencapsulated particles. This is the first time that ZYC300 and Cyclophosphamide will be given together. Cyclophosphamide is a chemotherapy drug approved by the FDA that has been used for many years in many different kinds of cancer. In this trial the study drug will be used to boost the immune system. Sometimes the immune system cannot fight infected or abnormal cells because of other cells called T reg cells. The T reg cells limit the immune systems attack on infected or abnormal cells. In this study, the hope is that Cyclophosphamide will inhibit the T regs cells so that the ZYC300 can work better to attack the cancer cells.</p>	
Completed	<p><u>Safety and Immune Response to a Multi-component Immune Based Therapy (MKC1106-PP) for Patients With Advanced Cancer</u></p> <p>Conditions: Ovarian; Melanoma; Renal; Prostate; Colorectal; Endometrial Carcinoma; Cervical Carcinoma; Testicular Cancer; Thyroid Cancer; Small Cell Lung Carcinoma; Mesothelioma; Breast Carcinoma; Esophageal Carcinoma; Gastric Cancer; Pancreatic Carcinoma; Neuroendocrine Cancer; Liver Cancer; Gallbladder Cancer; Biliary Tract Cancer; Anal Carcinoma; Bone Sarcomas; Soft Tissue Sarcomas;</p> <p>Intervention: Biological: PSMA/PRAME Mannkind Corporation 2007</p>	<p>PSMA/PRAME: DNA Vector pPRA-PSM With Synthetic Peptides E-PRA and E-PSM. Outcome: immunologic response to MKC1106-PP. blood plasmid levels by PCR. cytokine levels</p>
	<p>The majority of tumors are ignored by the immune system and it was thought for a long time that tumor antigens did not exist. However, recently a number of tumor antigens have been described. These antigens reside on cancer cells and can be recognized by specific T-cells which can ultimately attack and destroy the tumor.</p>	
Completed	<p><u>A Phase II Trial of CG 8020 and CG 2505 in Patients With Nonresectable or Metastatic Pancreatic Cancer</u></p>	<p>CG 8020 and CG 2505: pancreas tumor cell</p>

	<table border="1"> <tr> <td>Conditions:</td> <td>Metastatic Pancreatic Cancer; Nonresectable Pancreatic Cancer</td> </tr> <tr> <td>Intervention:</td> <td>Biological: CG 8020 and CG 2505 2005</td> </tr> </table>	Conditions:	Metastatic Pancreatic Cancer; Nonresectable Pancreatic Cancer	Intervention:	Biological: CG 8020 and CG 2505 2005	vaccine (pancreas GVAX, CG-8020 +. CG-2505; 5 x 10 ⁸ cells)		
Conditions:	Metastatic Pancreatic Cancer; Nonresectable Pancreatic Cancer							
Intervention:	Biological: CG 8020 and CG 2505 2005							
	<p>Outcome: PFS. and CA 19-9 serum marker levels. To evaluate clinical and laboratory safety of CG 8020 and CG 2505 and to evaluate the efficacy of CG 8020 and CG 2505 as measured by clinical benefit response, progression-free survival, survival and CA 19-9 serum marker levels in chemotherapy naive or experienced patients with nonresectable or metastatic adenocarcinoma of the pancreas</p>							
Completed	<table border="1"> <tr> <td colspan="2"><u>Phase II Trial of Allovectin-7® for Head and Neck Cancer</u></td> </tr> <tr> <td>Conditions:</td> <td>Head and Neck Cancer; Squamous Cell Carcinoma of the Oral Cavity or Oropharynx; Head and Neck Neoplasms; Carcinoma of the Head and Neck</td> </tr> <tr> <td>Intervention:</td> <td>Genetic: Allovectin-7® 2002-2008</td> </tr> </table>	<u>Phase II Trial of Allovectin-7® for Head and Neck Cancer</u>		Conditions:	Head and Neck Cancer; Squamous Cell Carcinoma of the Oral Cavity or Oropharynx; Head and Neck Neoplasms; Carcinoma of the Head and Neck	Intervention:	Genetic: Allovectin-7® 2002-2008	Allovectin-7®: a first-in-class DNA-based immunotherapeutic designed to stimulate both innate and adaptive immune responses
<u>Phase II Trial of Allovectin-7® for Head and Neck Cancer</u>								
Conditions:	Head and Neck Cancer; Squamous Cell Carcinoma of the Oral Cavity or Oropharynx; Head and Neck Neoplasms; Carcinoma of the Head and Neck							
Intervention:	Genetic: Allovectin-7® 2002-2008							
	<p>Treatment - If you take part in this trial you will be treated for about four weeks. You will receive an injection of Allovectin-7® by needle, directly into your tumor. This will be repeated 14 days later. The injections may be given in a doctor's office. A week later, you will undergo surgery to remove the tumor. Your tumor will be measured before Allovectin-7® treatment and before surgery to see if Allovectin-7® was effective in shrinking it. This will be done by general physical exams and scans (such as X-ray scans). There will also be tests on the removed tumor to see if Allovectin-7® helped to boost the immune system to attack the cancer</p>							
Recruiting	<table border="1"> <tr> <td colspan="2"><u>A Study of CDX-1401 in Patients With Malignancies Known to Express NY-ESO-1</u></td> </tr> <tr> <td>Condition:</td> <td>Advanced Malignancies</td> </tr> <tr> <td>Intervention:</td> <td>Biological: CDX-1401 in combination with Resiquimod and/or Poly-ICLC 2009</td> </tr> </table>	<u>A Study of CDX-1401 in Patients With Malignancies Known to Express NY-ESO-1</u>		Condition:	Advanced Malignancies	Intervention:	Biological: CDX-1401 in combination with Resiquimod and/or Poly-ICLC 2009	CDX-1401 in combination with Resiquimod and/or Poly-ICLC: a novel antibody-based targeted cancer vaccine CR/PR, (CR/PR/SD)
<u>A Study of CDX-1401 in Patients With Malignancies Known to Express NY-ESO-1</u>								
Condition:	Advanced Malignancies							
Intervention:	Biological: CDX-1401 in combination with Resiquimod and/or Poly-ICLC 2009							
	<p>NY-ESO-1 is a protein that is often made by some types of tumor cells, but only made by a few types of normal cells. Because it is primarily made by cancer cells, the NY-ESO-1 protein is a promising target against which to stimulate an immune response that may destroy cancer cells. CDX-1401 is a cancer vaccine that is specially designed to create this type of immune response. To enhance the immune response, CDX-1401 will be given with 1 or 2 immune stimulants called Resiquimod and poly-ICLC (Hiltonol). This clinical trial includes Phase 1 and Phase 2 segments. During the Phase 1 segment, five groups of 6 to 9 patients will be treated with different dose levels of CDX-1401 in combination with either one or both of the immune stimulants (Resiquimod and/or poly-ICLC). This phase of the study will test the safety profile of the vaccine treatment, and will assess which dose to test in future studies. During the Phase 2 segment, 11 patients whose cancer tested positive for the NY-ESO-1 protein in laboratory testing, will receive the study treatment to determine if it has an effect on their cancer. All patients enrolled in either part of the study may continue to receive study treatment until their disease has progressed or until it is necessary to stop the treatment for safety or other reasons. In addition, all patients will be "followed" for 24 months after enrollment in order to collect survival information.</p>							
Active, not recruiting	<table border="1"> <tr> <td colspan="2"><u>Study of Stimuvax in Patients With Slowly Progressive Multiple Myeloma With no Symptoms and Who Have Had no Chemotherapy</u></td> </tr> <tr> <td>Condition:</td> <td>Multiple Myeloma</td> </tr> <tr> <td>Interventions:</td> <td>Biological: L-BLP25, cyclophosphamide prior to first vaccination; Biological: L-BLP25 2010</td> </tr> </table>	<u>Study of Stimuvax in Patients With Slowly Progressive Multiple Myeloma With no Symptoms and Who Have Had no Chemotherapy</u>		Condition:	Multiple Myeloma	Interventions:	Biological: L-BLP25, cyclophosphamide prior to first vaccination; Biological: L-BLP25 2010	L-BLP25, cyclophosphamide prior to first vaccination: a synthetic MUC1 peptide (25mer) vaccine
<u>Study of Stimuvax in Patients With Slowly Progressive Multiple Myeloma With no Symptoms and Who Have Had no Chemotherapy</u>								
Condition:	Multiple Myeloma							
Interventions:	Biological: L-BLP25, cyclophosphamide prior to first vaccination; Biological: L-BLP25 2010							
	<p>Primary: Anti-MUC1 T-cell response [Time Frame: 2 years] [Designated as safety issue: No] Secondary : Various immune response measurements, also in relation to HLA subtypes as available from the various assessment visits [every 6 weeks]. /Objective clinical response (CR,PR,MR) as defined to Blade criteria over the whole study treatment period until progression disease [every 6 weeks]. /Time to progression including the whole study treatment period until progression of disease [every 6 weeks]. /Time to anti-tumor therapy including whole study treatment period and survival follow-up period until anti-tumor therapy is required [Time Frame: every 6 weeks .</p>							

Active, not recruiting	<u>IMA910 Plus GM-CSF With Low-dose Cyclophosphamide Pre-treatment in Advanced Colorectal Carcinoma Patients Following a Successful 12 Week First-line Treatment With Oxaliplatin-based Chemotherapy (IMA910-101)</u>		Endoxana, Leukine, IMA910 Endoxana, Leukine, IMA910, Aldara. single agent with GM-CSF in combination with imiquimod following pre-treatment with low-dose cyclophosphamide screening a CT or MRI of the chest, CR, PR
	Condition:	Colorectal Carcinoma	
	Interventions:	Drug: Endoxana, Leukine, IMA910; Drug: Endoxana, Leukine, IMA910, Aldara	
	<p>This study is being conducted in order determine whether IMA910 as single agent with GM-CSF as adjuvant following pre-treatment with low-dose cyclophosphamide is safe and shows sufficient anti-tumour effectiveness in patients with advanced CRC to warrant further development. Secondary objectives of this study are investigation of immunological parameters and additional effectiveness endpoints. Furthermore, safety, immunological parameters and effectiveness of IMA910 as single agent with GM-CSF in combination with imiquimod following pre-treatment with low-dose cyclophosphamide will be investigated in a 2nd cohort of patients.</p> <p>The regular study duration for individual patients in the 1st and 2nd cohort comprises regularly 18-42 days of screening (excluding HLA-typing), 33 weeks of treatment (16 vaccinations) and 4 weeks follow-up. Thus, the period between start of screening and end of trial is about 10 months per patient. Patients will be followed for response to subsequent treatments (chemotherapies with or without targeted agents) and survival every 2 months after EOS visit until death. Patients in the 1st and 2nd cohort will be withdrawn from study treatment once a progress according to RECIST is noted. An enrolment plan for the first 6 patients included into the 1st cohort will be part of this study to ensure maximum safety of the study participants. The enrollment of the first 6 patients into the 2nd cohort will also follow an enrolment plan to ensure maximum safety.</p>		
Recruiting	<u>Study of a DNA Immunotherapy to Treat Melanoma</u>		SCIB1: a DNA Immunotherapy, Cellular immune response. Tumour response
	Condition:	Malignant Melanoma	
	Intervention:	Biological: SCIB1 2010	
	<p>The study is an investigation of a novel immunotherapy, SCIB1, for the treatment of melanoma. SCIB1 is a solution of plasmid DNA molecules which will express a modified antibody in human cells. The antibody modifications are designed to stimulate the patient's immune T cells to have a strong and specific reaction against melanoma cells which should then be eliminated. SCIB1 is injected into muscle using a device which simultaneously delivers an electrical impulse to enhance the transfer of SCIB1 into muscle cells. The trial will assess the safety and tolerability of SCIB1, the safety and performance of the injection device and the immunological effects of SCIB1. This is the first study of SCIB1 in humans and the trial has two parts, in the first part the dose will be escalated to determine a safe and tolerable level up to a maximum of 4 mg per dose. In the second part patients will receive the dose determined in the first part. All patients will receive 5 injections of SCIB1 over 5.5 months. Patients will have stage III or IV melanoma, be HLA type A2 and have a life expectancy of at least three months. The study will be conducted at major cancer centres in the UK only and is expected to last for two years. Patients will be followed up for five years after they have completed the trial.</p> <p>Biological: SCIB1: Aqueous solution of plasmid DNA administered by intramuscular injection using the TDS-IM electroporation device (Ichor Medical Systems, Inc.) at weeks 0, 2, 6, 12 and 24. Part 1 of the study will escalate through 0.4, 0.8 and 4.0 mg dose levels to each of the patients. In Part 2 of the study, the</p>		
Completed	<u>Human Leukocyte Antigen (HLA) – A*2402 Restricted Peptide Vaccine Therapy in Patients With Advanced Gastric Cancer</u>		peptide vaccine: HLA-A*2402 Restricted Epitope Peptides Driven From URLC10.
	Condition:	Gastric Cancer	
	Intervention:	Biological: peptide vaccine 2009	

	<p>Efficacy evaluated by RECIST. Immunological responses.</p> <p>URLC10 has been identified as cancer specific molecules especially in non small cell lung cancer using genome-wide expression profile analysis by cDNA microarray technique. In a prior study, it has been shown that URLC10 are upregulated in esophageal cancer and gastric cancer and other cancer. The investigators identified that peptides derived from these proteins significantly induce the effective tumor specific CTL response in vitro. According to these findings, in this trial, the investigators evaluate the safety, immunological and clinical response of URLC10 peptide vaccine in the patients with gastric cancer. Patients will be vaccinated once in one week to the eighth vaccine and will be vaccinated once in two weeks from the ninth vaccine. On each vaccination day, the URLC10 peptide (1mg) mixed with Montanide ISA 51 will be administered by endodermic injector</p>	
Completed	<p><u>Human Leukocyte Antigen (HLA) – A*2402 Restricted Peptide Vaccine Therapy in Patients With Advanced Esophageal Cancer</u></p> <p>Condition: Esophageal Cancer</p> <p>Intervention: Biological: URLC10 2008</p>	<p>URLC10: HLA–A*2402 Restricted Epitope Peptides Drived From URLC10.</p>
	<p>Feasibility as evaluated by RECIST. Immunological responses.</p> <p>URLC10 have been identified as cancer specific molecules especially in non small cell lung cancer using genome-wide expression profile analysis by cDNA microarray technique. In a prior study, it has been shown that URLC10 are upregulated in human esophageal tumors. The investigators identified that peptides derived from these proteins significantly induce the effective tumor specific CTL response in vitro. According to these findings, in this trial, we evaluate the safety, immunological and clinical response of URLC10 peptide. Patients will be vaccinated once in one week to the eighth vaccine and will be vaccinated once in two weeks from the ninth vaccine. On each vaccination day, the URLC10 peptide (1mg) mixed with Montanide ISA 51 will be administered by endodermic injection</p>	
Completed	<p><u>Vaccine Therapy With or Without Donor Lymphocyte Infusion in Treating Patients With Acute Mveloid Leukemia, Acute Lymphoblastic Leukemia, or Multiple Myeloma Undergoing Donor Stem Cell Transplant</u></p> <p>Conditions: Leukemia; Multiple Myeloma and Plasma Cell Neoplasm</p> <p>Interventions: Biological: autologous tumor cell vaccine; Biological: peripheral blood lymphocyte therapy 2007</p>	<p>autologous tumor cell vaccine/ peripheral blood lymphocyte therapy: Donor Lymphocyte Infusions and Autologous Tumor Vaccines After HLA-Matched Transplant.</p>
	<p>OS, Tolerated dose of donor lymphocytes.</p> <p>RATIONALE: Vaccines made from the patient's cancer cells may help the body build an effective immune response to kill cancer cells. Giving vaccine therapy together with donor lymphocyte infusion after a stem cell transplant from the patient's brother or sister may kill any cancer cells that remain after transplant.</p> <p>PURPOSE: This clinical trial is studying the side effects, best dose, and how well vaccine therapy with or without donor lymphocyte infusion works in treating patients with acute myeloid leukemia, acute lymphoblastic leukemia, or multiple myeloma undergoing donor stem cell transplant.</p>	
Recruiting	<p><u>Reactogenicity Study of Cervarix and Gardasil in UK Adolescent Girls</u></p> <p>Condition: HPV Infections</p> <p>Interventions: Biological: Cervarix; Biological: Gardasil</p>	<p>Cervarix/Gardasil: UK Adolescent Girls Receiving CervarixTM or GardasilTM Human Papillomavirus Vaccines</p>
Active, not recruiting	<p><u>Cytotoxicity Induced by Tumor Lysate Pulsed Dendritic Cells Against Autologous Hepatocellular Carcinoma Cells</u></p> <p>Condition: Carcinoma, Hepatocellular</p> <p>Intervention: Biological: DC vaccine 2006</p>	<p>DC vaccine:</p>

	<p>Hepatoma ranks the first on the cancer mortality list in Taiwan, and there are currently no other effective treatment options for advanced HCC. Therefore, alternative medical intervention is needed to improve the survival and quality of life of these patients. Dendritic cells are the most potent type of antigen presenting cells in the human body, and are involved in the regulation of both innate and adoptive immune responses. If we use matured antigen presenting cells pulsed in vitro with appropriate tumor associated antigens under optimal activation conditions. It is anticipated that such treatment might generate or reactivate a cytotoxic T lymphocyte response against tumor cells and thereby inhibit tumor growth.</p> <p>Although there are excited results of tumor vaccine in animal models but successful clinical tries are rare. There are still some problems needed to be resolved such as immune deficiency of the cancer patients or the defect of T cell receptors or the problems of tumor escape. There are complex compositions in tumor cells to be a tumor antigen that will influence the efficacy of tumor vaccine, so we are going to use tumor lysate to be a tumor antigen.</p> <p>In this study, the generation of dendritic cells from the patient's peripheral blood will use rhGM-CSF and rhIL-4 as stimulating factors, and matured dendritic cells will pulse with tumor lysate, the ex vivo T cell cytotoxicity for the primary tumor cell will be test. We hope to cooperate with basic study group in our hospital to do more ex vivo tests and clinical trials in the future.</p>	
Active, not recruiting	<p><u>Vaccine Therapy Compared With Interferon Alfa in Treating Patients With Stage III Melanoma</u></p>	
	<p>Condition: Melanoma (Skin)</p> <p>Interventions: Biological: BCG vaccine; Biological: autologous tumor cell vaccine; Biological: recombinant interferon alfa; Drug: chemotherapy; Drug: cyclophosphamide 1999</p>	<p>BCG vaccine/autologous tumor cell vaccine/rIFN alfa: DNP-Modified Autologous Tumor Vaccine or IFN-Alpha-2b.</p>
	<p>OBJECTIVES: I. Compare the relapse-free and overall survival rates in patients with stage III melanoma treated with autologous tumor vaccine versus interferon alfa-2b as postsurgical adjuvant therapy. II. Compare the safety and tolerability of these regimens in this patient population.</p> <p>OUTLINE: This is a randomized, open-label, multicenter study. Patients are stratified according to number of metastatic lymph node sites (1 vs more than 1), number of positive lymph nodes in a single site (none vs 1 or more), presence of intransit metastases (yes vs no), and evidence of extranodal extension (yes vs no). Patients are randomized to one of two treatment arms. Arm I: Patients receive autologous tumor cell vaccine intradermally once a week for 7 weeks followed by a booster injection at 6 months. BCG is given concurrently with vaccine as an immune-stimulator for doses 2-8. Patients also receive cyclophosphamide 6 days after the first vaccine injection. Arm II: Patients receive interferon alfa-2b IV for 5 consecutive days a week for 4 weeks followed by maintenance doses given subcutaneously 3 times a week for 48 weeks. Patients are followed monthly for 1 year, every 2 months for 1 year, every 3 months for 1 year, and then every 6 months for 2 years.</p> <p>PROJECTED ACCRUAL: A total of 386-425 patients will be accrued for this study.</p>	
Recruiting	<p><u>Vaccine Therapy in Treating Patients With Stage III, Stage IV, or Relapsed Non-Small Cell Lung Cancer Treated With First-Line Chemotherapy</u></p>	
	<p>Condition: Lung Cancer</p> <p>Intervention: Biological: Ad100-gp96Ig-HLA A1 2007</p>	<p>Ad100-gp96Ig-HLA A1: Novel Tumor Vaccine gp96-Ig Fusion Protein. gp96-vaccineと比較gp96-Ig and HLA A1 transfected Non-Small Cell Lung Cancer cell</p>
	<p>Immunoresponse: CD8, CD4 and NK response.</p> <p>Overall Goals:- to evaluate the safety and induction of anti-tumor immunity by administration of an immunogenic human tumor cell vaccine, and assess immune response in relation to clinical outcome.</p> <p>Primary:- to evaluate the safety of administering a heat shock protein gp96-Ig-secreting allogeneic tumor cell-vaccine (gp96-Ig vaccine) in patients with advanced NSCLC.</p> <p>Secondary Aims:to study the immune response to vaccination, to monitor clinical responses and to recommend a dose-schedule combination for further testing in an initial Phase II trial of vaccine efficacy.</p>	
Active, not recruiting	<p><u>Vaccine and Chemotherapy for Previously Untreated Metastatic Breast Cancer</u></p>	
	<p>Conditions: Breast Neoplasms; Metastases, Neoplasm</p>	<p>recombinant fowlpox-CEA(6D)/TRICOM vaccineと recombinant vaccinia-</p>

	<p>Interventions: Biological: recombinant fowlpox-CEA(6D)/TRICOM vaccine; Biological: recombinant vaccinia-CEA(6D)/TRICOM vaccine; Biological: filgrastim; Biological: sargramostim; Drug: cyclophosphamide; Drug: doxorubicin hydrochloride; Drug: fludarabine phosphate; Drug: paclitaxel 2002</p>	CEA(6D)/TRICOM vaccine.G-CSF, GM-CSF Clinical evaluation and tumor measurements by imaging +OS
	<p>This study will evaluate the effectiveness of chemotherapy and a combination of vaccines to treat metastatic breast cancer (breast cancer that has spread beyond the breast) in patients whose cancer cells have a protein called CEA on their surface. Patients who require surgery or radiation therapy, or both, will receive these treatments as well.</p> <p>Patients 18 years of age and older with previously untreated metastatic breast cancer may be eligible for this study. Newly diagnosed patients may not have received prior chemotherapy. Patients previously diagnosed with local disease may have received chemotherapy or radiation therapy at least 18 months before entering the current study. Patients may have received hormonal therapy for stage IV disease. Candidates are screened with a medical history and physical examination, blood and urine tests, x-rays, heart and lung tests, and a test to determine the presence of CEA on their tumor cells.</p> <p>Participants undergo the following procedures:</p> <p>Central venous line: Under local or general anesthesia, an intravenous catheter (plastic tube) is inserted into a major vein in the chest. It is used to give chemotherapy and other medications and to withdraw blood samples.</p> <p>Apheresis: Before beginning treatment and at various times before and after chemotherapy, patients undergo apheresis to collect white blood cells for later re-infusion at the time of immunizations and to evaluate the body's response to the vaccines. For this procedure, blood is collected through the central venous catheter and circulated through a machine that separates the white cells from the rest of the blood. The white cells are removed and frozen for later use. The rest of the blood is returned to the patient through the catheter.</p> <p>First vaccine: Before starting chemotherapy, patients receive one subcutaneous (under the skin) injection of a vaccine called rV-CEA-Tricom, along with subcutaneous injections of GM-CSF (Sargramostim), a drug that stimulates the bone marrow to release white blood cells and white cell precursors into the bloodstream.</p> <p>Chemotherapy: Taxol (paclitaxel)/Cytoxan (cyclophosphamide): Patients receive three to five cycles of Taxol and Cytoxan. Taxol is given as a continuous 72-hour intravenous (IV, through a vein) infusion and Cytoxan is given daily for 3 days, intravenously, over 1 hour. Cycles are 21 to 42 (usually 28) days. After each cycle, patients also receive G-CSF (a drug that helps boost white cell</p>	
Active, not recruiting	<p><u>Phase II Study of CDX-110 in Patients With Glioblastoma Multiforme</u></p> <p>Condition: Malignant Glioma</p> <p>Interventions: Drug: CDX-110 with GM-CSF; Drug: temozolomide 2007</p>	CDX-110 (tumor specific molecule called EGFRvIII.) with GM-CSF:
	<p>PFS, Immune response; antibody response to vaccine. Immune response; HLA typing. OS.</p> <p>This study is designed to evaluate the clinical activity of CDX-110 vaccination when given with standard of care treatment (maintenance temozolomide therapy). Study treatment will be given until disease progression and patients will be followed for long-term survival information. Efficacy will be measured by the progression-free survival status at 5.5 months from the date of first dose.</p>	
Active, not recruiting	<p><u>Monoclonal Antibody Therapy in Treating Patients With Ovarian Epithelial Cancer, Melanoma, Acute Myeloid Leukemia, Myelodysplastic Syndrome, or Non-Small Cell Lung Cancer</u></p> <p>Conditions: Leukemia; Lung Cancer; Melanoma (Skin); Myelodysplastic Syndromes; Myelodysplastic/Myeloproliferative Neoplasms; Ovarian Cancer</p> <p>Intervention: Biological: ipilimumab 2002</p>	ipilimumab: Anti-Cytotoxic T-Lymphocyte-Associated Antigen-4 (Anti-CTLA-4) Humanized Monoclonal Antibody. Biologic activity by radiology and pathology every 2 months

	<p>OBJECTIVES:Determine the safety of anti-cytotoxic T-lymphocyte-associated antigen-4 monoclonal antibody in patients with ovarian epithelial cancer, melanoma, acute myeloid leukemia, myelodysplastic syndromes, or non-small cell lung cancer not previously treated with sargramostim (GM-CSF)-based autologous tumor vaccines. Determine, preliminarily, the biologic activity and efficacy of this drug in these patients.</p> <p>OUTLINE: Patients receive anti-cytotoxic T-lymphocyte-associated antigen-4 monoclonal antibody IV over 90 minutes on day 1. Courses repeat every 2 months in the absence of disease progression or unacceptable toxicity. Patients are followed monthly until disease progression.</p>	
Completed	<p><u>Safety and Immunological Response Rate Study of THERATOPE® Vaccine in Metastatic Breast Cancer Patients</u></p> <p>Condition: Breast Neoplasms</p> <p>Intervention: Drug: THERATOPE® vaccine 2002</p>	<p>THERATOPE® vaccine: consists of a synthetic version of the tumor-associated antigen Sialyl Tn (STn) linked to the protein carrier, keyhole limpet hemocyanin (KLH),</p>
	<p>The purpose of this study is to examine the immunological response rate to administration of the THERATOPE® vaccine in women with stable metastatic breast cancer who are being treated with aromatase inhibitors or Faslodex® and who do not require chemotherapy. Post-menopausal women on aromatase inhibitors or Faslodex® alone and pre-menopausal women on aromatase inhibitors plus luteinising hormone-releasing hormone (LH/RH)-agonist may be eligible to be enrolled. Patients must not have had radiotherapy or major surgery within four (4) weeks prior to entering the study. Information about the safety and tolerability of administration of the THERATOPE® vaccine will also be gathered during the course of the study.</p>	
Recruiting	<p><u>Novel Adjuvants for Peptide-Based Melanoma Vaccines</u></p> <p>Condition: Melanoma</p> <p>Intervention: Biological: MDX-CTLA4 Antibody; Tyrosinase/gp100/MART-1 Peptides Melanoma Vaccine 2002</p>	<p>MDX-CTLA4 Antibody; Tyrosinase/gp100/MART-1 Peptides Melanoma Vaccine. The peptides are tyrosinase 368-376 (370D); gp100 209-217 (210M); and MART-1 26-35 (27L)</p>
	<p>In the Phase I/II trial, patients with resected stages III and IV melanoma who have been rendered free of disease, but are at high risk of relapse, are treated with peptides/IFA at a dose of 0.5 mg each peptide plus CTLA-4 antibody given intravenously, 3 mg/kg, after each vaccination. In the Phase II randomized study, patients are treated with the melanoma peptide vaccine alone, with CTLA-4 antibody, or with CTLA-4 antibody combined with IL-12 at 30 ng/kg with alum. The peptides are tyrosinase 368-376 (370D); gp100 209-217 (210M); and MART-1 26-35 (27L) which are emulsified with IFA. The dosing schedule for both trials are at 1, 2, 3, 4, 5, and 6 months; then at 9 and 12 for a total of 8 vaccinations.</p>	
Recruiting	<p><u>Lentivirus Transduced Acute Myeloid Leukaemia Blasts Expressing B7.1 (CD80) and IL-2</u></p> <p>Condition: Leukemia, Myeloid, Acute</p> <p>Interventions: Biological: RFUSIN2-AML1; Biological: Donor leukocyte infusion (DLI); Biological: RFUSIN2-AML1 and donor leukocyte infusion 2008</p>	<p>RFUSIN2-AML1 vs. Donor leukocyte infusion (DLI), vs. RFUSIN2-AML1 and donor leukocyte infusion. Lentivirus Transduced Acute Myeloid Leukaemic Cells (AML) Expressing B7.1 (CD80) and IL-2 for the Potential Enhancement of Graft Versus</p>
Completed	<p><u>An Open Label Study of a Peptide Vaccine in Patients With Stage III Colon Cancer</u></p> <p>Conditions: Colonic Neoplasms; Colorectal Neoplasms</p> <p>Intervention: Biological: EP2101 2007</p>	<p>EP2101: Safety and Tolerance Study of EP2101 Peptide Vaccine</p>
	<p>EP2101 is a new cancer vaccine containing 10 different peptide antigens. The vaccine is designed to activate the immune system to develop a response against tumor cells in order to delay or prevent the recurrence of cancer. This study will test the safety and measure the level of immune stimulating capability of EP2101 in patients with Colon Cancer.</p>	