

	<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	Vaccine Therapy in Treating Patients With Non-Small Cell Lung Cancer (NSCLC) Stages IIIB/IV		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	Phase I Study of CDX-1307, hCG-B Vaccine, for Patients With Incurable, Locally Advanced or Metastatic Breast, Colorectal, Pancreatic, Bladder or Ovarian Cancer		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	GM-CSF Vaccinations After Allogeneic Blood Stem Cell Transplantation in Patients With Advanced Myeloid Malignancies		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>A Study of Stimuvax® in Combination With Hormonal Treatment Versus Hormonal Treatment Alone for First-line Therapy of Endocrine-sensitive Advanced Breast Cancer</p> <table border="1" data-bbox="257 967 1628 1082"> <tr> <td>Condition:</td> <td>Breast Cancer</td> </tr> <tr> <td>Interventions:</td> <td>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</td> </tr> </table>	Condition:	Breast Cancer	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>Stimuvax (L-BLP 25 or BLP25 liposome vaccine) vs. Placebo of Stimuvax (L-BLP 25 or BLP25 liposome vaccine): PFS</p>
Condition:	Breast Cancer					
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>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>Study of NY-ESO-1 ISCOMATRIX® in Patients With Measurable Stage III or IV Melanoma</p> <table border="1" data-bbox="257 1301 1628 1376"> <tr> <td>Condition:</td> <td>Melanoma</td> </tr> <tr> <td>Interventions:</td> <td>Biological: NY-ESO-1 ISCOMATRIX® vaccine; Drug: Cyclophosphamide 2007</td> </tr> </table>	Condition:	Melanoma	Interventions:	Biological: NY-ESO-1 ISCOMATRIX® vaccine; Drug: Cyclophosphamide 2007	<p>NY-ESO-1 ISCOMATRIX® vaccine: (100 microgram of NY-ESO-1 protein formulated with 120 microgram of ISCOMATRIX® adjuvant)</p>
Condition:	Melanoma					
Interventions:	Biological: NY-ESO-1 ISCOMATRIX® vaccine; Drug: Cyclophosphamide 2007					

	<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	A Study of CDX-1307, in Patients With Incurable Breast, Colorectal, Pancreatic, Ovarian or Bladder Cancer (CDX 1307-01)		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
	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	Study of NY-ESO-1 ISCOMATRIX® in Patients With High-Risk, Resected Melanoma		NY-ESO-1(protein) ISCOMATRIX® with ISCOMATRIX® adjuvant: Relapse-free Survival. NY-ESO-1 immunity
	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]</p> <p>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	Phase II Feasibility Study of Dendritic Cell Vaccination for Newly Diagnosed Glioblastoma Multiforme		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	Safety Study of NY-ESO-1 Protein Vaccine to Treat Cancer Expressing NY-ESO-1		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	Dendritic Cell Based Therapy of Malignant Melanoma		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	Immunotherapy With TG4010 in Patients With Advanced Non-Small Cell Lung Cancer		MVA-MUC1-IL2: Vaccine TG4010(MVA-MUC1-IL 2) as an Adjuvant to Standard
	Condition:	Carcinoma, Non-Small-Cell Lung	

	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	MUC1-IL2 as an adjuvant to standard chemotherapy.
	<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.</p> <p>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.</p> <p>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.</p> <p>The endpoint of the study is based on Progression Free Survival (PFS) at 6 months</p>		
Active, not recruiting	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		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
	Conditions:	Epithelial Ovarian Cancer; Fallopian Tube Cancer; Primary Peritoneal Cancer	
	Interventions:	Biological: NY-ESO-1 OLP4; Biological: NY-ESO-1 OLP4 + Montanide; Biological: NY-ESO-1 OLP4 + Montanide + Poly-ICLC 2008	
	<p>Immune response (NY-ESO-1 antibody, CD4+ and CD8+ cells)</p> <p>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 be 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>		
Active, not recruiting	Open Label Study of Sipuleucel-T		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.
	Condition:	Prostate Cancer	
	Intervention:	Drug: Sipuleucel-T Dendreon Comp. 2009	

	<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>To Evaluate Sipuleucel-T Manufactured With Different Concentrations of PA2024 Antigen</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>A Study of ZYC300 Administered With Cyclophosphamide Pre-Dosing</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>Safety and Immune Response to a Multi-component Immune Based Therapy (MKC1106-PP) for Patients With Advanced Cancer</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>A Phase II Trial of CG 8020 and CG 2505 in Patients With Nonresectable or Metastatic Pancreatic Cancer</p>	<p>CG 8020 and CG 2505: pancreas tumor cell</p>

	<p>Conditions: Metastatic Pancreatic Cancer; Nonresectable Pancreatic Cancer</p> <p>Intervention: Biological: CG 8020 and CG 2505 2005</p>	vaccine (pancreas GVAX, CG-8020 +. CG-2505; 5 x 10 ⁸ cells)
	<p>Outcome: PFS. and CA 19-9 serum marker levels.</p> <p>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	<p>Phase II Trial of Allovectin-7® for Head and Neck Cancer</p> <p>Conditions: Head and Neck Cancer; Squamous Cell Carcinoma of the Oral Cavity or Oropharynx; Head and Neck Neoplasms; Carcinoma of the Head and Neck</p> <p>Intervention: Genetic: Allovectin-7® 2002-2008</p>	Allovectin-7®: a first-in-class DNA-based immunotherapeutic designed to stimulate both innate and adaptive immune responses
	<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	<p>A Study of CDX-1401 in Patients With Malignancies Known to Express NY-ESO-1</p> <p>Condition: Advanced Malignancies</p> <p>Intervention: Biological: CDX-1401 in combination with Resiquimod and/or Poly-ICLC 2009</p>	CDX-1401 in combination with Resiquimod and/or Poly-ICLC: a novel antibody-based targeted cancer vaccine (CR/PR). (CR/PR/SD)
	<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).</p> <p>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	<p>Study of Stimuvax in Patients With Slowly Progressive Multiple Myeloma With no Symptoms and Who Have Had no Chemotherapy</p> <p>Condition: Multiple Myeloma</p> <p>Interventions: Biological: L-BLP25, cyclophosphamide prior to first vaccination; Biological: L-BLP25 2010</p>	L-BLP25, cyclophosphamide prior to first vaccination: a synthetic MUC1 peptide (25mer) vaccine
	<p>Primary: Anti-MUC1 T-cell response [Time Frame: 2 years] [Designated as safety issue: No]</p> <p>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	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)		Endoxana, Leukine, IMA910
	Condition:	Colorectal Carcinoma	Endoxana, Leukine, IMA910, Aldara. single agent with GM-CSF in combination with imiquimod following pre-treatment with low-dose cyclophosphamide
	Interventions:	Drug: Endoxana, Leukine, IMA910; Drug: Endoxana, Leukine, IMA910, Aldara	screening a CT or MRI of the chest, CR, PR
	<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	Study of a DNA Immunotherapy to Treat Melanoma		SCIB1: a DNA Immunotherapy,
	Condition:	Malignant Melanoma	Cellular immune response. Tumour response
	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, 4, 6 and 8. Part 1 of the study will escalate through 0.1, 0.2, 0.4 and 1.0 mg dose level cohorts, each of three patients. In Part 2 of the study the</p>		
Completed	Human Leukocyte Antigen (HLA) – A*2402 Restricted Peptide Vaccine Therapy in Patients With Advanced Gastric Cancer		peptide vaccine: HLA-A*2402 Restricted Epitope Peptides Drived 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>Human Leukocyte Antigen (HLA) – A*2402 Restricted Peptide Vaccine Therapy in Patients With Advanced Esophageal Cancer</p> <p>Condition: Esophageal Cancer</p> <p>Intervention: Biological: URLC10 2008</p>	URLC10: HLA–A*2402 Restricted Epitope Peptides Drived From URLC10.
	<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>Vaccine Therapy With or Without Donor Lymphocyte Infusion in Treating Patients With Acute Myeloid Leukemia, Acute Lymphoblastic Leukemia, or Multiple Myeloma Undergoing Donor Stem Cell Transplant</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>	autologous tumor cell vaccine/ peripheral blood lymphocyte therapy: Donor Lymphocyte Infusions and Autologous Tumor Vaccines After HLA–Matched Transplant.
	<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>Reactogenicity Study of Cervarix and Gardasil in UK Adolescent Girls</p> <p>Condition: HPV Infections</p> <p>Interventions: Biological: Cervarix; Biological: Gardasil</p>	Cervarix/Gardasil: UK Adolescent Girls Receiving Cervarix™ or Gardasil™ Human Papillomavirus Vaccines
Active, not recruiting	<p>Cytotoxicity Induced by Tumor Lysate Pulsed Dendritic Cells Against Autologous Hepatocellular Carcinoma Cells</p> <p>Condition: Carcinoma, Hepatocellular</p> <p>Intervention: Biological: DC vaccine 2006</p>	DC vaccine: