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| | •Percentage of Participants With Immune-Related Adverse Events (irAEs) [ Time Frame: On-study adverse events include all AEs reported between the first dose and 70 days after the last dose of study therapy (end of the study was defined as the time at which 481 deaths were observed [264 weeks]). ] [ Designated as safety issue: Yes ]<br>An immune related adverse event (irAE) was defined as an adverse event of unknown etiology, associated with study drug exposure and consistent with an immune phenomenon. The irAEs were programmatically determined from a predefined list of MedDRA version 12.0 high-level group terms, high-level terms and preferred terms of all ipilimumab related adverse event. The category of "Other irAEs" includes blood, eye, immune, infections, renal, and respiratory systems.<br>•Percentage of Participants With Worst On-Study Hematological Abnormalities [ Time Frame: On-study laboratory results are results reported after the first dose date and within 70 days of last dose of study therapy (end of the study was defined as the time at which 481 deaths were observed [264 weeks]). ] [ Designated as safety issue: Yes ]<br>ANC=Absolute Neutrophil Count. CTCAE v3.0 Grades 0 through 4 of severity for each AE based on this general guideline: Grade 0=Normal, Grade 1=Mild AE, Grade 2=Moderate AE, Grade 3=Severe AE, Grade 4=Life-threatening or disabling AE.<br>•Percentage of Participants With Worst On-Study Liver Abnormalities [ Time Frame: On-study adverse events include all AEs reported between the first dose and 70 days after the last dose of study therapy (end of the study was defined as the time at which 481 deaths were observed [264 weeks]). ] [ Designated as safety issue: Yes ]<br>ALT=alanine aminotransferase; AST=aspartate aminotransferase. CTCAE v3.0 Grades 0 through 4 of severity for each AE based on this general guideline: Grade 0=Normal, Grade 1=Mild AE, Grade 2=Moderate AE, Grade 3=Severe AE, Grade 4=Life-threatening or disabling AE.<br>•Percentage of Participants With Worst On-Study Renal Abnormalities [ Time Frame: On-study adverse events include all AEs reported between the first dose and 70 days after the last dose of study therapy (end of the study was defined as the time at which 481 deaths were observed [264 weeks]). ] [ Designated as safety issue: Yes ]<br>CTCAE v3.0 Grades 0 through 4 of severity for each AE based on this general guideline: Grade 0=Normal, Grade 1=Mild AE, Grade 2=Moderate AE, Grade 3=Severe AE, Grade 4=Life-threatening or disabling AE.<br>•Clinically Meaningful Changes in Vital Signs and Physical Examinations [ Time Frame: vital signs and physical examination were evaluated at screening and at Weeks 1, 4, 7, 10, 12, 16, 20, 24, 28, 36, and every 3 months thereafter ] [ Designated as safety issue: Yes ]<br>Clinically meaningful changes were according to investigator. Vital sign measurements include height, weight, temperature, pulse, and resting systolic and diastolic blood pressure. |
| Recruiting | Vaccine Therapy in Treating Patients Who Have Undergone a Donor Stem Cell Transplant and Have Cytomegalovirus Infection That Has Not Responded to Therapy |
| | Condition: Cancer |
| | Interventions: Biological: cytomegalovirus pp65-specific cytotoxic T lymphocytes; Genetic: polymerase chain reaction; Other: flow cytometry; Other: immunologic technique; Other: laboratory biomarker analysis |
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| Completed | Complementary Testing to Evaluate Immunogenicity of Human Papillomavirus (HPV) Vaccine (580299) in Healthy Female |
| Has Results | Conditions: Human Papillomavirus (HPV) Infection; Cervical Neoplasia |
| | Interventions: Biological: Placebo; Biological: Cervarix TM |
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| Completed | Vaccine Responses to Influenza A H1N1/09 Immunization in High-risk Patients | |
| | Conditions: HIV Infection; Rheumatic Disease; Cancer; Transplant; Pediatrics | |
| | Intervention: Biological: Adjuvanted influenza A(H1N1) vaccines | |
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| Recruiting | An Assessment of an Attenuated Live Listeria Vaccine in CIN 2+ | |
| | Condition: Cervical Intraepithelial Neoplasia (2010-2012) | |
| | Interventions: Biological: ADXS11-001 (Lm-LLO-E7); Drug: Placebo Control | |
| | Cervical cancer is associated with Human Papilloma Virus. About 57% of cervical cancer is the result of infection by Human Papilloma Virus strain 16 (HPV-16). HPV is a very common virus that can affect the cells of the cervix. E7 is a substance that is made by the HPV virus which causes cervical cancer. The purpose of the study is to test the safety, tolerability (how the drug makes you feel), immunology (effects on the immune system) and efficacy (disease curing effects) of a vaccine called Lovaxin C against E7. The vaccine is designed to cause the immune system to react against the E7 substance in a manner that is intended to reverse the changes to the cervix and prevent cervical cancer from occurring.<br>**Primary:** •The primary end point will be a histologic determination of whether CIN 2/3 present at entry had regressed. [11 months]<br>**Secondary:** •Secondary efficacy endpoints include whether HPV DNA was reduced or eliminated and a comparison of their excised cervical tissue controls to assess the extent of disease in treated vs. untreated patients. [ Time Frame: 11 months ]<br>Biological: ADXS11-001 (Lm-LLO-E7)<br>ADXS11-001 at one of three dose levels given as 3 vaccinations separated by 4 weeks with an oral antibiotic regimen subsequent to dosing.<br>Biological: ADXS11-001 (Lm-LLO-E7)<br>ADXS11-001 at one of three dose levels given as 3 vaccinations separated by 4 weeks with an oral antibiotic regimen subsequent to dosing.<br>Biological: ADXS11-001 (Lm-LLO-E7)<br>ADXS11-001 at one of three dose levels given as 3 vaccinations separated by 4 weeks with an oral antibiotic regimen subsequent to dosing.<br>Drug: Placebo Control<br>3 intravenous infusions of normal saline at 28 day intervals. All infusions will be preceded by prophylactic NSAID and antihistamine, and followed 3d later with antibiotic. | |
| Recruiting | HSPPC-96 Vaccine With Temozolomide in Patients With Newly Diagnosed GBM | |
| | Condition: Brain and Central Nervous System Tumors 2009-2012 | |
| | Intervention: Biological: HSPPC-96 | |

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| | The Phase 2 trial is a single-arm investigation designed to evaluate safety, survival, and immune response in patients treated with an**autologous tumor-derived heat shock protein peptide-complex** (HSPPC-96) administered at **25 µg per dose injected intradermally once weekly for 4 consecutive weeks** and monthly following standard treatment with radiation and temozolomide<br>**Primary:** •To evaluate the safety profile of HSPPC-96 administered concurrently temozolomide in patients with newly diagnosed GBM. [ Time Frame: survival ] • Survival Time [ Time Frame: survival ]<br>**Secondary** : •To evaluate the immunologic response to vaccine treatment [ Time Frame: survival ]<br>•Progression Free Survival from date of surgical resection [ Time Frame: survival ]<br>**Biological: HSPPC-96**<br>Patients will receive 4 weekly injections of HSPPC-96 followed by a 5th vaccine injection on the same day of the start of maintenance temozolomide administered 2 weeks (+ 4 days) following vaccine administration #4 on the same day of the start of maintenance temozolomide (Day 36). Monthly vaccine injections will then begin on day 21 (+/- 7 days) of the first 28 day temozolomide cycle (Day 56 of the study)3 weeks following vaccine administration #5 and will continue every 28 days until depletion of vaccine or progression.<br>Immune monitoring will be completed pre-operatively, intra-operatively, 48-hours post-surgery, prior to vaccine administration #1, at prior to vaccine administration #5 and at weeks 09, 13, 37 and 53.<br>The total volume of each vaccine or place provided is 0.47 mL. The total volume that should be administered is 0.4 mL (0.07 mL overage).<br>Other Name: Heat Shock Criteria: **Inclusion Criteria:** Pre-surgery tissue acquisition Inclusion criteria. 2.Life expectancy of greater than 12 weeks. |
| Completed | Vaccine Therapy Plus Sargramostim Following Chemotherapy in Treating Patients With Stage III or Stage IV Non-Hodgkin's<br>Condition: Lymphoma 2000-2010<br>Interventions: Biological: keyhole limpet hemocyanin; Biological: sargramostim; Biological: tumor cell-based vaccine therapy |

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| | RATIONALE: Drugs used in chemotherapy use different ways to stop tumor cells from dividing so they stop growing or die. Vaccines may make the body build an immune response to kill tumor cells. Sargramostim may stimulate a person's immune system and help to kill tumor cells.<br>PURPOSE: Phase II trial to study the effectiveness of vaccine therapy plus sargramostim following chemotherapy in treating patients who have stage III or stage IV non-Hodgkin's lymphoma.<br>Detailed Description:<br>OBJECTIVES: I. Determine the ability of recombinant idiotype immunotherapy to stimulate a specific immune response against the B cell idiotype of the malignant clone that constitutes the tumor in patients with previously untreated stage III or IV indolent non-Hodgkin's lymphoma. II. Determine the safety and toxicity of this treatment regimen using Genitope Corporation's molecular rescue technology in this patient population.<br>OUTLINE: Patients receive induction chemotherapy consisting of oral cyclophosphamide, vincristine, and prednisone (CVP). Treatment repeats every 3 weeks until the maximal clinical response is achieved followed by 2 additional courses of consolidation therapy for up to a maximum of 10 courses. Patients not achieving adequate response receive up to 6 courses of alternate chemotherapy consisting of cyclophosphamide, doxorubicin, vincristine, and prednisone. At 3 months or up to 1 year following completion of chemotherapy, patients achieving adequate disease response receive vaccination consisting of recombinant tumor derived immunoglobulin idiotype with keyhole limpet hemocyanin conjugate subcutaneously (SQ) at 2 sites immediately followed by sargramostim (GM-CSF) SQ on day 1. Patients receive GM-CSF alone on days 2-4. Vaccination repeats every 4 weeks for 4 doses, followed 12 weeks later by the fifth and final dose. Patients are followed every 3 months for 2 years, every 6 months for 2 years, and then annually thereafter until disease progression. PROJECTED ACCRUAL: Not specified |
| Active, not recruiting | Human Telomerase Reverse Transcriptase Messenger RNA (hTERT mRNA) Transfected Dendritic Cell Vaccines<br>Condition: Metastatic Prostate Cancer 2010–2011<br>Intervention: Biological: hTERT mRNA DC |

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| | The purpose of this research is to develop a new and powerful type of immune therapy for prostate cancer patients. This therapy involves vaccinations with special stimulator cells found in the human body called dendritic cells. These dendritic cells can take up proteins released from cancer cells and present pieces of these proteins to immune cells called T lymphocytes to create a strong stimulatory signal to fight the cancer.<br>One of these proteins is called telomerase, which is found on prostate cancers and is critically important for prostate cancer cells to grow. However, in most cancer patients, the immune system does not adequately destroy the tumor because the T cells are not stimulated sufficiently. T cells require strong stimulation before they grow and become active against cancer cells.<br>We have discovered that substances called ribonucleic acids (RNA), which carry the genetic instructions for the production of telomerase, can be used to overcome this problem and stimulate a strong immune response in cancer patients.<br>In order to test this hypothesis we have designed a clinical study and will enroll patients with**metastatic prostate cancer expressing telomerase** in order to determine whether or not this vaccine will stimulate T cells, which can recognize and kill prostate tumor cells.<br>The main objectives of this study are to find out whether injections with dendritic cells grown from blood cells and "pulsed" (mixed together for a short period of time) with RNA derived from the patient's own tumor are:<br>1.Safe without inducing any major side effects.<br>2.And effective in boosting the patient body's immunity against telomerase expressing prostate cancer cells.<br>3.Finally, we will test whether or not tumor shrinkage based on serum PSA levels or on X-ray studies will occur.<br>We hope that this new form of immune therapy, although in its infancy, will ultimately slow down tumor growth and prolong survival of prostate cancer patients.<br>**ARM1: Biological: hTERT mRNA DC.** Subjects receive 1x107 cells per infusion administered ID at study week 1, 2, 3, 4, 5, 6 then receive**5x106 cells per infusion administered ID at study weeks 10, 14, 18, 22, 26, 30, 34, 38, 42, 46 and 50.**<br>**ARM2: Biological: hTERT mRNA DC.** Subjects receive 1x107 cells per infusion administered ID at study week 1, 2, 3, 4, 5, 6 then receive**1x107 cells per infusion administered ID at study weeks 10, 14, 18, 22, 26, 30, 34, 38, 42, 46 and 50.** |

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| | Primary objectives of trial include to evaluate the safety and biologic efficacy of hTERT mRNA transfected dendritic cells (DC), applied in a prime-boost format, to stimulate **hTERT-specific CD4+ and CD8+ T-cell responses** in subjects with metastatic prostate cancer. Secondary objectives include estimating objective clinical response, the duration of such responses, **progression-free survival and overall survival** among all subjects. The hTERT mRNA-transfected DC vaccine platform has previously been studied in several phase I/II trials and has demonstrated safety and bioactivity in subjects with metastatic prostate and renal cell carcinomas. The objective of this trial is to enhance the observed bioactivity of the vaccine by using a prime-boost strategy. This is an open label, uncontrolled safety and efficacy study. Subjects with metastatic prostate cancer will be eligible for this study and will receive 1x107 cells administered ID at study week 1,2,3,4,5, and 6 (Prime). Thereafter, subjects will be randomized with equal probability to receive either 5x106 cells administered ID at study week 10 followed by monthly immunizations (Treatment arm A) or 1x107 cells administered ID at study week 10 followed by monthly immunizations (Treatment arm B). The safety, biologic and clinical efficacy of each regimen will be analyzed. The study will be solely conducted at the University of Florida in Gainesville, FL. Subjects will be recruited through the oncology clinics of the Departments of Urology and Radiation Oncology. The vaccine will be manufactured in a dedicated GMP-compliant cell production facility located on the 4th floor of the Cancer Genetics Research Institute. Immunological testing will be performed in the Immunological Monitoring Core laboratory of the Department of Urology using standardized assay systems. Subjects with histologically or clinically confirmed**metastatic prostate cancer (stages pT1-4, N0-3, M+)** are eligible for this study. **Subjects treated with medical hormone ablative therapy (LHRH analogues or estrogens**) should continue to receive LHRH analogues only. In subjects receiving nonsteroidal medical hormonal treatment (i.e. flutamide or bicalutamide) and who are experiencing a rising PSA, a 4 week period of observation will be required following the discontinuation of the nonsteroidal antiandrogen prior to study entry. Subjects will be excluded from study if they have received chemotherapy or other forms of immunotherapy in the 4 weeks prior to study entry. **They must not have a history of autoimmune disease,** serious intercurrent chronic or acute illness, pulmonary disease, active hepatitis, serologic evidence for HIV, or be receiving corticosteroid or immunosuppressive therapy. All subjects must be older than 18 years. This is a randomized phase II clinical trial, in which up to 36 subjects will be randomized with equal probability to one of the two treatment arms. The objective of this trial is to decide which of the two treatment regimens should be selected for further testing. Hence, the primary objective of this trial is to select the arm with the highest biologic response and the first ranked arm will be selected for further study in a larger efficacy trial. |
| Completed | Vaccine Therapy Plus Sargramostim Following Chemotherapy in Treating Patients With Previously Untreated Aggressive Non- |
| Condition: | Lymphoma 2000-2010 |
| Interventions: | Biological: keyhole limpet hemocyanin; Biological: sargramostim; Biological: tumor cell-based vaccine therapy; Drug: cyclophosphamide; Drug: doxorubicin hydrochloride; Drug: mitoxantrone hydrochloride; Drug: prednisone; Drug: vincristine sulfate |

RATIONALE: Drugs used in chemotherapy use different ways to stop cancer cells from dividing so they stop growing or die. Vaccines may make the body build an immune response to kill cancer cells. Colony-stimulating factors such as sargramostim may increase the number of immune cells found in bone marrow or peripheral blood and may help a person's immune system recover from the side effects of chemotherapy.
PURPOSE: Phase II trial of vaccine therapy plus sargramostim following chemotherapy in treating patients who have previously untreated aggressive non-Hodgkin's lymphoma.
OBJECTIVES: I. Determine the ability of recombinant idiotype immunotherapy to stimulate a specific immune response against the B cell idiotype of the malignant clone that constitutes the tumor in patients with previously untreated aggressive non-Hodgkin's lymphoma. II. Determine the safety and toxicity of this treatment regimen using Genitope Corporation's molecular rescue technology in this patient population.
OUTLINE: Patients receive induction chemotherapy consisting of cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) or cyclophosphamide, mitoxantrone, vincristine, and prednisone (CNOP). Treatment repeats every 3 weeks until the maximal clinical response is achieved followed by 2 additional courses of consolidation therapy for up to a maximum of 6 courses. At 2-6 months following completion of chemotherapy, patients achieving adequate disease response receive vaccination consisting of recombinant tumor derived immunoglobulin idiotype with keyhole limpet hemocyanin conjugate subcutaneously (SQ) followed by sargramostim (GM-CSF) SQ, each at 2 separate sites on day 1. Patients receive GM-CSF alone on days 2-4. Vaccination repeats every 4 weeks for 4 doses, followed 3 months later by the fifth and final dose. Patients are followed every 3 months for 2 years, every 6 months for 2 years, and then annually thereafter until disease progression.
PROJECTED ACCRUAL: Not specified

Active, not recruiting

Vaccine Therapy in Treating Patients With Primary Stage II Melanoma

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| Condition: | Melanoma (Skin) 2000–2009 |
| Interventions: | Biological: GM2–KLH vaccine; Biological: QS21; Procedure: adjuvant therapy |

Adjuvant Ganglioside **GM2-KLH/QS-21 V**accination: Post-Operative Adjuvant Ganglioside GM2-KLH/QS-21 (BMS-248479) Vaccination Treatment After Resection of Primary Cutaneous Melanoma Thicker Than 1.5mm (AJCC/UICC Stage II, T3-T4N0M0), a 2-Arm Multicenter Randomized Phase III Trial vs. Observation.
OBJECTIVES:
•Compare the effect of immunization with GM2-KLH and QS21 to observation on the **disease-free survival** of patients with primary cutaneous stage II melanoma after adequate surgery.
•Determine overall survival and toxicity in the two treatment arms.
OUTLINE: This is a randomized, open-label, parallel, multicenter study. Patients are stratified according to participating center, tumor thickness (**greater than 1.5 to 3.0 mm vs greater than 3.0 to 4.0 mm vs greater than 4.0 mm**), gender, ulceration (yes vs no), and presence of additional staging procedures of regional lymph nodes (yes vs no). Patients are randomized to one of two arms.
•Arm I: Patients are vaccinated with **GM2-KLH and QS21 subcutaneously on day 1 of weeks 1-4, 12, 24, 36, 48, 60, 72, 84, 96, 120, and 144 for a total of 14 vaccinations.**
•Arm II: Patients undergo observation. Patients are followed every **6 months for 7 years.**
PROJECTED ACCRUAL: A total of 1300 patients (650 per arm) will be accrued for this study within 36 months.

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| Active, not recruiting | Vaccine Therapy and Interleukin-12 With or Without Interleukin-2 in Treating Patients With Metastatic Melanoma | | MAGE-3/Melan-A/gp100/NA PBMC, rhIL-12<br>MAGE-3/Melan-A/gp100/NA17 Peptide-pulsed autologous PBMC, rhIL-12 with IL-2<br>MAGE-3/Melan-A/gp100/NA17 Peptide- |
| | Condition: | Melanoma (Skin) 2005-2011 | |
| | Interventions: | Biological: MART-1 antigen; Biological: NA17-A antigen; Biological: aldesleukin; Biological: gp100 antigen; Biological: recombinant MAGE-3.1 antigen; Biological: recombinant interleukin-12; Biological: therapeutic autologous lymphocytes | |

Purpose of investigation: Primary hypotheses: Immunization of patients with 4 melanoma antigen peptides will induce augmented specific IFN-y-producing CD8+ T cells against all 4 antigens simultaneously. Immunization with 4 melanoma antigen peptides will increase the response rate from 10% to 30%. Administration of low-dose IL-2 following each vaccine will result in a greater than 3-fold increase in specific T cells compared to no IL-2.
Secondary hypotheses: Immunization will clear the blood of detectable circulating melanoma cells. Tumors that grow despite induction of melanoma antigen-specific T cells may lack expression of antigens, class I MHC, or the TAP peptide transporter, or may fail to show increased expression of mRNA for IFN-y or perforin. Tumors that resist vaccination may express a different array of genes than those that are susceptible to vaccination.
**Primary:** •The primary hypothesis is immunization of patients with 4 melanoma antigen peptides will induce augmented **specific IFN-.-producing CD8+ T cells against all 4 antigens** simultaneously, and to determine the clinical response rate.
Based on the above preclinical and Phase I results, a logical strategy for a second generation melanoma vaccine has emerged. A randomized Phase II study in metastatic melanoma patients will be undertaken. Patients first will be HLA-typed; **HLA-A2-positive** patients will be eligible for screening. When feasible, each patient will undergo a tumor biopsy to screen for expression of MAGE-3, Melan-A, gplOO, and NAI 7 using RT-PCR and immunohistochemistry, to determine whether T cells are present in the lesion, to measure cytokine gene expression by RT-PCR, and to perform gene array analysis. In addition, blood cells will be analyzed for certain parameters of T cell function.
Patients will be randomized to cohorts A (no IL-2) or B (with low-dose IL-2). For treatment, peripheral blood will be collected and fractionated by density centrifugation to isolate PBMC as a source of APC. The PBMC will be divided into four pools, each of which will be incubated with one of the following peptides: MAGE-3, Melan-A, gp 100, or Ni 7A. The peptide-loaded cells will then be washed and recombined into a single suspension in PBS, and lethally irradiated. Approximately 120 x 106 pulsed cells will be injected subcutaneously at a site near a lymph node not thought to be involved with tumor. The subcutaneous route has been selected for the reasons of safety, efficacy in the preclinical model, and the goal of targeting the vaccine to a draining lymph node. rhIL-12 (4 .tg straight dose) will then be given subcutaneously adjacent to the vaccine site days 1,3, and 5 of each cycle. This dose and schedule was found to be effective in our phase I study. In one-half of the patients (cohort B), IL-2 (I MU straight dose) will be administered subcutaneously daily, days 7-18. Re-immunization along with rhIL-12 followed by IL-2 (if assigned) will be performed at 3 week intervals as in cycle I.

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| | On day 1 of each cycle, peripheral blood will be collected to measure peptide-specific IFN-γ production. Before treatment and after every 3 cycles, PBMC will be collected to quantify peptide specific CD8 T cells by flow cytometric analysis with peptide/HLA-A2 tetramers, and evidence for a molecular response will be assessed by performing RT-PCR. for melanoma antigens on peripheral blood samples. In addition, prior to treatment, after the first 3 cycles, and at the time of going off- study, a tumor biopsy will be performed to assess the immune response in the tumor microenvironment, including gene array analysis. It is hoped that these studies will uncover the reason for lack of clinical response in patients with residual tumors. Clinical response will be assessed as a secondary outcome. |
| Completed | Monoclonal Antibody A1G4 Plus BCG in Treating Patients With Cancer<br>Conditions: Neuroblastoma; Sarcoma 1999–2010<br>Interventions: Biological: BCG vaccine; Biological: monoclonal antibody A1G4 anti-idiotype vaccine |
| | Monoclonal antibodies can locate tumor cells and either kill them or deliver tumor-killing substances to them without harming normal cells. Combining monoclonal antibody A1G4 with BCG may kill more tumor cells.<br>PURPOSE: Phase I trial to study the effectiveness of monoclonal antibody A1G4 plus BCG in treating patients with cancer<br>OBJECTIVES:<br>•Assess the toxicity and feasibility of immunizing patients with anti-idiotypic rat monoclonal antibody A1G4 combined with Bacillus Calmette Guerin (BCG) adjuvant.<br>•Determine whether immunization with A1G4 combined with BCG results in an immune response directed against GD2 ganglioside in patients.<br>OUTLINE: All patients are treated with A1G4 diluted in sterile physiologic saline mixed with Bacillus Calmette Guerin (BCG) organisms. The vaccine is injected intradermally in multiple sites. Booster immunizations are administered during weeks 2, 4, 8, 12, 20, 28, 36, 44, 52. Immunizations are not administered in limbs where draining lymph nodes have been surgically removed or previously irradiated. Isoniazid is administered for 5 days after each BCG injection. If severe skin reactions are present at the injection site, the BCG dose is decreased. If skin reactions persist, the BCG dose is stopped but A1G4 injections continue.<br>At least 6 patients are accrued at each dose level of A1G4. Dose escalation is not carried out until patients have been followed for at least 8 weeks after the first immunization without encountering grade 3 or worse non-skin toxicity.<br>If 0-1 patient experiences dose limiting toxicity (DLT) at a given dose level, then patients are accrued to the next higher dose level. If 2 or more patients experience DLT, the MTD is defined as the previous dose level.<br>Patients are followed for at least 1 year.<br>PROJECTED ACCRUAL: A total of 24 patients are expected to complete this study. If patients are removed early from the study prior to evaluation for serological response, additional patients will be accrued until 6 patients are evaluable for serological response. |
| Active, not recruiting | Vaccine Therapy With or Without Imiquimod in Treating Patients Who Have Undergone Surgery for Stage II, Stage III, or Stage<br>Condition: Melanoma (Skin) 2005–2009 |

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| | Interventions: | Biological: incomplete Freund's adjuvant; Biological: multi-epitope melanoma peptide vaccine; Biological: sargramostim; Biological: tetanus toxoid helper peptide; Drug: dimethyl sulfoxide; Drug: imiquimod; Procedure: adjuvant therapy | |
| | **Primary:** •Safety if less than 33% of patients experience a dose-limiting at day 22 [ Designated as safety issue: Yes ]<br>**Secondary** •Immune response by Elispot assay at day 22 [ Designated as safety issue: No ]<br>**OJECTIVES: 1)** termine the safety of adjuvant transdermal vaccine therapy comprising **multi-epitope melanoma peptides** (MP), **tetanus toxoid helper peptide** (TET), and **GM-CSF** in combination with **Montanide ISA-51** or dimethyl sulfoxide with or without imiquimod in patients who have undergone surgical resection for stage II-IV melanoma. 2) etermine, preliminarily, the immunogenicity of these regimens in these patients. 3) orrelate, preliminarily, transdermal administration of these vaccines with the recruitment and maturation of epidermal Langerhans cells in these patients. 4) etermine, preliminarily, the effects of timing of subsequent vaccine therapy comprising MP, TET, and GM-CSF emulsified in Montanide ISA-51, administered intradermally and subcutaneously, on the persistence of immune response in these patients.<br>**OUTLINE:** This is a randomized, open-label study. Patients are randomized to 1 of 4 treatment arms.<br>**•Arm I:** Patients receive vaccine therapy comprising multi-epitope melanoma peptides, tetanus toxoid helper peptide, and GM-CSF emulsified in Montanide ISA-51 transdermally (TD) on days **1, 8, and 15**. Patients then receive the vaccine intradermally (ID) and subcutaneously (SC) on days**29, 50, 71, 92, 113, and 134**.<br>**•Arm II:** Patients receive vaccine therapy as in arm I. Patients also receive imiquimod topically on days 0, 7, and 14.<br>**•Arm III:** Patients receive vaccine therapy comprising MP, TET, GM-CSF, and dimethyl sulfoxide TD on days 1, 8, and 15. Patients then receive vaccine therapy comprising MP, TET, and GM-CSF emulsified in Montanide ISA-51 ID and SC on days 29, 50, 71, 92, 113, and 134.<br>**•Arm IV:** Patients receive vaccine therapy as in arm III and imiquimod as in arm II.<br>In all arms, treatment continues in the absence of disease progression or unacceptable toxicity.<br>After completion of study treatment, patients are followed at 3 and 5 weeks and then at disease progression. | |
| Active, not recruiting | Vaccine Therapy With or Without Sargramostim in Treating Patients With Stage IIB, Stage IIC, Stage III, or Stage IV Melanoma | | ·Diagnosis of melanoma<br>◦Stage IIB, IIC, III, or IV disease<br>·Must express HLA-A1, -A2, or -A3 |
| | Condition: | Melanoma (Skin) 2004-2009 | |
| | Interventions: | Biological: incomplete Freund's adjuvant; Biological: multi-epitope melanoma peptide vaccine; Biological: sargramostim | |
| | **OBJECTIVES: 1)** Compare immune response in patients with stage IIB-IV melanoma treated with vaccination comprising multiple synthetic melanoma peptides and Montanide ISA-51 with vs without sargramostim (GM-CSF). 2) Compare immune response in patients treated with these vaccinations administered at 1 vs 2 sites.<br>**OUTLINE:** This is a randomized, open-label study. Patients are randomized to 1 of 4 treatment arms.<br>•Arm I: Patients receive vaccination comprising multiple synthetic melanoma peptides and Montanide ISA-51 at 1 injection site.<br>•Arm II: Patients receive vaccination comprising multiple synthetic melanoma peptides and Montanide ISA-51 at 2 injection sites.<br>•Arm III: Patients receive vaccination comprising multiple synthetic melanoma peptides, Montanide ISA-51, and sargramostim (GM-CSF) at 1 injection site.<br>•Arm IV: Patients receive vaccination comprising multiple synthetic melanoma peptides, Montanide ISA-51, and GM-CSF at 2 injection sites.<br>**In all arms, treatment repeats once weekly for 6 weeks**. Patients return for booster vaccinations at weeks **12, 26, 39, and 52.**<br>PROJECTED ACCRUAL: A maximum of 124 patients will be accrued for this study. | | |
| Active, not recruiting | Vaccine Therapy Plus Interleukin-2 With or Without Interferon Alfa-2b in Treating Patients With Stage III Melanoma | | |
| | Condition: | Melanoma (Skin) 1999-2011 | |
| | Interventions: | Biological: interleukin-2 liposome; Biological: polyvalent melanoma vaccine; Biological: recombinant interferon | |