

|            |   |  |
|------------|---|--|
|            | <p><b>Primary:</b> Determine and <b>monitor biological responses</b> in patients with NHL including follicular lymphoma, diffuse large cell lymphoma, mantle cell lymphoma and SLL/CLL treated with repeat intranodal injections of <b>Ad-ISF35</b>. [ Time Frame: 2 Years (evaluation will be approx. 4 months per patient) ]</p> <p><b>Secondary:</b> Determine the safety of repeat administration of Ad-ISF35 injected directly into lymph nodes of patients with NHL including follicular lymphoma, diffuse large cell <b>lymphoma, mantle cell lymphoma and SLL/CLL</b>. [ Time Frame: 2 Years (evaluation will be approximately 1 year per patient) ] /Determine pharmacodynamic parameters in patients treated with repeat intranodal injections of Ad-ISF35. [ Time Frame: 2 Years (evaluation will be approximately 4 months per patient) ]</p> <p>This is a phase II clinical trial in which study subjects will be treated with multiple doses of Ad-ISF35 given via intranodal injection using <i>afixed dose of <math>3.3 \times 10^{10}</math> ISF35 viral</i> particles. Intranodal injections will be administered every 2-4 weeks up to six total injections.</p> <p>This will be the first time that repeat administration of Ad-ISF35 will be performed via intranodal injection in subjects with a diagnosis other than CLL/SLL. Therefore, in order to allow sufficient time to evaluate the safety and toxicity of this procedure in non-CLL/SLL patients, we will treat the first three non-CLL/SLL subjects with inpatient admission for 24 hours observation at the GCRC-UCSD. If no serious adverse events are observed in these first three patients after they have received their first two injections of ISF35 and have been observed for at least 28 days, then we will proceed with enrollment of cohorts of four subjects per month. This will be done at one week intervals until study enrollment is completed. These subjects will be treated as outpatients at the GCRC and observed for 3 hours prior to discharge.</p> <p>All subjects with a diagnosis of CLL or SLL will be treated as outpatients at the GCRC and observed for 3 hours prior to discharge. These subjects will not need to be treated in an inpatient setting, based on our previous clinical experience with subjects enrolled on the phase II study of repeat intranodal injections of Ad-ISF35 ISF35 has already been used in Phase I clinical trials. The trials demonstrated that ISF35 treatment is well-tolerated and patients did not experience any significant or unexpected adverse events. Patients reported flu-like symptoms from ISF35, which disappeared within one to three days.</p> |  |
| Recruiting | <p><a href="#">Vaccine Therapy and Aldesleukin in Treating Women With Metastatic Breast Cancer</a></p> <p>Condition: <b>Breast Cancer</b></p> <p>Interventions: <b>Biological: allogeneic large multivalent immunogen breast cancer vaccine; Biological: aldesleukin</b></p>  | <p>allogeneic large multivalent immunogen breast cancer vaccine<br/>+ aldesleukin. Allogeneic tumor cell</p> |
|            | <p><b>Primary:</b> Disease Response [ 2 months]. /Percentage of patients achieving complete response, partial response, or disease stabilization as assessed by RECIST</p> <p><b>Secondary:</b> Immune response [48 hours] . /Immune responses will be assessed by DTH responses to LMI, IFN-gamma production by CD8+ T cells using the ELISPOT assay, and CD8+ T cell binding to HLA-A2 multimers complexed with breast cancer-derived peptides (multimer analysis).</p> <p>Progression-free survival. /Progression free survival will be measured in months from time of response to time of disease progression as defined by RECIST (appendix II), "at least a 20% increase in the sum of the longest diameters of target lesions, taking as reference the smallest sum longest diameter recorded since the baseline measurements, or the appearance of one or more new lesion(s)." / Overall survival [ 1 Year and 2 Years ]</p> <p>Overall survival at one and two years will be determined by longitudinal follow-up</p>   |  |
|            | <p>OUTLINE: Patients receive allogeneic large multivalent immunogen (LMI) vaccine intradermally on day 1 and aldesleukin subcutaneously on days 7 and 8. Treatment repeats every 28 days in the absence of disease progression or unacceptable toxicity. Patients with disease progression after 2 courses of vaccine therapy resume the chemotherapy regimen for which prior disease stabilization was achieved. Beginning 2-4 days after completion of chemotherapy, patients receive one dose of LMI vaccine followed by aldesleukin on days 7 and 8. Patients achieving at least stable disease continue to receive LMI vaccine and aldesleukin as above. Treatment repeats every 28 days in the absence of disease progression or unacceptable toxicity.</p> <p>Peripheral blood mononuclear cell samples are collected periodically for research studies. Samples are analyzed to assess the frequency of leukocyte subsets (including B cells, T cells, NK cells, and monocytes) via flow cytometry; frequency of T-regs (T cells that express CD4, CD25, and FoxP3); and responses to keyhole limpet hemocyanin and tetanus toxoid via ELISA assay. Other immunological studies are also performed.</p>   |  |

|                        |  |  |  |
|------------------------|--|--|--|
| Recruiting             | <a href="#">Vaccine Therapy in Treating Patients With HER2/Neu Positive or Negative Stage IV Breast Cancer or Other HER2/Neu Positive Cancers</a>  |  | allogeneic GM-CSF-secreting breast cancer vaccine + IFN- $\alpha$ . Vaccine Using Whole Cells From the SVBR- 1-GM Cell Line Genetically Engineered To GM-CSF |
|                        | Conditions:  | Breast Cancer; Unspecified Adult Solid Tumor, Protocol Specific  |  |
|                        | Interventions:   | Biological: allogeneic GM-CSF-secreting breast cancer vaccine; Biological: recombinant interferon alfa; Drug: cyclophosphamide 2004  |  |
|                        | <p><b>OBJECTIVES:</b> Determine the safety, tolerability, and feasibility of vaccine therapy comprising an allogeneic (non-self) tumor cell line transfected with the sargramostim (GM-CSF) gene combined with low-dose interferon alfa and low-dose cyclophosphamide in patients with stage IV breast cancer or other solid tumors. Determine the clinical response, time to progression, and survival of patients treated with this regimen. Correlate clinical response with immunological response in patients treated with this regimen.</p> <p><b>OUTLINE:</b> Patients receive low-dose cyclophosphamide IV once 2-3 days before each tumor vaccine. Patients then receive tumor vaccine comprising HER2/neu-positive allogeneic (non-self) breast cancer cells transfected with the sargramostim (GM-CSF) gene intradermally (ID) on day 1. Patients also receive low-dose interferon alfa ID approximately 48 and 96 hours after each tumor vaccine. Treatment repeats every 2 weeks for 3 vaccinations and then monthly for 3 vaccinations in the absence of disease progression or unacceptable toxicity. Patients are followed at 2 weeks and then every 3 months thereafter.</p>  |  |  |
| Active, not recruiting | <a href="#">Biological Therapy in Treating Patients With Metastatic Cancer</a>   |  | carcinoembryonic antigen RNA-pulsed DC cancer vaccine:   |
|                        | Conditions:  | Breast Cancer; Colorectal Cancer; Extrahepatic Bile Duct Cancer; Gallbladder Cancer; Gastric Cancer; Head and Neck Cancer; Liver Cancer; Lung Cancer; Metastatic Cancer; Ovarian Cancer; Pancreatic Cancer; Testicular Germ Cell Tumor |  |
|                        | Intervention:  | Biological: carcinoembryonic antigen RNA-pulsed DC cancer vaccine 2000   |  |
|                        | <p><b>OBJECTIVES:</b> I. Determine the safety and dose limiting toxicity of an intravenous vaccine of autologous, cultured, dendritic cells pulsed with carcinoembryonic antigen (CEA) RNA in patients with metastatic adenocarcinoma expressing CEA. II. Assess the cellular immune response to the CEA protein. III. Assess the clinical and biochemical response to the treatment and the duration of such response.</p> <p><b>OUTLINE:</b> This a three tiered, open label, uncontrolled, dose escalation study. The first 3 patients receive a low dose of intravenous carcinoembryonic antigen (CEA) RNA-pulsed autologous dendritic cells (DC) at weeks 0, 1, 2, and 3. Patients are evaluated for dose limiting toxicity (DLT), immune response, and the antitumor response for at least 1 week before dose escalation may proceed. If there is no DLT in the first three, the next 3 patients are treated at a medium dose of CEA RNA-pulsed autologous DC at 0, 1, 2, and 3 weeks. Finally, if DLT is not seen at the medium dose, the final 6 patients receive intravenous infusions of a high dose of CEA RNA-pulsed autologous DC at weeks 0, 1, 2, and 3. If 1-2 patient(s) experience DLT at the either the low or medium dose levels, 3 more patients are entered at the same dose. If no further DLT occurs, then dose escalation continues. As soon as 3 toxic events occur in 3-6 patients at one dose level, accrual at that level ceases. The MTD is defined as the dose level immediately below that at which more than 3 of 6 patients develop DLT.</p> |  |  |
| Active, not recruiting | <a href="#">Immunotherapy in Treating Patients With Metastatic Breast Cancer</a>   |  | carcinoembryonic antigen RNA-pulsed DC cancer vaccine  |
|                        | Condition:   | Breast Cancer  |  |
|                        | Intervention:  | Biological: carcinoembryonic antigen RNA-pulsed DC cancer vaccine 1999   |  |

|                    |  |   |
|--------------------|--|---|
|                    | <p><b>OBJECTIVES:</b> Evaluate the ability of active immunotherapy with carcinoembryonic antigen (CEA) RNA pulsed dendritic cells to induce CEA specific T cells in patients with metastatic breast cancer in complete remission following peripheral blood stem cell transplant. Determine the clinical efficacy in terms of overall and recurrence free survival of immunotherapy with CEA RNA pulsed dendritic cells in this patients population.</p> <p><b>OUTLINE:</b> Dendritic cells are taken from the leukapheresis product obtained during the peripheral blood stem cell transplant procedure performed prior to treatment on this study. The dendritic cells are pulsed with carcinoembryonic antigen (CEA) RNA. Approximately 60-90 days after the peripheral blood stem cell transplant, patients receive CEA RNA pulsed dendritic cells IV every 3 weeks for a total of 4 doses. Patients undergo a second leukopheresis after the last dose of immunotherapy to obtain specimens for immunologic tests. Patients are followed every 3 months for the first year and annually thereafter.</p> |   |
| Completed          | <p><a href="#">Immunotherapy in Treating Patients With Resected Liver Metastases From Colon Cancer</a></p> <p>Conditions: Colorectal Cancer; Metastatic Cancer</p> <p>Intervention: Biological: carcinoembryonic antigen RNA-pulsed DC cancer vaccine 1999</p>   | carcinoembryonic antigen RNA-pulsed DC cancer vaccine   |
|                    | <p><b>OBJECTIVES:</b> Determine the cellular immune response to carcinoembryonic antigen pulsed dendritic cells in patients with adenocarcinoma of the colon metastatic. Evaluate the overall and recurrence free survival in this patient population.</p> <p><b>OUTLINE:</b> Patients undergo leukapheresis for up to 4.5 hours to collect dendritic cells. The separated dendritic cells are pulsed with carcinoembryonic antigen (CEA) RNA. Patients receive CEA RNA pulsed dendritic cells intravenously every 2 weeks for a total of 4 doses. Patients undergo a second leukapheresis 2 weeks after the last dendritic cell infusion to obtain specimens for immunologic tests. Patients with extra doses of dendritic cells available may receive additional doses of CEA RNA pulsed dendritic cells every 2 months in the absence of unacceptable toxicity. Patients are followed at weeks 12, 24, 36, and 48, and every 6 months thereafter.</p>   |   |
| Recruiting         | <p><a href="#">Trial of Autologous, Hapten-Modified Vaccine, OVAX, in Patients With Relapsed Stage III or IV Ovarian Cancer</a></p> <p>Condition: Adenocarcinoma of the Ovary</p> <p>Intervention: Biological: OVax: Autologous, DNP-Modified Ovarian Cancer Vaccine 2008</p>  | Autologous, DNP-Modified Ovarian Cancer Vaccine: tumor cells  |
|                    | <p>Primary Outcome Measures: Cell-mediated immunity to autologous tumor cells [ Time Frame: 3 months ]</p> <p>Secondary Outcome Measures: Safety [ Time Frame: 9 months ]</p>  |   |
| Not yet recruiting | <p><a href="#">Study of IMF-001 in Patients With Malignancies Expressing NY-ESO-1</a></p> <p>Condition: NY-ESO-1 Positive Solid Tumors or Melanoma</p> <p>Intervention: Biological: IMF-001 2010</p>   | IMF-001 is a CHP-NY-ESO-1 complex consisting of recombinant NY-ESO-1 protein and cholesteryl hydrophobized pullulan (CHP) |

|                        |   |   |   |
|------------------------|---|---|---|
|                        | <p><b>Primary:</b> 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><b>[Secondary]:</b> 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              | <a href="#">Provenge® (Sipuleucel-T) Active Cellular Immunotherapy Treatment of Metastatic Prostate Cancer After Failing Hormone Therapy</a>  |   |   |
| 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:<br/>         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>  |   | Sipuleucel-T: a minimum of 50 million autologous CD54+ cells activated with a PAP-GM-CSF. .   |
| Active, not recruiting | <a href="#">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</a>  |   | MAGE-A1, Her-2/neu, FBP peptides ovarian cancer vaccine + tetanus toxoid helper peptide. Pepitde-specific Cytotoxic T-cell response |
|                        | 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><b>Primary:</b> Cytotoxic T-cell response to vaccine therapy comprising 5 synthetic ovarian cancer-associated peptides, as assessed using peripheral blood during course 1</p> <p><b>Secondary:</b> 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><b>[Purpose]:</b> 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><a href="#">IMA901 in Patients Receiving Sunitinib for Advanced/Metastatic Renal Cell Carcinoma</a></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><b>Primary:</b> Overall survival [ Time Frame: 2014 (estimated) ]</p> <p><b>Secondary:</b> 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 multi-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><a href="#">The Development of Human Papillomavirus Type 16 E7-Specific Human Immunologic Assays in Non-HLA2 Type Human Being</a></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><a href="#">Vaccine Therapy in Treating Patients With Stage D0 Prostate Cancer</a></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><b>Primary:</b> Time to PSA progression [ Designated as safety issue: No ]</p> <p><b>Secondary:</b> Toxicity. /Immunologic response as assessed by ELISPOT assay. /PSA kinetics (doubling time/velocity) of treatment. /Time to testosterone recovery</p> <p><b>Primary</b> 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><b>Secondary</b> 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><b>OUTLINE:</b> Patients are stratified according to estimated PSA doubling time (&lt; 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 | <p><u>Vaccine Therapy in Treating Patients With Persistent or Recurrent Cervical Cancer</u></p> <p>Condition: Cervical Cancer</p> <p>Interventions: Biological: live-attenuated Listeria monocytogenes cancer vaccine ADXS11-001; Other: laboratory biomarker analysis 2010</p>   | <p>live-attenuated Listeria monocytogenes cancer vaccine ADXS11-001. OS, PFS, objective tumor response</p> |
|                    | <p><b>Primary]</b> 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><b>Secondary]</b> To characterize the distribution of progression-free survival and overall survival. /To examine the proportion of patients with objective tumor response.</p> <p><b>Tertiary]:</b> 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><b>OUTLINE:</b> 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          | <p><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></p> <p>Conditions: Fallopian Tube Cancer; Ovarian Cancer; Peritoneal Cavity Cancer</p> <p>Interventions: Biological: oregovomab; Drug: cyclophosphamide; Other: immunoenzyme technique; Other: laboratory biomarker analysis; Procedure: adjuvant therapy 2007</p>  | <p>oregovomab: humoral immune response, as measured by HAMA and anti-idiotypic antibodies</p>              |

|            |   |  |
|------------|---|--|
|            | <p><b>Primary Outcome:</b> 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><b>Secondary Outcome:</b> 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><a href="#">Active Immunotherapy CEA Vaccine in Patients With Malignancies Expressing CEA</a></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><b>Primary:</b> 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><b>Secondary:</b> 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><b>Detailed:</b> 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 &lt;33% of patients treated at a dosage level experience DLT (e.g. 0 of 3, &lt;1 of 6, &lt;3 of 12 or &lt;5 of 18 patients)</p> |  |
| Recruiting | <p><a href="#">Ipilimumab +/- Vaccine Therapy in Treating Patients With Locally Advanced, Unresectable or Metastatic Pancreatic Cancer</a></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><b>Purpose]</b> 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><b>Primary]</b> 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><b>Secondary Objectives:</b> To estimate overall survival (OS) which will serve as the primary efficacy signal.<br/>To explore an association of T cell responses and immunological responses with OS in patients receiving treatment.<br/>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.<br/>To measure tumor marker kinetics (CA 19-9) in patients receiving treatment.</p>   |  |

|            |  |   |
|------------|--|---|
| Recruiting | <a href="#">Vaccination With Dendritic Cell/Tumor Fusions With Autologous Stem Cell Transplants in Patients With Multiple Myeloma</a>  | Dendritic Cell Tumor Fusion: dendritic cell/myeloma fusions and GM-CSF  |
|            | Condition: Multiple Myeloma  |   |
|            | Intervention: Biological: Dendritic Cell Tumor Fusion 2007   |   |
|            | <p><b>Primary:</b> 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><b>Secondary:</b> 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 | <a href="#">A Pilot Study of Vaccination With Epitope-Enhanced TARP Peptide and TARP Peptide-Pulsed Dendritic Cells in the Treatment of Stage D0 Prostate Cancer</a>   | 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><b>Background:</b> 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><a href="#">Long Term Follow Up Of Patients Who Have Received Gene Therapy Or Gene Marked Products</a></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><b>Primary:</b> 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><a href="#">Vaccine Therapy in Treating Patients With Stage III or Stage IV Ovarian Epithelial Cancer</a></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 | <a href="#">Phase I/II Clinical Trial Combining hTERT Tumor Vaccine &amp; Autologous T Cells in Patients With Advanced Myeloma</a>  | Telomerase (hTERT vaccine + pneumoccal conjugate vaccine (PCV))   |
|                        | Condition: Multiple Myeloma 2008<br>Interventions: Biological: Telomerase (hTERT vaccine + pneumoccal conjugate vaccine (PCV)); Biological: PCV vaccine   |   |
|                        | <p><b>Primary:</b> Does combination therapy delay hematopoietic recovery or induce other autoimmune events. [ Time Frame: 2 yrs ] [ Designated as safety issue: Yes ]</p> <p><b>Secondary:</b> Does combination therapy generate cytotoxic T-cell responses to autologous myeloma cells in-vivo. [ Time Frame: 2 yrs ]</p> <p><b>This protocol proposes</b> 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              | <a href="#">Safety and Efficacy Study of HER2/Neu (E75) Vaccine in Node-Positive Breast Cancer Patients</a>   | E75 + GM-CSF vaccine: HER2/Neu Peptide (E75) Vaccine. in vivo peptide-specific immune response.                                   |
|                        | Condition: Breast Cancer<br>Intervention: Biological: E75 + GM-CSF vaccine  |   |
| Recruiting             | <a href="#">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</a>   | Allogeneic Tumor Cell Vaccine (K562): Tumor Cell Vaccine With Metronomic Oral Cyclophosphamide and Celecoxib as Adjuvant Therapy. |
|                        | Conditions: Lung Cancer; Esophageal Cancer; Malignant Pleural Mesothelioma; Thymoma; Thymic Carcinoma<br>Interventions: Biological: Allogeneic Tumor Cell Vaccine (K562); Drug: Celecoxib; Drug: cyclophosphamide 2010  |   |