	A Trial Of Vaccination With The Carcinoembryonic Antigen **(CEA) Peptide Cap 1-6D** With **Montanide ISA 51** Adjuvant Or Granulocyte-Macrophage Colony Stimulating Factor (GM-CSF) In HLA-A2+ Patients With CEA Producing Adenocarcinomas Of Gastrointestinal (GI) Tract Origin **Primary: 1) Production of CAP 1-6D T cells**.2) **Production of cytotoxic T cells.** 3) **Antitumor response**. 4) Frequency and severity of toxic effects **OBJECTIVES: 1)** Determine whether immunization with carcinoembryonic antigen (CEA) peptide 1-6D (CAP 1-6D) emulsified in Montanide ISA-51 adjuvant or dissolved in sargramostim (GM-CSF) can generate CAP 1-6D-specific T cells in patients with CEA-producing adenocarcinomas of gastrointestinal tract origin. 2) Determine whether vaccination with CAP 1-6D can generate cytotoxic T cells against CEA-expressing tumors in these patients. 3) Determine whether this vaccine can produce antitumor responses in these patients. 4) Determine the frequency and severity of toxic effects associated with this vaccine in these patients. **OUTLINE:** This is a randomized study. Patients are randomized to 1 of 2 treatment arms. Arm I: Patients receive carcinoembryonic antigen peptide 1-6D (CAP 1-6D) emulsified in Montanide ISA-51 adjuvant subcutaneously on day 1. Arm II: Patients receive CAP 1-6D dissolved in sargramostim **(GM-CSF)** intradermally on day 1. Treatment repeats in both arms every 3 weeks for 6 courses in the absence of disease progression or unacceptable toxicity. Patients are followed at 3 weeks and then as necessary. PROJECTED ACCRUAL: A total of 10-36 patients (5-18 per arm) will be accrued for this study within 36 months	
Completed Has Results	Human Papilloma Virus (HPV) Vaccine Trial in Young Adolescent Women With GlaxoSmithKline Biologicals' (GSK Bio) HPV-	
	Conditions: Papillomavirus Infection; Cervical Intraepithelial Neoplasia	
	Interventions: Biological: GSK Biologicals' HPV-16/18 Vaccine (Cervarix™); Biological: Havrix™	
Recruiting	Evaluation of Safety of a Vaccine Against Cervical Cancer in Healthy Korean Females	
	Conditions: HPV-16/18 Infections and Associated Cervical Neoplasia; Papillomavirus Vaccines	
	Intervention: Biological: Cervarix.	
Recruiting	Follow-Up Evaluation of Patients With Solid Tumors Previously Enrolled in a Vaccine Therapy Clinical Trial	
	Conditions: Breast Cancer; Colorectal Cancer; Long-term Effects Secondary to Cancer Therapy in Adults; Metastatic 2007-2012 Cancer; Ovarian Cancer; Prostate Cancer; Unspecified Adult Solid Tumor, Protocol Specific	
	Interventions: Other: follow-up care; Procedure: assessment of therapy complications; Procedure: examination	

	This study aims to provide long-term follow-up care of patients previously enrolled in a vaccine study that involved poxviral vectors. Vectors are sequences of genetic material that can be used to introduce specific genes into genetic makeup. The study does not involve the use of any drug or biologic agent. Participants will undergo an annual health history. Because certain viruses enter into cells and create proteins from the viral genes, the type of vaccine treatment used is referred to gene therapy. The genes expressed by poxviral vectors do not become part of the genetic material left behind. Because gene therapy is a somewhat new technology, a prolonged monitoring of patients' health status is necessary, according to new specific reporting requirements for harmful events in patients who undergo such gene therapy studies. The risk of any long-term negative effects from the gene therapy that patients had received is quite small. Still, it is important that there be updates at least annually. This annual monitoring of health status will extend for 15 years, according to guidelines from the Food and Drug Administration, or for as long as patients are willing to participate. Patients who received poxviral vectors (vaccinia or fowlpox, or both) at the National Cancer Institute, through a trial affiliated with the Laboratory of Tumor Immunology and Biology, may be eligible for this study. Participants will be involved in the following forms of data collection: Annual medical history and physical examinations for the first 5 years following the last vaccine. Annual telephone contact during the last 10 years. Health status check, including primary cancer status, secondary malignancies, neurologic disorders, autoimmune disorders, and hematologic disorders. Blood tests for the presence of HIV antibodies. Reporting of medical problems, including information on unexpected hospitalizations and medications. If a participant has died, the study will document the cause of death and autopsy information if available.
Completed	Vaccine Therapy in Treating Patients With Refractory Stage IV Cancer Condition: Unspecified Adult Solid Tumor, Protocol Specific 2003–2011 Interventions: Biological: **CMV pp65 peptide**; Biological: carcinoembryonic antigen **peptide 1–6D**; Biological: **therapeutic autologous dendritic cells**
	A Phase I Study of Active Immunotherapy With CAP-1 (6D) and CMVpp65 Peptide-Pulsed, Autologous Dendritic Cells Produced in the Aastromreplicell Cell Production System in Patients With Stage IV CEA Expressing Malignancies. **OBJECTIVES:** Determine the safety and feasibility of administering 1 or 2 courses of vaccination with carcinoembryonic antigen peptide 1-6D (CAP 1-6D)- and CMV pp65 peptide-pulsed autologous dendritic cells in patients with refractory stage IV CEA-expressing malignancies. Determine the ability of this regimen to induce CAP 1-6D- and CMV pp65-specific T cells in these patients. Determine the antitumor effect of this regimen, in terms of progression-free survival, of these patients. **OUTLINE:** This is an open-label, dose-escalation study. Patients undergo leukapheresis and collection of peripheral blood monocytes from which **dendritic cells (DC) are generated and pulsed with carcinoembryonic antigen peptide 1-6D (CAP 1-6D) and CMV pp65 peptide**. Patients are assigned to 1 of 2 vaccination cohorts. Cohort I: Patients receive vaccination with CAP 1-6D-pulsed DC and CMV pp65 peptide-pulsed DC subcutaneously and intradermally every 3 weeks for a total of 4 vaccinations. Cohort II: Patients receive vaccinations as in cohort I every 3 weeks for a total of 8 vaccinations. For both cohorts, a safe dose of the vaccine is defined as the dose at which no more than 1 of 6 patients experiences unacceptable toxicity. Patients are followed every 3 months for 1 year.
Terminated	Vaccine Therapy and GM-CSF in Treating Patients With Progressive Non-Hodgkin's Lymphoma Condition: Lymphoma 2005–2010

	Interventions: Biological: autologous immunoglobulin idiotype-KLH conjugate vaccine ; Biological: sargramostim	
	Phase II Trial of FavId™ (Patient-Specific Idiotype/KLH) and GM-CSF in Subjects Who Demonstrated Progressive Disease and Did Not Receive FavId on Study FavId-06 **Primary:** Provide treatment with autologous immunoglobulin idiotype-KLH conjugate vaccine (FavId)™ and sargramostim (GM-CSF) to patients with progressive grade 1, 2, or 3 follicular B-cell non-Hodgkin's lymphoma who did not receive FavId™ while enrolled on protocol FAV-ID-06. **Secondary:** Determine the response rate and duration of response in patients treated with this regimen. Determine the response rate and response rate improvement after best response to prior salvage therapy in patients treated with this regimen. Determine the time to progression in patients treated with this regimen. Determine the safety of this regimen in these patients. OUTLINE: This is a multicenter study. Patients are assigned to 1 of 2 groups according to timing of disease progression while enrolled on protocol FAV-ID-06 (disease progression after prior rituximab AND never randomized vs disease progression after randomization to placebo arm). Patients receive autologous immunoglobulin idiotype-KLH vaccine subcutaneously (SC) on day 1. Patients also receive sargramostim (GM-CSF) SC on days 1-4. Treatment repeats monthly for 6 months in the absence of disease progression or unacceptable toxicity. Patients with stable or responding disease may receive additional treatment as above every 2 months for 1 year (6 treatments) and every 3 months until disease progression. After completion of study treatment, patients are followed for 30 days or until the start of subsequent treatment. PROJECTED ACCRUAL: Approximately 238 patients (67 in group I and 171 in group II) will be accrued for this study.	
Recruiting	Trial of a WT-1 Analog Peptide Vaccine in Patients With Acute Myeloid Leukemia (AML)	
	Condition: Acute Myeloid Leukemia 2010-2012	
	Intervention: Biological: WT1 peptide vaccine	
	Phase II Trial of a **WT-1 Analog Peptide** Vaccine in Patients in Complete Remission (CR) From Acute Myeloid Leukemia (AML) or Acute Lymphoblastic Leukemia (ALL) **Primary**: 1) To assess the safety [at weeks 2 and 4 with routine toxicity throughout the trial], of the WT1 peptide vaccine administered to patients in CR from AML. Early toxicity will be assessed at weeks 2 and 4,. Routine toxicity assessments will continue throughout the trial. Any toxicity noted in the trial will be graded in accordance with Common Toxicity Criteria, version 4.0 (CTCAE 4.0) developed by the National Cancer Institute. 2) To assess the efficacy of the WT1 peptide vaccine administered to patients in CR from AML. [3 years] The primary efficacy measure is defined as overall survival at 3 years. **Secondary: 1) Disease free survival [3 years**], 2) To assess the immunologic responses of vaccine administration [at week 12], via **CD4+ T cell proliferation, CD3+ T cell interferon- γ release (ELISPOT and / or flow cytometry)** and **WT1 peptide tetramer staining**. 3) •To assess any effect **on minimal residual disease [at week 12] as measured by RT-PCR for WT1 transcript** **Biological: WT1 peptide vaccine** Six vaccinations of the **WT1 peptide preparation** (1.0 ml of emulsion) will be **administered on weeks 0, 2, 4, 6, 8, and 10**. All vaccinations will be administered subcutaneously with vaccination sites rotated among extremities. Patients who are clinically stable and have not had disease progression may **receive up to 6 more vaccinations administered appropriately every month**	
Completed	Vaccine Therapy in Treating Patients With Stage I, Stage II, or Stage IIIA Non-small Cell Lung Cancer or With Stage I or Stage	
	Conditions: Lung Cancer; Malignant Mesothelioma 1999-2011	
	Interventions: Biological: lung tumor associated antigen; Drug: DetoxPC; Drug: chemotherapy; Drug: cyclophosphamide	

	An Evaluation of the Immunological Parameters Associated With a Skin-Test and Immunization of Lung and Mesothelioma Cancer Patients With Autologous Lung Tumor Associated Antigen: Characterization of the Patients' Cytolytic and Helper T Cell Reactivity for Identification of the Specific Antigen(s): A Pilot Study OBJECTIVES: I. Define the immunological parameters of **cytolytic T cell and T helper cell activity** associated with **skin testing** and vaccination with **autologous lung tumor associated antigen and detoxPC** in patients with curatively resected stage I, II, or IIIA non-small cell lung cancer (NSCLC) or stage I or II mesothelioma. II. Evaluate any responses associated with an enhanced antitumor immune status in this patient population with this treatment regimen. OUTLINE: Patients undergo **delayed type hypersensitivity** skin testing with **autologous tumor associated antigen (TAA)** and **memory antigens** (i.e., **Monilia, PPD, and Trichophyton**) intradermally at 1-4 weeks following surgical tumor resection. At week 4-9, patients receive low dose cyclophosphamide IV once. At 3 days following chemotherapy, patients receive autologous TAA with DetoxPC intradermally for up to 3 doses over 4 weeks. At 2-3 weeks following vaccination, patients undergo repeat skin testing. At week 6-12, patients with a positive skin test undergo biopsy of the skin test/vaccination site followed by leukapheresis at week 12-20 if T cells exhibit active antitumor reactivity. Patients with stable or regressive disease receive additional vaccination courses at week 20 and thereafter. Patients are followed for 5 years. PROJECTED ACCRUAL: A total of 20 patients will be accrued for this study within 2 years.
Completed	Monoclonal Antibody Vaccine Therapy in Treating Patients With Ovarian Epithelial, Fallopian Tube, or Peritoneal Cancer Conditions: Fallopian Tube Cancer; Ovarian Cancer; Peritoneal Cavity Cancer 2003–2011 Intervention: Biological: abagovomab
	Phase I Trial of the **Monoclonal Anti-Idiotype Antibody ACA125** in Patients With Epithelial Ovarian, Fallopian Tube, or Peritoneal Cancer **OBJECTIVES: 1)** Determine the safety of varying routes and doses of monoclonal antibody ACA125 anti-idiotype vaccine in patients with ovarian epithelial, fallopian tube, or peritoneal cancer. 2) Determine an optimal dose and route of this vaccine for a phase II study. 3) Determine the immune response induced by this vaccination in these patients. 4) Determine the time to development of objective tumor response in patients treated with this regimen. **OUTLINE:** This is a multicenter study. Patients are randomized to 1 of 4 treatment arms. Arm I: Patients receive lower-dose monoclonal antibody ACA125 anti-idiotype vaccine (MOAB ACA125) intramuscularly (IM) on weeks 0, 2, 4, 6, 10, and 14 in the absence of disease progression or unacceptable toxicity. Arm II: Patients receive higher-dose MOAB ACA125 IM as in arm I. Arm III: Patients receive lower-dose MOAB ACA125 subcutaneously (SC) on weeks 0, 2, 4, 6, 10, and 14 in the absence of disease progression or unacceptable toxicity. Arm IV: Patients receive higher-dose MOAB ACA125 SC as in arm III. Patients are followed every 6-12 weeks for 2 years. PROJECTED ACCRUAL: A total of 40 patients (10 patients per cohort) will be accrued for this study
Active, not recruiting	Vaccine Therapy in Treating Patients With Stage IIB, Stage IIC, Stage III, or Stage IV Melanoma Condition: Melanoma (Skin) 2005–2009 Interventions: Biological: human gp100 plasmid DNA vaccine; Biological: mouse gp100 plasmid DNA vaccine

	Injection of AJCC Stage IIB, IIC, III, and IV Melanoma Patients With **Human and Mouse gp100 DNA**: A Phase I Trial to Assess Safety and Immune Response **Primary** 1) Determine the safety and feasibility of vaccination with human and mouse gp100 DNA in patients with stage IIB, IIC, III, or IV melanoma. 2) Determine the maximum tolerated dose of this regimen in these patients. 3) Compare the antibody and T-cell response in patients treated with two different vaccination schedules. **Secondary: 1)** Assess antitumor response in patients treated with this regimen. 2) OUTLINE: This is a randomized, crossover, dose-escalation study. Patients are randomized to 1 of 2 treatment arms. 3) Arm I: Patients receive human gp100 DNA vaccine intramuscularly (IM) once in weeks 1, 4, and 7. Patients then receive mouse gp100 DNA vaccine IM once in weeks 10, 13, and 16. 4) Arm II: Patients receive mouse gp100 DNA vaccine IM once in weeks 1, 4, and 7. Patients then receive human gp100 DNA vaccine IM once in weeks 10, 13, and 16. 5) In both arms, treatment continues in the absence of disease progression or unacceptable toxicity. Cohorts of 6-9 patients (at least 3 per treatment arm) receive escalating doses of human and mouse gp100 DNA vaccines until the maximum tolerated dose (MTD) is determined. The MTD is defined as the dose preceding that at which 2 of 9 patients experience dose-limiting toxicity. After completion of study treatment, patients are followed at 3 weeks and then annually for 15 years. PROJECTED ACCRUAL: Approximately 18-27 patients will be accrued for this study within 6-9 months.	
Recruiting	MAGE-A3/HPV 16 Vaccine for Squamous Cell Carcinoma of the Head and Neck Condition: Squamous Cell Carcinoma of the Head and Neck 2005-2009 Interventions: Biological: MAGE-A3; Biological: HPV-16 vaccine	

	A Phase 1 Open Label, Dose Escalation Study to Evaluate the Effect of Four Doses of MAGE-A3/HPV 16 Trojan Peptides 0001 and 0002 Administered Subcutaneously in Combination With Montanide and GM-CSF on Immunological Response, Safety, Tolerability, and Preliminary Efficacy in Patients With Squamous Cell Carcinoma of the Head and Neck. Three dose levels of MAGE-A3 vaccine and HPV 16will be tested : 500ug, 1000 ug and 1500 ug Squamous Cell Carcinoma of the Head and Neck affects 43,000 individuals in the United States annually with an estimated overall survival rate of 50%. In order to improve both the survival rate and quality of life for patients who develop unresectable disease recurrence, new therapeutic alternatives are mandated. One potential treatment alternative for this patient population is the use of peptide-based immunotherapy. Despite the success fo preclinical studies using peptide vaccines, therapeutic responses in patients have been sporadic. The reasons for failure are multifactorial and include problems with patient selection, a limited number of antigenic targets, and an inability to correlate immunologic response with therapeutic efficacy. Specifically, patients with disseminated SCCHN have defects in antigen processing, presentation and effector mechanisms that limit their ability to respond to T cell based immunotherapy. Additionally, a paucity of antigenic peptide epitopes are defined for SCCHN, and immunologic monitoring does not correlate well with clinical response. Recently several investigators, including our research team, have identified a high prevalence of MAGE-A3 and HPV 16 on SCCHN, and characterized several putative cytolytic and helper epitopes. Additionally, we have defined a novel method to enhance the immune response to therapeutic peptide vaccines using Trojan complexes composed of CD4 and CD8 T-cell epitopes, connected by furin cleavable linkers. In order to define the feasibility and safety of these agents in combination with GM-CSF and montanide ISA 51 for the immunotherapy of SCCHN, in this proposed trial, we will screen patients for immunologic competence based on specific eligibility criteria including both antigen and HLA-A2 expression on tumors. In registered patients, we will test the ability of two novel Trojan peptide complexes, composed of MAGE-A3 and human papilloma virus 16 (HPV 16) epitopes, to stimulate antigen-specific CD 4 and CD 8 T-cell responses. Finally, we will correlate immunologic response with cell dose and the generation of both HPV 16 and MAGE-A3 antigen loss and HLA-A2 loss variants on tumors by evaluating patients for: 1) Changes in tumor size by both physical measurement and CT plus PET measurement; 2) Determining what proportions of individuals who achieve a complete response (CR), partial response (PR), or have stable disease (SD); 3) Progression-free survival; 4) Survival. Successful completion of this clinical trial will result in the development of a strong foundation for a Phase II/III clinical trial using HPV 16 and MAGE-A3 Trojan peptides for the immunotherapy of SCCHN.
Recruiting	Safety Study of Multiple-Vaccine to Treat Metastatic Breast Cancer Condition: Metastatic Breast Cancer 2010-2012 Intervention: Biological: CDCA1, URLC10, KIF20A, DEPDC1 and MPHOSPH1

	Phase I Study of Multiple-Vaccine Therapy Using Epitope Peptides Restricted to HLA-A*2402 in Treating Patients With Refractory Breast Cancer Primary: safety (Phase I: toxicities as assessed by NCI CTCAE version3) [Time Frame: 1 month] Secondary: 1) •to evaluate efficacy (feasibility as evaluated by RECIST) [Time Frame: 2 months]. 2) to evaluate overall survival to evaluate progression free survivial to evaluate efficacy (feasibility as evaluated by RECIST) to evaluate immunological responses to evaluate quality of life Biological: CDCA1, URLC10, KIF20A, DEPDC1 and MPHOSPH1 CDCA1, URLC10, KIF20A, DEPDC1 and MPHOSPH1 peptides mixed with Montanide ISA 51 Patients will be vaccinated once a week until patients develop progressive disease or unacceptable toxicity. On each vaccination day, CDCA1 URLC10, KIF20A, DEPDC1 and MPHOSPH1 peptides (0.5, 1 or 2mg of each peptide) mixed with Montanide ISA 51 will be administered by subcutaneous injection. CDCA1, URLC10, KIF20A, DEPDC1 and MPHOSPH1 have been identified as cancer specific molecules especially in breast cancer using genome-wide expression profile analysis by cDNA microarray technique. We have determined the HLA-A*2402 restricted epitope peptides derived from these molecules and identified that these peptides significantly induce the effective tumor specific CTL response in vitro and vivo. According to these findings, in this trial, we evaluate the safety, immunological and clinical response of these peptides. Patients will be vaccinated once a week until patients develop progressive disease or unacceptable toxicity. On each vaccination day, CDCA1, URLC10, KIF20A, DEPDC1 and MPHOSPH1 peptides (0.5, 1 or 2mg of each peptide) mixed with Montanide ISA 51 will be administered by subcutaneous injection. Repeated cycles of vaccine will be administered until patients develop progressive disease or unacceptable toxicity, whichever occurs first. In the phase I study, we evaluate the safety and tolerability of these peptides vaccine. Also we evaluate the immunological and clinical response of this vaccine therapy.
Completed	flt3L With or Without Vaccine Therapy in Treating Patients With Metastatic Melanoma or Renal Cell Cancer Conditions: Stage IV Melanoma; Stage IV Renal Cell Cancer; Recurrent Renal Cell Cancer; Recurrent Melanoma 2007- Interventions: Drug: flt3 ligand; Drug: gp100 antigen; Drug: MART-1 antigen; Drug: Montanide ISA-51; Drug: tyrosinase
	The drug **flt3L** may stimulate a person's immune system and help to kill tumor cells. Vaccines made from melanoma cells may make the body build an **immune response to and kill their tumor cells**. PURPOSE: Phase II trial to study the effectiveness of flt3L with or without vaccine therapy in treating patients with metastatic melanoma or renal cell cancer. OBJECTIVES: I. Evaluate the immunologic and biologic activity of flt3 ligand (Flt3L) alone in patients with metastatic renal cell cancer or HLA-A2.1 negative melanoma. II. Evaluate the immunologic and biologic activity of Flt3L alone or in combination with melanoma peptide immunization (MART-1, gp100:209-217, gp100:280-288, and tyrosinase) in patients with metastatic, HLA-A2.1 positive melanoma. PROTOCOL OUTLINE: Patients are assigned to 1 of 3 treatment groups: Group 1 (renal cell cancer): Patients receive Flt3 ligand (Flt3L) subcutaneously (SQ) alone on days 1-14. Group 2 (HLA-A2.1 negative melanoma): Patients receive Flt3L SQ alone on days 1-14. Group 3 (HLA-A2.1 positive melanoma): Patients may receive either Flt3L SQ alone on days 1-14 or in combination with melanoma peptide immunization. Patients may receive melanoma peptide immunization comprised of MART-1 immunodominant peptide, gp100:209-217, gp100:280-288, and tyrosinase peptide emulsified in Montanide ISA-51 SQ on day 12 of Flt3L administration. Treatment repeats every 4 weeks for 2 courses. Patients with no response or minor response may receive 2 additional courses. Patients with disease progression after 1 course are removed from study. PROJECTED ACCRUAL: Approximately 54-96 patients (18-32 per treatment group) will be accrued for this study within 16 months
Active, not recruiting	Antiangiogenic Peptide Vaccine Therapy With Gemcitabine in Treating Patient With Pancreatic Cancer Condition: Pancreatic Cancer 2008 Intervention: Biological: VEGFR1-1084, VEGFR2-169, and gemcitabine

	Phase I Sturdy on **Antiangiogenic Vaccine** Therapy Using Epitope Peptide Derived From VEGFR1 and VEGFR2 With Gemcitabine in Treating Patients With Unresectable, Recurrent, or Metastatic Pancreatic Cancer Primary: •Adverse effect, toxicities as assessed by NCI CTCAE version3.0 [Time Frame: 3 months] [Designated as safety issue: Yes] Secondary: •feasibility [Time Frame: 2 years] [Designated as safety issue: No] **VEGFR1-1084, VEGFR2-169**, and gemcitabine. One mg of each peptide will be administered by subcutaneous injection on days 1, 8, 15, and 22 of each 28-day treatment cycles. Gemcitabine will be administered intravenously at a fixed dose of 1000mg/m2 on day 1, 8 and 15. Vascular endothelial growth factor receptor 1 and 2 (VEGFR1 andVEGFR2) are essential targets to tumor angiogenesis, and we identified that peptides derived from these receptors significantly induce the effective tumor specific CTL response in vitro and in vivo. According to these findings, in this trial, we evaluate the safety, tolerability and immune response of these peptide emulsified with Montanide ISA 51 in combination with gemcitabine
Completed	Gemcitabine With Antiangiogenic Peptide Vaccine Therapy in Patients With Pancreatic Cancer Condition: Pancreatic Cancer 2008-2009 Intervention: Biological: VEGFR2-169 and gemcitabine
	Primary: 1) Safety(toxicities as assessed by NCI CTCAE version 3) [Time Frame: 3 months] **Secondary**: 1) VEGFR2 peptide specific CTL induction in vitro [3 mos], 2) DTH to VEGFR2 peptide [3 mo], 3) Changes in levels of regulatory T cells [3 mo], 4) Objective response rate as assessed by RECIST criteria [1 year], 5) Time to progression [1 yrs], 6) survival [1 yrs], Biological: VEGFR2-169 and gemcitabine Escalating doses of VEGFR2-169 will be administered by subcutaneous injection on days 1,8,15 and 22 of each 28-day treatment cycles(doses of 0.5,1.0,2.0mg/body are planned). Gemcitabine will be administered intravenously at a fixed dose of 1000mg/m2 on days 1,8 and 15. Repeated cycles of VEGFR2-169 and gemcitabine will be administered until patients develop progressive disease or unacceptable toxicity,or for maximum 2 cycles, whichever occurs first. Vascular endothelial growth factor receptor 2(VEGFR2) is essential target for tumor angiogenesis, and VEGFR2-169 induces specific Cytotoxic T lymphocytes (CTL) against VEGFR2 expressed targets. VEGFR2-169 shows strong anti-tumor effects restricted to HLA-A*2402 in vitro, and this peptide induces CTL from cancer patients. 60% in Japanese population have HLA-A*2402. VEGFR2-169 is suitable for clinical trial, and gemcitabine has been approved against pancreatic cancer. Gemcitabine is reported to improve immune-response, therefore synergistic effect between vaccine therapy and chemotherapy will be expected. In this clinical trial, we evaluate the safety, tolerability and immune response of different doses of VEGFR2-169 emulsified with Montanide ISA 51 in combination with gemcitabine and to determine the recommended phase II dose of peptide.
Active, not recruiting	Peptide Vaccine and S-1/CPT-11 Therapy for Patients With Unresectable Advanced Colorectal Cancer Condition: Colorectal Cancer 2008- Intervention: Biological: RNF43-721

	The purpose of this study is to evaluate the safety and immune response of different doses of RNF43-721 emulsified with Montanide ISA 51 in combination with S-1/CPT-11 chemotherapy. Primary: •Safety (toxicities as assessed by NCI CTCAE version 3) [Time Frame: 2 months] Secondary: Specific CTL induction in vitro, Objective rate as assessed by RECST criteria [Time Frame: 2 months RNF43 (0.5mg, 1.0mg, 3.0mg/body/week) is a cancer testis antigen which express widely in colorectal cancer tissue but not in normal organs. RNF43-721 induces HLA A24 restricted specific cytotoxic T lymphocytes (CTL) against RNF43 expressed target. S-1/CPT-11 chemotherapy is performed unresectable advanced colorectal cancer in Japan and is reported to be obtained almost the same result compared with FOLFOX or FOLFIRI as first-line chemotherapy for advanced colorectal cancer. Because synergistic effect between vaccine therapy and chemotherapy will be expected, we plan phase I study to evaluate the safety and immune response of different doses of RNF43-721 emulsified with Montanide ISA 51 in combination with S-1/CPT-11 chemotherapy
Recruiting	Evaluate Safety of a Vaccine Against Cervical Cancer (HPV-16/18 L1/AS04) in Healthy Filipino Females Aged 10 Yrs & Above Conditions: HPV-16/18 Infections and Associated Cervical Neoplasia; Papillomavirus Vaccines Intervention: Biological: Cervarix
Recruiting	A Phase I/II Study Of Immunization With Lymphotactin And Interleukin 2 Gene Modified Neuroblastoma Tumor Cells Condition: Neuroblastoma 2008-2012 Intervention: Biological: SJNB-JF-IL2 and SJNB-JF-Lptn cells and SKNLP Unmodified Neuroblastoma Cell Lines

	The investigators intend to test the safety, and immunologic and clinical efficacy of a combination of 2 allogeneic neuroblastoma tumor cell line vaccines, one of which has been genetically modified to secrete the cytokine/chemokine combination of IL-2 and lymphotactin, in patients undergoing chemotherapy for newly diagnosed, high risk neuroblastoma who receive single autologous stem cell rescue as consolidation therapy. This protocol will be carried out as a Phase I/IIa study to evaluate the safety and toxicity of adding a previously unstudied, unmodified, irradiated neuroblastoma cell line (SKNLP) to a studied, safe dose of a gene modified, IL-2/Lptn secreting neuroblastoma cell line SJNB-JF-IL2/Lptn to be given as a vaccine to patients diagnosed with high risk neuroblastoma. **Primary**: 1) Evaluate the safety of repeated immunization with gene-modified, IL-2/lymphotactin secreting SJNB-JF-IL2 and SJNB-JF-Lptn cells co-administered with the unmodified SKNLP neuroblastoma cell line. [1 year], 2) Evaluate the immune response to these immunizations. [1 year], 3) Evaluate changes in minimal residua disease load by polymerase chain reaction pre- and post-vaccination. [1 year] **Secondar**: 1) Estimate 3 year progression free survival (PFS) and overall survival (OS) in vaccinated patients. Biological: SJNB-JF-IL2 and SJNB-JF-Lptn cells and SKNLP Unmodified Neuroblastoma Cell Lines *SJNB-JF-IL2 and SJNB-JF-Lptn cells are each dosed at 1x10e7 cells/m2/vaccination. •Dose Level 1 (3-6 patients) 1x10e6 cells/m2/vaccination dose of SKNLP Unmodified Neuroblastoma Cell Line Vaccine Component. • Dose Level 2 (3-6 patients) 1x10e7 cells/m2/vaccination dose of SKNLP Unmodified Neuroblastoma Cell Line Vaccine Component. TREATMENT PLAN: Standard Chemotherapy for Neuroblastoma: Standard therapy for neuroblastoma is given in 3 phases: induction, consolidation, and maintenance. For enrollment in this vaccine study patients and their physicians must anticipate therapy that will include consolidation with high dose chemotherapy with stem cell rescue. They will be eligible for enrollment in the phase I or phase II trial of vaccination with gene modified and unmodified, allogeneic neuroblastoma cell lines. Patients will receive Induction, Consolidation, and Maintenance therapy per their institutional standards. A general description of the therapy follows: •Induction: Induction consists of multiple cycles of induction chemotherapy with harvest of autologous stem cells immediately following a particular cycle of chemotherapy per institutional standards. Local control of the tumor with radiation therapy and/or surgery occurs following a few cycles of induction chemotherapy or immediately prior to consolidation therapy. •Consolidation: Consolidation must consist of high dose chemotherapy with autologous stem cell rescue (HDT/SCR). •Maintenance: Starting day +90 after HDT/SCR, patients will be treated with Isotretinoin (Cis-Retinoic Acid, CRA).