	VACCINE DOSING: Vaccine components SJNB-JF-IL2 and SJNB-JF-Lptn will each be dosed at 1x10e7 cells/m2. This will be given in conjunction with an escalating dose of SKNLP vaccine in the phase I portion of this study. In the phase II portion of this study, the same dose of SJNB-JF-IL2 and SJNB-JF-Lptn will be given in conjunction with the highest dose of SKNLP determined in the phase I portion. Vaccination will be administered on an inpatient or outpatient basis. Patient will be notified of which dose of vaccine cells they will receive if enrolled in the study. Phase I Dose Escalation Component: While the investigators do not suspect that addition of a second irradiated, unmodified neuroblastoma tumor cell line to the previously tested SJNB-JF gene modified cell line will affect the safety profile of the vaccine, as the SKNLP has not been tested previously in vaccine studies, the investigators will perform an abbreviated dose escalation study of the combined vaccine to assess safety. The investigators know that the vaccine given to patients whose neuroblastoma returned was safe. The vaccine that was given to those patients was treated with the viruses to make cytokines. The investigators have never used the 2nd cell group in patients. Because of this, the investigators plan to treat 3 to 6 patients at a lower dose of cells to see if adding the second cell line is safe to give. •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 ◦SJNB-JF-IL2 and SJNB-JF-Lptn cells are each dosed at 1x10e7 cells/m2/vaccination Duration of Therapy: In the absence of treatment delays due to adverse events, treatment may continue with immunizations per the treatment plan up to 12 vaccinations or until one of the following criteria applies: - Disease progression - Intercurrent illness that
Completed	LMB-2 Immunotoxin and Vaccine Therapy in Treating Patients With Metastatic Melanoma That Cannot Be Removed By Conditions: Melanoma (Skin); Non-Melanomatous Skin Cancer 2006-2012 Interventions: Biological: LMB-2 immunotoxin; Biological: **MART-1** antigen; Biological: **gp100** antigen; Biological: incomplete Freund's adjuvant
	RATIONALE: The **LMB-2 immunotoxin can find tumor cells and kill them without harming normal cells**. Vaccines made from peptides may help the body build an effective immune response to kill tumor cells. Giving LMB-2 immunotoxin together with vaccine therapy may kill more tumor cells. PURPOSE: This phase II trial is studying how well giving LMB-2 immunotoxin together with vaccine therapy works in treating patients with metastatic melanoma that cannot be removed by surgery. **Primary:** •Objective clinical response rate [Designated as safety issue: No] **Secondary** : 1) Changes in levels of **CD4+, CD25+ regulatory T cells** 2) Ability of LMB-2 to augment peptide vaccination. 3) Toxicity **Primary:** Determine objective clinical response in patients with progressive, unresectable metastatic melanoma treated with recombinant LMB-2 immunotoxin and peptide vaccination comprising **gp100:209-217 (210M) antigen, MART-1:27-35 antigen,** and **Montanide ISA-51**. **Secondary:** 1) termine changes in levels of CD4+, CD25+ regulatory T cells in peripheral blood before and after treatment in patients treated with this regimen. 2) determine the ability of recombinant immunotoxin LMB-2 to augment peptide vaccination in these patients. 3) Determine the toxicity profile of this regimen in these patients. OUTLINE: Patients receive LMB-2 immunotoxin IV over 30 minutes twice on days 1-3. Patients then receive peptide vaccinations comprising gp100:209-217 (210M) antigen emulsified in Montanide ISA-51 subcutaneously (SC), and MART-1:27-35 vaccine emulsified in Montanide ISA-51 SC on days 4, 5, 6, and 24-27 (course 1). After week 8, patients achieving tumor response may receive 1 additional course in the absence of disease progression or unacceptable toxicity. After completion of study treatment, patients are followed periodically in the absence of disease progression. PROJECTED ACCRUAL: A total of 26 patients will be accrued for this study.

Completed	Dendritic Cell Vaccine for High Risk Ovarian Cancer Patients	
	Condition: Ovarian Cancer 2007-2011	
	Intervention: Biological: DC-Ova	
	This is a randomized Phase I/II study designed to assess the induction of an anti-tumor immune response; the effect of **cyclophosphamide** on the vaccine; and to assess safety in subjects with advanced ovarian cancer or primary serous peritoneal cancer given a **multivalent DC vaccine**, with or without a single dose of cyclophosphamide. Potential benefit may range from no direct benefit to the study participants to stimulation of the subject's **own immune system to attack ovarian cancer to** prevent relapse Randomized Phase I/II Pilot Study of the Immunogenicity of Cyclophosphamide With Peptide Pulsed Mature Dendritic Cells for Patients With Previously Treated Ovarian Epithelial or Primary Peritoneal Carcinoma	
Completed	A Phase I Study of gp100 Human Melanoma Peptide Vaccine With Incomplete Freund's Adjuvant	
	Condition: Melanoma 1999-2008	
	Intervention: Biological: gp100 human melanoma peptide	
	This is a phase I study of melanoma tumor antigen peptide vaccines. The **nine amino acid peptides representing HLA-A2 restricted T cell epitope of the melanoma antigen, gp100** will be administered to patients emulsified in Incomplete Freund's Adjuvant, (IFA). The study is designed to evaluate the toxicity, immunologic effects and potential therapeutic role of repeated doses of gp100 peptide vaccines administered subcutaneously. Immune reactivity to the gp100 epitope peptides will be monitored in all patients by analysis of melanoma-specific T cell precursor frequency prior to and after immunization. This is a phase I study of melanoma tumor antigen peptide vaccines. The nine amino acid peptides representing HLA-A2 restricted T cell epitope of the melanoma antigen, gp100 will be administered to patients emulsified in Incomplete Freund's Adjuvant, (IFA). The study is designed to evaluate the toxicity, immunologic effects and potential therapeutic role of repeated doses of gp100 peptide vaccines administered subcutaneously. Immune reactivity to the gp100 epitope peptides will be monitored in all patients by analysis of melanoma-specific T cell precursor frequency prior to and after immunization.	
Completed	Evaluation of Immunogenicity and Safety of Human Papillomavirus (HPV) Vaccine Co-administered With Another Vaccine in	
Has Results	Conditions: Papillomavirus Vaccines; Human Papillomavirus Infection	
	Interventions: Biological: HPV Vaccine (GSK580299) Cervarix TM; Biological: Engerix B	
Completed	Safety of Peptide Vaccination for Patients With Myelodysplastic Syndrome	
	Condition: Myelodysplastic Syndrome (MDS) 2005-2012	
	Intervention: Drug: WT1 and PR1 Peptide Vaccine	

	This study will test whether certain patients with myelodysplastic syndrome (MDS), acute myeloid leukemia (AML) or chronic myeloid leukemia (CML) can safely be vaccinated with two peptide vaccines derived from proteins called proteinase 3 (PR1) and Wilm's tumor-1 (WT1). These proteins are produced in large amounts by cells of MDS, AML and CML patients. The peptides are combined with an "adjuvant" called Montanide to make the vaccines, and the vaccines are given with GM-CSF (sargramostim). Both Montanide and sargramostim help the immune system respond to the vaccines. The vaccines then activate the immune system to make specialized cells that search out and kill the MDS, AML and CML cells containing the two proteins. Patients with MDS, AML or CML who are 18 years of age or older may be eligible for this study. Candidates are screened with a medical history and physical examination, blood tests, chest x-ray, and bone marrow aspirate and biopsy. For the bone marrow biopsy, the area of the hip is anesthetized and a special needle is used to draw marrow from the hipbone. Participants receive an injection (shot) of each peptide vaccine into deep tissue of the upper arm, upper leg, or the abdomen and two separate shots of sargramostim in the same area as the vaccine shots. Patients' vital signs (heart rate, breathing rate, temperature, blood pressure) are measured before and after they receive the vaccines and they are watched for 2 hours after the shots for possible side effects, such as chills, pain at the injection site, stomach upset, allergic reaction, low blood counts, and infection. Patients return to the clinic 1, 2, 3 and 4 weeks after receiving the vaccines for a brief physical evaluation and blood tests. A chest x-ray is also done at the 4-week visit. Patients may receive whole blood or platelet transfusions if needed to treat the MDS, growth factors (filgrastim, erythropoietin, or others) if needed, and medications to treat any infections that may develop primary: To evaluate the safety of and toxicity assoc. with a single dose of a comb. of**PR1:169-177 and WT-1:126-134 peptide (in Montanide adjuvant)** vaccination admin. concomitantly with GM-CSF (Sargramostim) in selected patients with myeloid malignancie... The immunological graft-versus-leukemia (GVL) effect seen after allogeneic stem cell transplantation suggests that stimulating the patient's own T cell responses to MDS and leukemia with a vaccine might also retard disease progression and even achieve disease remissions. WT1 and PR1 were identified as target antigens because both antigens are highly expressed by CD34+ stem cells of most patients with myeloid malignancies but not by normal marrow cells. An immunotherapeutic approach to vaccinate against PR1 and WT1 antigens could induce T cell response against MDS and leukemic cells while sparing normal cells and by using a combination of two antigens the risk of disease escape by antigen down regulation should be further diminished. Therefore, we propose to evaluate a vaccine composed of peptides derived from two proteins over-expressed in MDS and leukemia stem cells - proteinase 3 (PR1) and Wilms tumor-1 (WT1). This protocol, the first in a series of planned research, will evaluate the safety of a single dose of a combination of two peptide vaccines, namely PR1:169-177 and WT-1:126-134 in Montanide adjuvant administered concomitantly with GM-CSF (Sargramostim) in select subjects diagnosed with MDS, AML and CML
Completed	Human Papillomavirus Vaccine Safety & Immunogenicity Trial in Healthy Young Adult Women With HPV Vaccine Conditions: Human Papillomavirus (HPV) Infection; Cervical Neoplasia Interventions: Biological: Cervarix TM; Biological: GSK Biologicals' HPV vaccine (GSK1674330A)
Completed	Autologous T-Cell Transplantation and the Immunotherapy of Residual Disease in Breast Cancer: Pilot Study of Vaccine-Driven T-Cell Expansion in Patients Treated With Dose-Intensive Chemotherapy Conditions: Breast Neoplasm; Neoplasm Metastasis 2006-2008 Interventions: Procedure: Autologous T cells; Drug: Interleukin-2

	Pilot Study of **Autologous T Cells and/or IL-2** for the Enhancement of Immune Reconstitution After Dose-Intensive Chemotherapy for Breast Cancer **Detailed Description**: The process of T cell immune reconstitution post-chemotherapy in breast cancer patients is impaired. Such a deficit in T cell immunity likely represents an important obstacle to tumor vaccine therapy in breast cancer patients. In an attempt to enhance T cell immune reconstitution, we have administered cryopreserved T cells and interleukin-2 to breast cancer patients post-chemotherapy. Initial data from the first 13 patients enrolled on this study suggests that the administration of T cells and IL-2 resulted in improved T cell reconstitution relative to untreated patients or patients receiving only IL-2. Importantly, recipients of the combination of T cells and IL-2 had an enhanced recovery of CD4+CD45RA+ T cells; because this T cell subset represents a naive T cell phenotype that generally maintains a capacity to respond to antigen, enhanced regeneration of this population may result in improved immune function and may allow for a more successful immune response to tumor vaccines. It will be important to now evaluate what effect T cell administration alone (without IL-2 treatment) has on immune reconstitution post-chemotherapy. Determination of the relative benefits of T cell and/or cytokine administration on T cell recovery post-chemotherapy may assist in the development of breast cancer vaccine protocols where a T cell-mediated immune response may be necessary for optimal response to the vaccine.	
Completed Has Results	Evaluation of Safety and Immunogenicity of Co-administering HPV Vaccine With Other Vaccines in Healthy Female Subjects Conditions: Human Papillomavirus Type-16/-18 Infection; Cervical Neoplasia Interventions: Biological: Boostrix TM; Biological: Different formulations of GSK Biologicals' HPV vaccine (580299); Biological: Menactra TM	
Active, not recruiting Has Results	An Investigational Study of Gardasil (V501) in Reducing the Incidence of Anogenital Warts in Young Men (V501-020) Condition: Condylomata Acuminata Interventions: Biological: (Gardasil) human papillomavirus (types 6, 11, 16, 18) recombinant vaccine; Biological: Comparator: placebo (unspecified)	
Active, not recruiting	Vaccination Therapy in Treating Patients With Limited-Stage Small Cell Lung Cancer Condition: Lung Cancer 1999-2012 Interventions: Biological: BCG vaccine; Biological: monoclonal antibody BEC2	
	Detailed Description: OBJECTIVES: I. Determine the impact of adjuvant monoclonal antibody BEC2 and BCG on survival of patients with limited stage small cell lung cancer. II. Determine the safety of this regimen in these patients. III. Determine progression-free survival and quality of life of these patients treated with this regimen. OUTLINE: This is a randomized, multicenter study. Patients are stratified according to center, Karnofsky performance status (60-70% vs 80-100%), and response to first-line combined modality treatment (complete vs partial). Within 3-7 weeks after completion of prior induction chemoradiotherapy, responding patients are randomized to 1 of 2 treatment arms. Arm I: Patients receive best supportive care and are observed until disease progression is documented. Arm II: Patients receive adjuvant monoclonal antibody BEC2 and BCG intradermally on day 1 of weeks 0, 2, 4, 6, and 10. Treatment consists of 5 vaccinations over a period of 10 to 12 weeks in the absence of unacceptable toxicity or disease progression. Quality of life is assessed at baseline, at weeks 6, 12, and 24, and then every 6 months thereafter. Patients are followed every 3 months. PROJECTED ACCRUAL: Approximately 500 patients will be accrued for this study within 4 years.	

Completed	Cervical Intraepithelial Neoplasm (CIN)-Warts Efficacy Trial in Women (Gardasil)	
Has Results	Conditions: Cervical Cancer; Genital Warts	
	Interventions: Biological: V501; Biological: Comparator: Placebo; Biological: Human Papillomavirus (HPV) 16 Monovalent	
Completed	Human Papillomavirus (HPV) Vaccine (Cervarix TM) Efficacy, Immunogenicity & Safety Trial in Adult Japanese Women With	
Has Results	Conditions: Human Papillomavirus (HPV) Infection; Cervical Neoplasia	
	Interventions: Biological: HPV-16/18 vaccine (Cervarix™); Biological: Aimmugen™	
Completed	Chemotherapy and Peripheral Stem Cell Transplantation Followed By Immunotherapy in Treating Patients With Multiple	
	Conditions: Infection; Multiple Myeloma and Plasma Cell Neoplasm 2002-2009	
	Interventions: Biological: filgrastim; Biological: pneumococcal polyvalent vaccine; Biological: therapeutic autologous lymphocytes; Biological: therapeutic tumor infiltrating lymphocytes; Drug: carmustine; Drug: cyclophosphamide; Drug: melphalan; Procedure: bone marrow ablation with stem cell support; Procedure:	
	OBJECTIVES: •Determine the feasibility of expanding ex vivo autologous T cells and infusing these cells after high-dose chemotherapy and autologous peripheral blood stem cell rescue in patients with multiple myeloma. •Determine the response rate and progression-free survival of patients who receive anti-CD3/anti-CD28 expanded autologous T cells on either day 14 or day 100 post-transplantation. •Compare response and survival rates of these patients to historical controls. •Determine the optimal schedule for pneumococcal conjugate vaccine (PCV) to induce an anti-pneumococcal immune response post-transplantation in these patients. •Determine whether "vaccine education" of antigen-presenting cells (APCs) in the stem cell graft results in an earlier and/or enhanced immune response than with a graft containing "non-educated" APCs in these patients. •Determine whether an infusion of T cells presensitized to the PCV and expanded ex vivo contributes to the anti-pneumococcal immune response in these patients. OUTLINE: This is a randomized, multicenter study. Patients receive cyclophosphamide IV over 12 hours on day 1 and filgrastim (G-CSF) subcutaneously (SC) daily beginning on day 2. Patients undergo leukapheresis to collect mononuclear cells for autologous T cells (ATCs) and peripheral blood stem cells (PBSCs). ATCs are generated by ex vivo expansion for 8-14 days and selection for CD3+/CD28+ cells. Patients then receive high-dose therapy comprising carmustine IV over 2 hours on day -2 and melphalan IV over 20 minutes on day -1 or melphalan IV alone on days -2 and -1 (or day -1 only). Autologous PBSCs are reinfused on day 0. Patients also receive G-CSF SC beginning on day 1 and continuing until blood counts recover. Patients who choose to receive pneumococcal conjugate vaccine (PCV) are randomized to 1 of 4 treatment arms. •Arm I: Patients receive PCV intramuscularly prior to transplantation (10-14 days before lymphocyte collection) and post-transplantation (1 and 3 months) plus costimulated ATCs IV over 20-60 minutes around day 12-14 post-transplantation. •Arm II: Patients receive PCV as in arm I but receive ATCs around day 100 post-transplantation. •Arm III: Patients receive PCV post-transplantation only (at 1 and 3 months) plus ATCs as in arm I. •Arm IV: Patients receive PCV as in arm III and ATCs as in arm II. Patients who choose not to receive the PCV receive ATCs on about day 12-14 after PBSC transplantation. All patients are offered standard pneumococcal polysaccharide vaccine at 12 months. Patients are followed twice weekly until day 60, weekly for 4 months, monthly for 6 months, andthen every 3 months thereafter.	

Completed	Human Papillomavirus Vaccine Immunogenicity and Safety Trial in Young Adult Women With GSK Biologicals Novel HPV	
	Condition: Prophylaxis for HPV Infections and Cervical Neoplasia	
	Interventions: Biological: CervarixTM; Biological: HPV investigational vaccine GSK568893A, different formulations	
Recruiting	Vaccination With GM-K562 Cells in Patients With Advanced Myelodysplastic Syndrome (MDS) or Acute Myeloid Leukemia (AML) After Allogeneic Hematopoetic Stem Cell Transplantation	
	Conditions: Acute Myeloid Leukemia; Chronic Myelomonocytic Leukemia; Myelodysplastic Syndrome-Refractory Anemia With Excess Blasts 2008-2012	
	Intervention: Biological: GM-K562/leukemia cell vaccine	
	Primary: •To assess the safety of vaccination, as measured by vaccine related reactions and incidence of grade III-IV acute GVHD. 2 years] **Secondary** : •To assess the efficacy of vaccination with GM-K562/leukemia cell vaccine following allogeneic stem cell transplantation in this patient population. [2 year]. •To characterize the biologic responses and leukemia specific immune responses after vaccination with GM-K562/leukemia cell vaccine following allogeneic stem cell transplant. [2 years]•To determine duration of disease response, disease free and overall survival [2 years] Detailed Description: •Participants will be given the GM-K562/Leukemia call vaccine as in injection under the skin a total of six times. The first 3 vaccines will be given weekly and vaccines 4 through 6 will be given every other week. Therefore, it is expected that the vaccines will be completed over a period of 9 weeks. •During the 9 week vaccination period, participants will have physical exams to monitor for any side effects or graft-versus-host disease (GVHD). Bone marrow biopsies will be performed a the time of enrollment for this study, 4 weeks after completion of 6 GM-K562/Leukemia cell vaccines, and 1 year after the participants transplant. •As a way of testing whether the GM-K562/Leukemia cell vaccine is triggering any immune response to the participants leukemia, we will be injecting a small amount of leukemia cells (after they are killed with radiation) under the participants skin to see if the body will generate a reaction to the leukemia cells. This test is called a leukemia cell delayed hypersensitivity test (DTH). This test will be performed three times during the study, on the weeks of the 1st vaccine, 5th vaccine and 4 weeks after the 6th vaccine. •There are a total of 5 skin biopsies required as part of this study. Biopsies will be taken from the vaccination sites 2-3 days after the first and fifth vaccine. Similar biopsies will be taken from the DTH sites after the 1st vaccination, 5th vaccination and 4-6 weeks after the 6th vaccination.	
Completed	Human Papilloma Virus Vaccine Consistency and Non-Inferiority Trial in Young Adult Women With GSK Bio HPV-16/18	
	Conditions: HPV-16/18 Infections; Cervical Neoplasia	
	Intervention: Biological: HPV-16/18 L1/AS04	
Enrolling by invitation	Safe Study of Dendritic Cell (DC) Based Therapy Targeting Tumor Stem Cells in Glioblastoma	
	Conditions: Glioblastoma; Brain Tumor 2009-2011	
	Intervention: Biological: Dendritic cell vaccine with mRNA from tumor stem cells	

	The study induces an immune response towards the stem-cell like part of glioblastomas in combination with standard therapy. The aim is to define and characterize the feasibility, potential adverse effects of such therapy and measure time to progression and survival Primary: •Adverse events [Time Frame: During follow-up] [Designated as safety issue: Yes] Secondary : •Evaluation of immunological response, time to disease progression and survival time [Time Frame: 5 years]
Recruiting	Safety Study of Adjuvant Vaccine to Treat Melanoma Patients Condition: Melanoma 2010 Intervention: Biological: NY-ESO-1 protein; Poly-ICLC; Montanide
	Primary: •Phase I, to define the safety of subcutaneous vaccination with **NY-ESO-1 protein, Montanide and escalating doses of Poly-ICLC** [Time Frame: **Disease status is assessed at baseline, wks 4 & 12 and after 4th vaccination (wks 14 & 22). At wk 52, disease status is assessed through patient follow-up with study physicians or through contact with the patient's regular treating physician.**] Up to 3 cohorts of 3 patients will be given a subcutaneous vaccination of 100μg NY-ESO-1 protein emulsified in 1.1mL Montanide® ISA-51VG (day 1) with escalating doses of Poly-ICLC. Dose-escalation will continue if no DLTs are observed in the 3 patients in a given cohort. **Secondary** : •To evaluate the induction of **humoral and T cell (CD4+ and CD8+) immunity** to subcutaneous vaccination with NY-ESO-1 protein in combination with Poly-ICLC when given with or without Montanide. [Time Frame: Disease status is assessed at baseline, wks 4 & 12 and after 4th vaccination (wks 14 & 22). At wk 52, disease status is assessed through patient follow-up with study physicians or through contact with the patient's regular treating physician.] When Phase I is complete (no cohort 3 DLT observed) 24 new patients are randomized in **Phase II** to receive treatment under Arm A or Arm B. They receive s.c. vaccinations of 100μg NY-ESO-1 protein with Poly-ICLC alone dose TBD (Arm A); or with 100μg NY-ESO-1 protein, Poly-ICLC dose TBD and 1.1mL Montanide (Arm B). **Administrations occur every 3 wks on study wks 1,4,7,&10.** Injections may occur w/in +/-3 days of planned date. **Blood samples are obtained at baseline, 1 wk after vaccinations, and 1&3 months after last vaccination for assessment of NY-ESO-1 specific antibodies and CD4+ & CD8+ T cell** **Detailed Description:** This is a Phase I open label dose escalation study of the TLR3 agonist Poly-ICLC as an adjuvant for NY-ESO-1 protein vaccination in patients with high risk melanoma in clinical complete remission (cCr), followed by a randomized Phase II component in which patients will be randomized to subcutaneous vaccination of NY-ESO-1 protein with Poly-ICLC alone dose TBD (Arm A) or with NY-ESO-1 protein, Poly-ICLC dose TBD and Montanide® ISA-51 VG (Montanide) (Arm B). Patients with histological confirmed malignant melanoma, AJCC Stages: IIB, IIC, III or IV, who are in complete clinical remission (cCr) but at high risk of disease recurrence, will be eligible for enrollment, regardless of whether antigen expression in the autologous tumor can be demonstrated by either PCR or immunohistochemistry. **Primary Objectives: 1) P**hase I: To define the safety of subcutaneous vaccination with NY-ESO-1 protein, Montanide and escalating doses of Poly-ICLC. 2)•Phase II: To evaluate the induction of humoral and T cell (CD4+ and CD8+) immunity to subcutaneous vaccination with NY-ESO-1 protein in combination with Poly-ICLC when given with or without Montanide. **Exploratory:** 1) Evaluation of primary tumor expression of NY-ESO-1 by IHC or RT-PCR. 2) Histologic quantitation of original tumor TILs (tumor infiltrating lymphocytes), CD3+ cells, evaluation of mitotic index and correlation of this data with immunologic response. 3) orrelation of NY-ESO-1 specific T cell responses with HLA type. 4) Investigation of polymorphisms for TLR3 through germline SNP analysis. 5) Clinical Outcome (Time to Progression) reported descriptively. 6) kin section analysis of protein/adjuvant treated sites for immune cell infiltration and gene expression analysis
Completed	Human Papilloma Virus Vaccine Safety and Immunogenicity Trial in Young Adolescent Women With GSK Bio HPV-16/18. Conditions: HPV-16/18 Infections; Cervical Neoplasia

	Intervention: Biological: HPV-16/18 L1/AS04	
Completed	Efficacy Study of HPV-16/18 Vaccine (GSK 580299) to Prevent HPV-16 and/or -18 Cervical Infection in Young Healthy	
	Condition: Papillomavirus Infections	
	Interventions: Biological: Cervarix; Biological: placebo	
Completed	MDX-010 Antibody, MDX-1379 Melanoma Vaccine, or MDX-010/MDX-1379 Combination Treatment for Patients With	
	Conditions: Melanoma; Metastases 2004-2011	
	Interventions: Drug: MDX-010 (anti-CTLA4) monoclonal antibody; Biological: MDX-1379 Melanoma Peptide Vaccine	
	The purpose of this study is to determine the safety and efficacy of **ipilimumab** (anti-CTLA4) in combination with MDX-1379 (**gp100**, BMS-734019) in patients with previously treated, unresectable Stage III or IV melanoma. Survival time will be evaluated, as well as patient responses and time to disease progression. Eligible patients are those who in response to a single **regimen containing interleukin-2 (IL-2), dacarbazine, and/or temozolomide, have 1)** relapsed following an objective response (**partial response/complete response [PR/CR]**); 2) failed to demonstrate an objective response (**PR/CR**); or 3) could not tolerate such a regimen due to unacceptable toxicity. Patients will be randomized into one of three groups, and will receive one of the following treatments: MDX-010 alone, MDX-1379 alone, or MDX-010 in combination with MDX-1379. **Primary:** •Overall Survival (OS) (Time-to-Death) Difference Between MDX-010 in Combination With gp 100 Melanoma Peptide Vaccine Versus gp 100 Melanoma Peptide Vaccine Alone [Time Frame: From randomization until the end of the study, which was defined as the time at which 481 deaths were observed (264 weeks)] OS was defined as the time from randomization until death from any cause. If a participant did not expire, the subject was censored at the time of last contact (last known alive date). 95% confidence intervals (CI) for median were computed using Brookmeyer and Crowley method. **Secondary:** •Overall Survival (OS) (Time-to-Death) Difference Between MDX-010 Monotherapy Versus gp100 Melanoma Peptide Vaccine Alone and MDX-010 in Combination With gp100 Melanoma Peptide Vaccine Versus MDX-010 Monotherapy [From randomization until the end of the study, which was defined as the time at which 481 deaths were observed (264 weeks)] OS was defined as the time from randomization until death from any cause. If a participant did not expire, the subject was censored at the time of last contact (last known alive date). 95% confidence intervals (CI) for median were computed using Brookmeyer and Crowley method. •12-, 18-, and 24-Month Survival Rates [Month 12, Month 18, Month 24] The probability that a subject is alive at 12 months, 18 months, and 24 months following randomization, estimated via the non-parametric method (Kaplan-Meier method). For calculating 95% CI, bootstrap method was used with 20000 simulated trials. •Progression Free Survival (PFS) [From randomization until the end of the study, which was defined as the time at which 481 deaths were observed (264 weeks)] PFS was defined as the number of days between the date of randomization and the date of the progression or the date of death. A subject who died without prior progression was considered to have progressed on the date of death. PFS was determined by investigator. 95% confidence intervals (CI) for median were computed using Brookmeyer and Crowley method. •Percentage of Participants With Progression Free Survival (PFS) at Week 12 and Week 24 [Week 12, Week 24] PFS at Week 12 was defined as the probability that the subject was progression-free at 12 weeks and 24 weeks following the start of randomization. It was computed via Kaplan-Meier method, truncated at Week 12 and Week 24. PFS was determined by investigator. 95% confidence intervals (CI) for median were computed using Brookmeyer and Crowley method	

	•Time to Progression (TTP) [Time Frame: from time of randomization to date of PD or death due to PD (end of the study was defined as the time at which 481 deaths were observed [264 weeks])] [Designated as safety issue: No] TTP was defined as the number of days between the date of the randomization and date of PD or death due to PD. For subjects who had not progression and remained alive, TTP was censored on the date of last assessment; those who remained alive and had no recorded post-baseline assessment, TTP was censored on the date of randomization; those who remained alive and had randomized but were not treated, TTP was censored at the date of randomization; for those who died without reported disease progression, TTP was censored on the date of death. •Best Overall Response (BOR): Complete Response (CR), Partial Response (PR), Stable Disease (SD), Progressed Disease (PD) [Time Frame: BOR was determined between Weeks 12 and Week 24 confirmation at least 4 weeks later at Cycle 1.] [Designated as safety issue: No] Investigator's assessment, modified World Health Organization criteria. CR: disappearance of all lesions by 2 consecutive observations >=4 weeks apart, no evidence of PD. PR: >=50% ↓ in sum of products of longest diameter & greatest perpendicular diameter of all target lesions compared to baseline by 2 observations >=4 weeks apart. SD: Neither sufficient ↓ to qualify for PR nor sufficient ↑ to qualify for PD. PD: ↑ >=25% in sum of products of longest diameter & greatest perpendicular diameter of target lesions compared to smallest recorded sum during study, or appearance of >= 1 new lesion. •Determination of Best Overall Response Rate (BORR) [Time Frame: Up to week 24] [Designated as safety issue: No] Response was based on the investigators' assessment using modified WHO criteria. BORR is defined as the number of subjects whose BOR is complete or partial response (CR or PR) divided by the total number of subjects in the group. BORR was comprised of responder and non-responder. The definition of a responder in BORR was either confirmed CR or PR, and a non-responder was defined as stable disease (SD), progressed disease (PD), unconfirmed CR (uCR), unconfirmed PR (uPR), and not evaluated. •Time to Response [Time Frame: From randomization until the end of the study, which was defined as the time at which 481 deaths were observed (264 weeks)] [Designated as safety issue: No] Time to response was defined as the number of days from the date of randomization to the date when measurement criteria are met for BOR of CR or PR, as determined by investigator. •Duration of Response [Time Frame: from time of initial drug administration to date of PD or death due to PD (the end of the study was defined as the time at which 481 deaths were observed [264 weeks])] [Designated as safety issue: No] Kaplan-Meier medians along with Brookmeyer and Crowley 95% confidence intervals (CI) for were computed. Duration of response was defined in subjects whose BOR was CR or PR as the number of days between the date of response (CR or PR) and the date of PD or the date of death (whichever occurs first).

	•Disease Control Rate (DCR) [Time Frame: Up to week 24] [Designated as safety issue: No] Response was based on the investigators' assessment using modified WHO criteria. DCR is defined as the number of subjects whose BOR is CR, PR, or SD divided by the total number of subjects in the group. •Delayed Response (Response Beyond Week 24) [Time Frame: from Week 24 to end of study (the end of the study was defined as the time at which 481 deaths were observed [264 weeks])] [Designated as safety issue: No] Response was based on the investigators' assessment using modified World Health Organization (WHO) criteria. Delayed response is defined as post Week 24 overall response for the subjects who have PD before or at Week 24. Evaluation of delayed overall response is compared to baseline assessment. Delayed response includes delayed late CR, delayed late PR, delayed late SD, continued PD, unknown, and missing after Week 24. The delayed response of CR and PR also must have been confirmed. •Change From Baseline in Health-Related Quality of Life (QOL) as Measured by the European Organization for Research and Treatment of Cancer Core Quality of Life Questionnaire (EORTC QLQ-C30) Instrument at Week 12 [Time Frame: Baseline (Day 1, Cycle1), Week 12] [Designated as safety issue: No]•The 30 items were grouped into the following: 1 global QOL scale, 5 functional scales (Physical, Role, Cognitive, Emotional, Social), and 9 symptom scales/items (Fatigue, Nausea and Vomiting, Pain, Dyspnea, Sleep Disturbance, Appetite Loss, Constipation, Diarrhea, Financial Impact). All scores were linearly transformed to a 0 to 100 scale. For global QOL and functional items, a higher score represents a better level of functioning (100=best/0=worst). For symptom items, a higher score represents a higher level of symptoms (0=no symptom at all/100=very much severe). •Percentage of Participants With On-Study Adverse Events (AEs) and AEs With an Outcome of Death [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] An AE was defined as any undesirable sign, symptom, clinically significant laboratory abnormality, or medical condition occurring after starting study treatment, even if the event was not considered to be treatment-related. Adverse events are graded using the Cancer Therapy Evaluation Program (CTEP) Common Terminology Criteria for Adverse Events (CTCAE), Version 3.0. If CTCAE grading does not exist for an adverse event, the intensity of mild (1), moderate (2), severe (3), and life-threatening (4) were used.