

## **Vaccine Therapy With or Without Cyclophosphamide and Doxorubicin in Women With Stage IV Breast Cancer**

**This study is currently recruiting participants.**

**Information provided by National Cancer Institute (NCI)**

**This Tabular View shows the required WHO registration data elements as marked by †**

### Descriptive Information Fields

Brief Title † Vaccine Therapy With or Without Cyclophosphamide and Doxorubicin in Women With Stage IV Breast Cancer

Official Title † A Phase I Vaccine Safety and Chemotherapy Dose-Finding Trial of an Allogeneic GM-CSF-Secreting Breast Cancer Vaccine Given in a Specifically Timed Sequence With Immunomodulatory Doses of Cyclophosphamide and Doxorubicin  
Brief Summary

**RATIONALE:** Vaccines made from a person's tumor cells may make the body build an immune response to kill tumor cells. Drugs used in chemotherapy, such as cyclophosphamide and doxorubicin, work in different ways to stop tumor cells from dividing so they stop growing or die. Combining vaccine therapy with cyclophosphamide and doxorubicin may kill more tumor cells.

**PURPOSE:** This phase I trial is studying the side effects and best dose of cyclophosphamide and doxorubicin when given with vaccine therapy in treating women with stage IV breast cancer.

### Detailed Description

### OBJECTIVES:

#### Primary

\* Determine the safety of vaccination comprising allogeneic sargramostim (GM-CSF)-secreting breast cancer cells with or without immunomodulation using cyclophosphamide and doxorubicin in women with stage IV breast cancer.

\* Determine the doses of cyclophosphamide and doxorubicin that maximize vaccine-induced immunity, in terms of immune response to HER2/neu, in patients treated with these regimens.

\* Compare in vivo immune response induced by these regimens, as measured by immunohistochemical analysis of vaccine site biopsies from these patients, with responses seen in prior preclinical and clinical studies.

#### Secondary

\* Determine the time to disease progression in patients treated with these regimens.

OUTLINE: This is a dose-finding study.

The first 6 patients receive 1 of 2 doses of vaccine comprising allogeneic sargramostim (GM-CSF)-secreting breast cancer cells intradermally (ID) on day 0. Subsequent patients receive cyclophosphamide IV on day -1, vaccine at the higher dose ID on day 0, and doxorubicin IV on day 7. Treatment in all patients repeats every 4-6 weeks for 3 courses in the absence of disease progression or unacceptable toxicity. Patients with stable or responding disease after the third course receive a fourth course of treatment at approximately 4 months after completion of the third course.

Cohorts of 2-3 patients receive a fixed dose of vaccine in combination with escalating doses of doxorubicin and cyclophosphamide. Doses of cyclophosphamide and doxorubicin are escalated until an optimal dose of combination chemotherapy with a fixed dose of vaccine is achieved.

Patients are followed at 1 month and 4 months after completion of study therapy and then annually thereafter.

PROJECTED ACCRUAL: A total of 6-60 patients will be accrued for this study.

Study Phase Phase I

Study Type † Interventional

Study Design † Treatment, Open Label

Primary Outcome Measure † Toxicity of vaccine w/ & w/o cyclophosphamide+doxorubicin by history and phys. exam. at 28-42 days after each vaccination, 56-84 days after third vaccination, 6 months after first vaccination, and annually after first vaccination [ Designated as safety issue: Yes ]

Toxicity of vaccine w/ & w/o cyclophosphamide+doxorubicin by CBC w/ differential at days 7, 14, 21, and 28-42 days after each vaccination, 56-84 days after third vaccination, 6 months after first vaccination, and annually after first vaccination [ Designated as safety issue: Yes ]

Toxicity of vaccine w/ & w/o cyclophosphamide+doxorubicin by comprehensive metabolic panel at day 7 and 28-42 days after each vaccination, 56-84 days after third vaccination, 6 months after first vaccination, and annually after first vaccination [ Designated as safety issue: Yes ]

Immune resp. of HER-2/neu by serum antibody titers, delayed hypersensitivity to HER-2/neu-derived peptides, and CD4+ T-cell resp. by ELISPOT at days 28-42 after each vaccination and days 56-84 after third vaccination [ Designated as safety issue: No ]

Immune responses by immunohistochemical analysis of vaccine site biopsies at days 3 and 7 after the first and third vaccinations [ Designated as safety issue: No ]

Secondary Outcome Measure † Time to disease progression by history and physical examination, computed tomography, bone scans, and tumor markers as appropriate at days 28-42 after third and fourth vaccinations and days 56-84 after third vaccination [ Designated as safety issue: No ]

Condition † Breast Cancer

Intervention † Drug: allogeneic GM-CSF-secreting breast cancer vaccine

Drug: cyclophosphamide

Drug: doxorubicin hydrochloride

Procedure: chemotherapy

Procedure: non-specific immune-modulator therapy

Procedure: tumor cell-derivative vaccine therapy

MEDLINE PMIDs 15018740

Links Clinical trial summary from the National Cancer Institute's PDQ® database This link exits the ClinicalTrials.gov site

Recruitment Information Fields

Recruitment Status † Recruiting

Enrollment † 60

Start Date † January 2004

Completion Date

Eligibility Criteria †

#### DISEASE CHARACTERISTICS:

\*

Histologically confirmed adenocarcinoma of the breast

o Stage IV disease

\* Stable disease for  $\geq 28$  days

\* Measurable or evaluable disease OR no evidence of disease

\* Not eligible for potentially curative therapy

\* Adequately treated CNS metastases are allowed

\*

Hormone receptor status:

o Not specified

\*

HER-2/neu status:

o Not specified

#### PATIENT CHARACTERISTICS:

Age

\* 18 and over

Sex

\* Female

Menopausal status

\* Not specified

#### Performance status

\* ECOG 0-1

#### Life expectancy

\* Not specified

#### Hematopoietic

\* Absolute neutrophil count  $> 1,000/\text{mm}^3$

\* Platelet count  $> 100,000/\text{mm}^3$

#### Hepatic

\* Bilirubin  $\leq 2.0$  mg/dL (unless due to Gilbert's syndrome)

\* AST and ALT  $\leq 2$  times upper limit of normal (ULN)

\* Alkaline phosphatase  $\leq 5$  times ULN

#### Renal

\* Creatinine  $< 2.0$  mg/dL

#### Cardiovascular

\* Ejection fraction  $\geq 45\%$  by echocardiogram or MUGA

#### Pulmonary

\* Asthma or chronic obstructive pulmonary disease allowed provided daily systemic corticosteroid therapy is not required

#### Immunologic

\*

No active autoimmune disease requiring systemic immunosuppressive therapy, including any of the following:

- o Inflammatory bowel disease
- o Systemic vasculitis
- o Scleroderma
- o Psoriasis
- o Multiple sclerosis

- o Hemolytic anemia
- o Immune-mediated thrombocytopenia
- o Rheumatoid arthritis
- o Systemic lupus erythematosus
- o Sjögren's syndrome
- o Sarcoidosis
- o Other rheumatologic disease
- \* HIV negative
- \* No active acute or chronic infection
- \* No allergy to corn

#### Other

- \* No other malignancy within the past 5 years except carcinoma in situ of the cervix, superficial nonmelanoma skin cancer, or superficial bladder cancer
- \* No active major medical or psychosocial problem that would preclude study participation
- \* Not pregnant or nursing
- \* Negative pregnancy test
- \* Fertile patients must use effective contraception during and for 3 months after study participation

#### PRIOR CONCURRENT THERAPY:

##### Biologic therapy

- \* More than 28 days since prior biologic therapy
- \* No other concurrent biologic therapy, including trastuzumab (Herceptin®)

##### Chemotherapy

- \* Prior adjuvant chemotherapy allowed
- \*

- Prior doxorubicin and cyclophosphamide allowed
  - o Prior doxorubicin dose combined with planned study therapy dose must not exceed a lifetime cumulative dose of  $\geq 450 \text{ mg/m}^2$
  - \* More than 28 days since prior systemic chemotherapy
  - \* No other concurrent systemic chemotherapy

##### Endocrine therapy

- \* More than 28 days since prior systemic corticosteroids
- \*

Concurrent hormonal or endocrine therapy allowed

o No concurrent systemic corticosteroids

#### Radiotherapy

- \* More than 28 days since prior radiotherapy
- \* No concurrent radiotherapy

#### Surgery

- \* Not specified

#### Other

- \* More than 28 days since prior participation in another investigational drug trial
- \* No other concurrent investigational drugs
- \* Concurrent bisphosphonates allowed

Gender Female

Ages 18 Years and older

Accepts Healthy Volunteers No

Contacts ††

Location Countries † United States

Administrative Information Fields

NCT ID † NCT00093834

Organization ID CDR0000391826

Secondary IDs †† JHOC-J0085, JHOC-RPN-01012502, JHOC-RAC-0304-578

Study Sponsor † Sidney Kimmel Comprehensive Cancer Center

Collaborators †† National Cancer Institute (NCI)

Investigators †

Principal Investigator: Leisha A. Emens, MD, PhD Sidney Kimmel

Comprehensive Cancer Center

Information Provided By National Cancer Institute (NCI)

Verification Date January 2007

First Received Date † October 6, 2004

Last Updated Date December 25, 2007

† Required WHO trial registration data element.

†† WHO trial registration data element that is required only if it exists.

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## **Clinical Trials-Metastatic Breast Cancer-State of Maryland**

### Study List:

#### Study 1:

Title: A Study to Evaluate the Safety and Efficacy of Bevacizumab in Combination With Chemotherapy in Previously Treated Metastatic Breast Cancer (RIBBON 2)

Recruitment: Recruiting

Conditions: Metastatic Breast Cancer

Interventions: Drug: bevacizumab|Drug: chemotherapy|Drug: placebo

URL: <http://ClinicalTrials.gov/show/NCT00281697>

#### Study 2:

Title: ABI-007 In Combination With Bevacizumab in Women With Metastatic Breast Cancer

Recruitment: Recruiting

Conditions: Metastatic Breast Cancer

Interventions: Drug: ABI-007|Drug: Bevacizumab

URL: <http://ClinicalTrials.gov/show/NCT00394082>

#### Study 3:

Title: Doxil & Carboplatin Plus HER2+ in Metastatic Breast Cancer

Recruitment: Recruiting

Conditions: Metastatic Breast Cancer

Interventions: Drug: Doxil|Drug: Carboplatin|Drug: Herceptin

URL: <http://ClinicalTrials.gov/show/NCT00303108>

#### Study 4:

Title: A Study of Sunitinib in Combination With Bevacizumab and Paclitaxel in Previously Untreated Patients With Metastatic Breast Cancer (SABRE-B)

Recruitment: Recruiting

Conditions: Metastatic Breast Cancer

Interventions: Drug: bevacizumab|Drug: sunitinib|Drug: paclitaxel

URL: <http://ClinicalTrials.gov/show/NCT00434356>

#### Study 5:

Title: Two Dose Levels of Capecitabine With Docetaxel in Treating Women With Locally Advanced or Metastatic Breast Cancer That Has Not Responded to Previous Anthracycline-Based Chemotherapy

Recruitment: Recruiting

Conditions: Breast Cancer

Interventions: Drug: capecitabine|Drug: docetaxel|Procedure: chemotherapy

URL: <http://ClinicalTrials.gov/show/NCT00083200>

Study 6:

Title: EAP (Expanded Access Protocol) Of Lapatinib Combined With Capecitabine In Metastatic Breast Cancer

Recruitment: Recruiting

Conditions: Breast Cancer

Interventions: Drug: lapatinib + capecitabine

URL: <http://ClinicalTrials.gov/show/NCT00338247>

Study 7:

Title: Capecitabine in Treating Patients With Metastatic Breast Cancer

Recruitment: Recruiting

Conditions: Breast Cancer

Interventions: Drug: capecitabine|Procedure: chemotherapy

URL: <http://ClinicalTrials.gov/show/NCT00274768>

Study 8:

Title: Weekly vs. Every 2 Week vs. Every 3 Week Administration of Abraxane/Bevacizumab Combination in Metastatic Breast Cancer

Recruitment: Recruiting

Conditions: Breast Neoplasms|Neoplasm Metastasis

Interventions: Drug: ABI-007 (Abraxane) and Bevacizumab

URL: <http://ClinicalTrials.gov/show/NCT00281528>

Study 9:

Title: Vaccine Therapy Before and After Dose-Intensive Induction Chemotherapy Plus Immune-Depleting Chemotherapy in Treating Patients With Metastatic Breast Cancer

Recruitment: Recruiting

Conditions: Breast Cancer

Interventions: Drug: cyclophosphamide|Drug: doxorubicin hydrochloride|Drug: filgrastim|Drug: fludarabine phosphate|Drug: paclitaxel|Drug: recombinant fowlpox-CEA(6D)/TRICOM vaccine|Drug: recombinant vaccinia-CEA(6D)-TRICOM vaccine|Drug: sargramostim|Drug: therapeutic autologous lymphocytes|Procedure: chemotherapy|Procedure: colony-stimulating factor therapy|Procedure: peripheral blood lymphocyte therapy|Procedure: recombinant viral vaccine therapy

URL: <http://ClinicalTrials.gov/show/NCT00053170>

Study 10:

Title: First-Line Chemotherapy and Trastuzumab With or Without Bevacizumab in Treating Patients With Metastatic Breast Cancer That Overexpresses HER2/Neu

Recruitment: Recruiting

Conditions: Breast Cancer

Interventions: Drug: bevacizumab|Drug: carboplatin|Drug: paclitaxel|Drug: trastuzumab|Procedure: antiangiogenesis therapy|Procedure: chemotherapy|Procedure: monoclonal antibody therapy

URL: <http://ClinicalTrials.gov/show/NCT00520975>

Study 11:

Title: Gemcitabine Plus Bevacizumab in Locally Recurrent or Metastatic Breast Cancer

Recruitment: Recruiting

Conditions: Metastatic Breast Cancer|Locally Advanced Breast Cancer

Interventions: Drug: Gemcitabine|Drug: Bevacizumab

URL: <http://ClinicalTrials.gov/show/NCT00623233>

Study 12:

Title: A Study to Evaluate Pertuzumab + Trastuzumab + Docetaxel vs. Placebo + Trastuzumab + Docetaxel in Previously Untreated Her2-Positive Metastatic Breast Cancer (CLEOPATRA)

Recruitment: Recruiting

Conditions: Metastatic Breast Cancer

Interventions: Drug: pertuzumab|Drug: placebo|Drug: trastuzumab|Drug: docetaxel

URL: <http://ClinicalTrials.gov/show/NCT00567190>

Study 13:

Title: A Study of AMG 706 or Bevacizumab, in Combination With Paclitaxel Chemotherapy, as Treatment for Breast Cancer

Recruitment: Recruiting

Conditions: Breast Neoplasms|Breast Tumors|Breast Cancer|Locally Recurrent and Metastatic Breast Cancer

Interventions: Drug: AMG 706 placebo|Drug: Bevacizumab|Drug: AMG 706

URL: <http://ClinicalTrials.gov/show/NCT00356681>

Study 14:

Title: Fulvestrant With or Without Lapatinib in Treating Postmenopausal Women With Stage III or Stage IV Breast Cancer That is Hormone Receptor-Positive

Recruitment: Recruiting

Conditions: Breast Cancer

Interventions: Drug: fulvestrant|Drug: lapatinib ditosylate|Procedure: antiestrogen therapy|Procedure: protein tyrosine kinase inhibitor therapy

URL: <http://ClinicalTrials.gov/show/NCT00390455>

Study 15:

Title: A Study of Effectiveness of Trabectedin for the Treatment of Patient With Specific Subtypes of Metastatic Breast Cancer

Recruitment: Recruiting

Conditions: Breast Tumors

Interventions: Drug: Trabectedin; ET 743; Yondelis

URL: <http://ClinicalTrials.gov/show/NCT00580112>

Study 16:

Title: Sorafenib and Anastrozole in Treating Postmenopausal Women With Metastatic Breast Cancer  
Recruitment: Recruiting  
Conditions: Breast Cancer  
Interventions: Drug: anastrozole|Drug: sorafenib tosylate|Procedure: antiangiogenesis therapy|Procedure: aromatase inhibition therapy|Procedure: drug resistance inhibition treatment|Procedure: enzyme inhibitor therapy  
URL: <http://ClinicalTrials.gov/show/NCT00217399>

Study 17:

Title: Anastrozole With or Without Fulvestrant as First-Line Therapy in Treating Postmenopausal Women With Metastatic Breast Cancer  
Recruitment: Recruiting  
Conditions: Breast Cancer  
Interventions: Drug: anastrozole|Drug: fulvestrant|Procedure: antiestrogen therapy|Procedure: aromatase inhibition therapy  
URL: <http://ClinicalTrials.gov/show/NCT00075764>

Study 18:

Title: Trastuzumab, Cyclophosphamide, and Vaccine Therapy in Treating Patients With Metastatic Breast Cancer  
Recruitment: Recruiting  
Conditions: Breast Cancer  
Interventions: Drug: allogeneic GM-CSF-secreting breast cancer vaccine|Drug: cyclophosphamide|Drug: trastuzumab|Procedure: biopsy|Procedure: chemotherapy|Procedure: diagnostic procedure|Procedure: flow cytometry|Procedure: gene expression profiling|Procedure: immunoenzyme technique|Procedure: immunohistochemistry staining method|Procedure: immunologic technique|Procedure: immunopotential therapy|Procedure: monoclonal antibody therapy|Procedure: tumor cell-derivative vaccine therapy  
URL: <http://ClinicalTrials.gov/show/NCT00397371>

Study 19:

Title: Docetaxel With or Without Vaccine Therapy and GM-CSF in Treating Patients With Metastatic Breast Cancer  
Recruitment: Recruiting  
Conditions: Breast Cancer  
Interventions: Drug: docetaxel|Drug: falimarev|Drug: inalimarev|Drug: sargramostim|Procedure: chemotherapy|Procedure: colony-stimulating factor therapy|Procedure: non-specific immune-modulator therapy|Procedure: recombinant viral vaccine therapy  
URL: <http://ClinicalTrials.gov/show/NCT00217750>

Study 20:

Title: T-Cell-Depleted Allogeneic Stem Cell Transplantation Followed By Donor T Cells, Given After Chemotherapy and Reduced-Intensity Transplantation Conditioning in Treating Patients With Metastatic Breast Cancer

Recruitment: Recruiting

Conditions: Breast Cancer

Interventions: Drug: cyclophosphamide|Drug: cyclosporine|Drug: filgrastim|Drug: fludarabine phosphate|Procedure: chemotherapy|Procedure: colony-stimulating factor therapy|Procedure: graft versus host disease prophylaxis/therapy|Procedure: graft-versus-tumor induction therapy|Procedure: peripheral blood lymphocyte therapy|Procedure: peripheral blood stem cell transplantation

URL: <http://ClinicalTrials.gov/show/NCT00082953>

Study 21:

Title: Treatment Decision Making Based on Blood Levels of Tumor Cells in Women With Metastatic Breast Cancer Receiving Chemotherapy

Recruitment: Recruiting

Conditions: Breast Cancer

Interventions: Procedure: biological therapy|Procedure: chemotherapy|Procedure: diagnostic laboratory biomarker analysis|Procedure: diagnostic procedure|Procedure: endocrine drug therapy

URL: <http://ClinicalTrials.gov/show/NCT00382018>

Study 22:

Title: Trial of Myocet in Metastatic Breast Cancer

Recruitment: Recruiting

Conditions: Breast Cancer

Interventions: Drug: Myocet

URL: <http://ClinicalTrials.gov/show/NCT00294996>

Study 23:

Title: This is a Study of Ixabepilone Plus Capecitabine or Docetaxel Plus Capecitabine in Metastatic Breast Cancer

Recruitment: Recruiting

Conditions: Breast Neoplasms

Interventions: Drug: Ixabepilone + Capecitabine|Drug: Docetaxel + Capecitabine

URL: <http://ClinicalTrials.gov/show/NCT00546364>

Study 24:

Title: 1st or 2nd Line MBC (Metastatic Breast Cancer) With Previous Avastin (Bevacizumab) Therapy

Recruitment: Recruiting

Conditions: Breast Cancer

Interventions: Drug: Gemcitabine|Drug: Sorafenib|Drug: Placebo|Drug: Gemcitabine

URL: <http://ClinicalTrials.gov/show/NCT00493636>

Study 25:

Title: Trastuzumab, Cyclophosphamide, and an Allogeneic GM-CSF-Secreting Breast Tumor Vaccine for the Treatment of HER-2/Neu-Overexpressing Metastatic Breast Cancer

Recruitment: Recruiting

Conditions: Breast Neoplasms

Interventions: Biological: Allogeneic GM-CSF-secreting breast cancer vaccine|Drug: Trastuzumab|Drug: Cyclophosphamide

URL: <http://ClinicalTrials.gov/show/NCT00399529>

Study 26:

Title: Evaluation of a New Agent for Treatment of Advanced Stage Breast Cancer

Recruitment: Recruiting

Conditions: Breast Neoplasm

Interventions: Drug: SHY03757 (ZK- ZK-Epothilone : ZK-219477)|Drug: SHY03757 (ZK- ZK-Epothilone : ZK-219477)

URL: <http://ClinicalTrials.gov/show/NCT00313248>

Study 27:

Title: Vorinostat, Paclitaxel, and Bevacizumab in Treating Patients With Metastatic Breast Cancer and/or Breast Cancer That Has Recurred in the Chest Wall and Cannot be Removed by Surgery

Recruitment: Recruiting

Conditions: Breast Cancer

Interventions: Drug: bevacizumab|Drug: paclitaxel|Drug: vorinostat|Procedure: antiangiogenesis therapy|Procedure: chemotherapy|Procedure: enzyme inhibitor therapy|Procedure: monoclonal antibody therapy

URL: <http://ClinicalTrials.gov/show/NCT00368875>

Study 28:

Title: Vaccine Therapy With or Without Cyclophosphamide and Doxorubicin in Women With Stage IV Breast Cancer

Recruitment: Recruiting

Conditions: Breast Cancer

Interventions: Drug: allogeneic GM-CSF-secreting breast cancer vaccine|Drug: cyclophosphamide|Drug: doxorubicin hydrochloride|Procedure: chemotherapy|Procedure: non-specific immune-modulator therapy|Procedure: tumor cell-derivative vaccine therapy

URL: <http://ClinicalTrials.gov/show/NCT00093834>

Study 29:

Title: Breast Imaging Using Indium In 111 CHX-A DTPA Trastuzumab in Women With Stage I, Stage II, Stage III, or Stage IV Breast Cancer

Recruitment: Recruiting

Conditions: Breast Cancer

Interventions: Drug: indium In 111 CHX-A DTPA trastuzumab|Procedure: breast imaging study|Procedure: diagnostic procedure|Procedure: fluorescence in situ hybridization|Procedure: immunohistochemistry staining method|Procedure: laboratory

biomarker analysis|Procedure: pharmacological study|Procedure: radionuclide imaging|Procedure: single photon emission computed tomography  
URL: <http://ClinicalTrials.gov/show/NCT00474578>

Study 30:

Title: Genetic and Protein Profiling in Normal and Cancerous Breast Tissue  
Recruitment: Recruiting  
Conditions: Breast Neoplasms  
Interventions:  
URL: <http://ClinicalTrials.gov/show/NCT00083733>

Study 31:

Title: Tumor Necrosis Factor in Patients Undergoing Surgery for Primary Cancer or Metastatic Cancer  
Recruitment: Recruiting  
Conditions: Adrenocortical Carcinoma|Breast Cancer|Colorectal Cancer|Gastrointestinal Cancer|Kidney Cancer|Liver Cancer|Melanoma (Skin)|Ovarian Cancer|Pancreatic Cancer|Sarcoma  
Interventions: Drug: colloidal gold-bound tumor necrosis factor|Procedure: conventional surgery|Procedure: diagnostic procedure|Procedure: electron microscopy|Procedure: pharmacological study|Procedure: tumor necrosis factor therapy  
URL: <http://ClinicalTrials.gov/show/NCT00436410>

Study 32:

Title: Vaccine Therapy and Sargramostim in Treating Adults With Metastatic Cancer  
Recruitment: Recruiting  
Conditions: Breast Cancer|Colorectal Cancer|Ovarian Cancer|Unspecified Adult Solid Tumor, Protocol Specific  
Interventions: Drug: falimarev|Drug: inalimarev|Drug: sargramostim|Procedure: non-specific immune-modulator therapy|Procedure: recombinant viral vaccine therapy  
URL: <http://ClinicalTrials.gov/show/NCT00091000>

Study 33:

Title: Cyclophosphamide and Fludarabine Followed By White Blood Cell Infusion and High-Dose Aldesleukin in Treating Patients With Metastatic Cancer That Overexpresses p53  
Recruitment: Recruiting  
Conditions: Breast Cancer|Colorectal Cancer|Kidney Cancer|Lung Cancer|Melanoma (Skin)|Ovarian Cancer|Pancreatic Cancer|Unspecified Adult Solid Tumor, Protocol Specific  
Interventions: Drug: aldesleukin|Drug: anti-p53 T-cell receptor-transduced peripheral blood lymphocytes|Drug: cyclophosphamide|Drug: filgrastim|Drug: fludarabine phosphate|Drug: therapeutic autologous lymphocytes|Procedure: chemotherapy|Procedure: colony-stimulating factor therapy|Procedure: gene therapy|Procedure: interleukin therapy|Procedure: peripheral blood lymphocyte therapy

URL: <http://ClinicalTrials.gov/show/NCT00393029>

Study 34:

Title: Sorafenib and Bevacizumab in Treating Patients With Refractory, Metastatic, or Unresectable Solid Tumors

Recruitment: Recruiting

Conditions: Cancer

Interventions: Drug: bevacizumab|Drug: sorafenib tosylate|Procedure: antiangiogenesis therapy|Procedure: enzyme inhibitor therapy|Procedure: monoclonal antibody therapy

URL: <http://ClinicalTrials.gov/show/NCT00098592>

Study 35:

Title: Montelukast in Treating Patients With Bronchiolitis Obliterans After Donor Stem Cell Transplant

Recruitment: Recruiting

Conditions: Cancer

Interventions: Drug: montelukast sodium|Procedure: flow cytometry|Procedure: laboratory biomarker analysis|Procedure: management of therapy complications|Procedure: pulmonary complications management|Procedure: quality-of-life assessment

URL: <http://ClinicalTrials.gov/show/NCT00656058>

Study 36:

Title: Study to Evaluate Combination Treatment of MGCD0103 and Docetaxel (Taxotere®) for Subjects With Advanced Cancer Tumors

Recruitment: Recruiting

Conditions: Breast Cancer|Lung Cancer|Pulmonary Cancer|Non-Small-Cell Lung Carcinoma|Prostate Cancer|Prostatic Cancer|Gastric Cancer|Stomach Cancer

Interventions: Drug: MGCD0103 & Docetaxel

URL: <http://ClinicalTrials.gov/show/NCT00511576>

Study 37:

Title: Breast Duct Lavage, Breast Duct Endoscopy, and Gene Expression Profiling in Women With Breast Cancer Compared With Healthy Women Who Are and Are Not at High Risk for Breast Cancer

Recruitment: Recruiting

Conditions: Breast Cancer

Interventions: Procedure: breast duct lavage|Procedure: breast imaging study|Procedure: comparative genomic hybridization|Procedure: cytology specimen collection procedure|Procedure: diagnostic procedure|Procedure: endoscopic biopsy|Procedure: gene expression profiling|Procedure: proteomic profiling

URL: <http://ClinicalTrials.gov/show/NCT00070460>

Study 38:

Title: Efficacy And Safety Of Sunitinib In Women With Advanced Breast Cancer

Recruitment: Recruiting

Conditions: Breast Neoplasms  
Interventions: Drug: Sunitinib  
URL: <http://ClinicalTrials.gov/show/NCT00471276>

Study 39:

Title: Peripheral Stem Cell Transplant and White Blood Cell Transfusions in Treating Patients With Refractory Metastatic Solid Tumors

Recruitment: Recruiting

Conditions: Breast Cancer|Carcinoma of Unknown Primary|Colorectal Cancer|Esophageal Cancer|Gallbladder Cancer|Gastric Cancer|Liver Cancer|Lung Cancer|Pancreatic Cancer|Prostate Cancer|Sarcoma

Interventions: Drug: anti-thymocyte globulin|Drug: cyclophosphamide|Drug: cyclosporine|Drug: fludarabine phosphate|Drug: therapeutic allogeneic lymphocytes|Procedure: chemotherapy|Procedure: graft versus host disease prophylaxis/therapy|Procedure: graft-versus-tumor induction therapy|Procedure: non-specific immune-modulator therapy|Procedure: peripheral blood lymphocyte therapy|Procedure: peripheral blood stem cell transplantation

URL: <http://ClinicalTrials.gov/show/NCT00003839>

Study 40:

Title: Evaluating the Physical and Psychological Effects of Cancer Treatment in Patients With Breast Cancer

Recruitment: Recruiting

Conditions: Breast Cancer|Long-Term Effects Secondary to Cancer Therapy in Adults

Interventions: Procedure: management of therapy complications|Procedure: medical chart review|Procedure: quality-of-life assessment|Procedure: questionnaire administration|Procedure: survey administration

URL: <http://ClinicalTrials.gov/show/NCT00513838>

Study 41:

Title: AZD2281 and Carboplatin in Treating Patients With BRCA1/BRCA2-Associated or Hereditary Metastatic or Unresectable Breast and/or Ovarian Cancer

Recruitment: Recruiting

Conditions: Breast Cancer|Hereditary Breast/Ovarian Cancer (brca1, brca2)|Ovarian Cancer

Interventions: Drug: PARP inhibitor AZD2281|Drug: carboplatin|Procedure: chemosensitization/potential therapy|Procedure: enzyme inhibitor therapy|Procedure: immunoenzyme technique|Procedure: laboratory biomarker analysis|Procedure: mutation analysis|Procedure: parenteral chemotherapy|Procedure: polymorphism analysis

URL: <http://ClinicalTrials.gov/show/NCT00647062>

Study 42:

Title: Cyclophosphamide and Cryoablation in Treating Patients With Advanced or Metastatic Epithelial Cancer

Recruitment: Recruiting

Conditions: Cancer

Interventions: Drug: cyclophosphamide|Procedure: biopsy|Procedure: chemotherapy|Procedure: cryosurgery|Procedure: diagnostic procedure|Procedure: laboratory biomarker analysis|Procedure: non-specific immune-modulator therapy

URL: <http://ClinicalTrials.gov/show/NCT00499733>

Study 43:

Title: Hepatic Arterial Infusion of Melphalan With Hepatic Perfusion in Treating Patients With Unresectable Liver Cancer

Recruitment: Recruiting

Conditions: Cancer

Interventions: Drug: melphalan|Procedure: chemotherapy|Procedure: intrahepatic infusion procedure|Procedure: isolated perfusion

URL: <http://ClinicalTrials.gov/show/NCT00096083>

Study 44:

Title: Clinical Evaluations and Laboratory Studies in Patients With Chronic Graft-Versus-Host Disease Who Have Undergone a Previous Donor Stem Cell Transplant

Recruitment: Recruiting

Conditions: Cancer

Interventions: Procedure: biopsy|Procedure: diagnostic procedure|Procedure: laboratory biomarker analysis|Procedure: management of therapy complications|Procedure: physiologic testing

URL: <http://ClinicalTrials.gov/show/NCT00331968>

Study 45:

Title: Education Sessions for Young Sibling Stem Cell Donors

Recruitment: Recruiting

Conditions: Cancer

Interventions: Procedure: counseling|Procedure: educational intervention|Procedure: psychosocial assessment and care

URL: <http://ClinicalTrials.gov/show/NCT00445380>

Study 46:

Title: 5-Fluoro-2'-Deoxycytidine and Tetrahydrouridine in Treating Patients With Advanced Solid Tumors

Recruitment: Recruiting

Conditions: Breast Cancer|Unspecified Adult Solid Tumor, Protocol Specific

Interventions: Drug: 5-fluoro-2-deoxycytidine|Drug: tetrahydrouridine|Procedure: biopsy|Procedure: chemotherapy|Procedure: diagnostic procedure|Procedure: pharmacological study

URL: <http://ClinicalTrials.gov/show/NCT00378807>

Study 47:

Title: Study of Symptoms Caused by Cancer and Cancer Therapy in Patients With Invasive Breast, Lung, Prostate, or Colorectal Cancer

Recruitment: Recruiting  
Conditions: Breast Cancer|Cognitive/Functional Effects|Colorectal Cancer|Lung Cancer|Pain|Prostate Cancer|Psychosocial Effects/Treatment  
Interventions: Procedure: assessment of therapy complications|Procedure: cognitive assessment|Procedure: psychosocial assessment and care  
URL: <http://ClinicalTrials.gov/show/NCT00303914>

Study 48:

Title: Liposomal Doxorubicin Before Mastectomy in Treating Women With Invasive Breast Cancer  
Recruitment: Recruiting  
Conditions: Breast Cancer  
Interventions: Drug: pegylated liposomal doxorubicin hydrochloride|Procedure: chemotherapy|Procedure: conventional surgery|Procedure: neoadjuvant therapy  
URL: <http://ClinicalTrials.gov/show/NCT00290732>

Study 49:

Title: Study to Evaluate the Safety and Effects AZD0530 on Prostate and Breast Cancer Subjects With Metastatic Bone Disease.  
Recruitment: Recruiting  
Conditions: Breast Cancer|Prostate Cancer|Bone Neoplasms  
Interventions: Drug: AZD0530|Drug: Zoledronic Acid|Drug: Calcium|Drug: Vitamin D  
URL: <http://ClinicalTrials.gov/show/NCT00558272>

Study 50:

Title: Follow-Up Evaluation of Patients With Solid Tumors Previously Enrolled in a Vaccine Therapy Clinical Trial  
Recruitment: Recruiting  
Conditions: Breast Cancer|Colorectal Cancer|Long-Term Effects Secondary to Cancer Therapy in Adults|Metastatic Cancer|Ovarian Cancer|Prostate Cancer|Unspecified Adult Solid Tumor, Protocol Specific  
Interventions: Procedure: management of therapy complications|Procedure: observation  
URL: <http://ClinicalTrials.gov/show/NCT00451022>

Study 51:

Title: Identification of a Screening Tool and Treatment of Lymphedema Secondary to the Management of Breast Cancer Study  
Recruitment: Recruiting  
Conditions: Breast Cancer|Lymphedema  
Interventions: Device: High Risk Lymphedema Education and Device Intervention  
URL: <http://ClinicalTrials.gov/show/NCT00282529>