

## Brain

*No open to accrual studies at this time.*

## Breast

**ID Number:** NSABP B- 43

**Principal Investigator:** Drs. Charlie Pan & Patrick Mansky

**Title:** Comparing Trastuzumab Given Concurrently with Radiation Therapy and Radiation Therapy Alone for Women with HER2-Positive DCIS Resected by Lumpectomy

**Phase:** III

**Purpose:** This study is being done to compare the effects, good and/or bad, of adding the drug trastuzumab (also called Herceptin®) to breast radiation therapy. Radiation therapy is the standard treatment for patients with DCIS.

**ID Number:** CO10104

**Principal Investigator:** Dr. Patrick Mansky

**Title:** Phase II study of dose-dense TC (docetaxel + cyclophosphamide) with pegfilgrastim support for adjuvant therapy of breast Cancer

**Phase:** II

**Purpose:** The purpose of this study is to determine the feasibility of giving standard TC chemotherapy on a dose dense schedule (ddTC) as well as evaluating the nature and frequency of ddTC side effects. Data gathered in this study could also be used to help determine whether giving TC on a dose dense schedule is more effective. *NOTE: This protocol is temporarily closed to accrual. It has met it's accrual for the first phase of the study. The second phase is expected to open to accrual in December 2011.*

**ID Number:** CO09711

**Principal Investigator:** Dr. Patrick Mansky

**Title:** Phase II Study of High Dose Estradiol of Metastatic Triple Negative Breast Cancer

**Phase:** II

**Purpose:** The purpose of the study is to determine the effectiveness of Estradiol treatment for advanced breast cancer that is hormone receptor negative and Her2/neu negative.

## Pancreas

**ID Number:** RTOG 0848

**Principal Investigator:** Drs. Charlie Pan & Patrick Mansky

**Title:** A phase III Trial Evaluating both Erlotinib and Chemoradiation as Adjuvant Treatment for Patients with Resected Head of Pancreas Adenocarcinoma

**Phase:** III

**Purpose:** The standard treatment for patients with pancreatic cancer that was removed by surgery is to receive the chemotherapy drug gemcitabine. In this study, patients will get either gemcitabine alone or gemcitabine combined with erlotinib. Erlotinib is a pill that may help treat cancers by blocking a gene that is important in cancer growth. The use of erlotinib to try to prevent the recurrence of pancreatic cancer after surgery is investigational.

## Colon

**ID Number:** NSABP P5

**Principal Investigator:** Dr. Patrick Mansky

**Title:** Statin Polyp Prevention Trial in Patients with Resected Colon Cancer

**Phase:** Phase III

**Purpose:** The primary aim is to determine the effect of rosuvastatin administered postoperatively for 5 years on the 5-year occurrence of APMC+ R in patients with resected colon cancer.

**ID Number:** CALGB 80702

**Principal Investigator:** Dr. Patrick Mansky

**Title:** A Phase III Trial of 6 versus 12 Treatments of Adjuvant FOLFOX Plus CELCOXIB or PLACEBO for Patients with Resected Stage III Colon Cancer

**Phase:** Phase III

**Purpose:** The primary objective of this study is to determine if the addition of celecoxib to standard chemotherapy (FOLFOX) improves disease-free survival when compared to standard chemotherapy alone (FOLFOX) after surgery in patients with stage III colon cancer

## Prostate

**ID Number:** RTOG 0534

**Principal Investigator:** Dr. Charlie Pan

**Title:** Short Term Androgen Deprivation With Pelvic Lymph Node Or Prostate Bed Only Radiotherapy (SPORT) In Prostate Cancer Patients With A Rising PSA After Radical Prostatectomy

**Phase:** III

**Purpose:** The purpose of this study is to compare the effects, good and/or bad of three treatment methods on participants and their cancer.

External beam radiation therapy is one of the standard treatments for men with prostate cancer who have a rising PSA after surgery. Different methods of radiation therapy are used, and it is not known which one is best. Most commonly, the area where the prostate was originally located before being removed (the prostate bed) is treated, without treating the lymph nodes in the pelvis.

Prostate cancer feeds on male hormones, such as testosterone. Drugs that reduce or block testosterone (hormone therapy) can cause some prostate cancer cells to die and others to become sick so that they don't grow. Some patients treated with a combination of these drugs and radiation have a greater chance of not having the cancer return when compared to men treated with radiation alone. These studies were done in men who did not have surgery. Since hormone therapy can result in increased side effects, the benefit of combining hormone therapy with radiation therapy needs to be tested

**ID Number:** RTOG 0815

**Principal Investigator:** Dr. Charlie Pan

**Title:** A Phase III Prospective Randomized Trial Of Dose-Escalated Radiotherapy With or Without Short-Term Androgen Deprivation Therapy for Patients with Intermediate-Risk Prostate Cancer

**Phase:** III

**Purpose:** The primary objective of this study is to demonstrate an overall survival advantage for the addition of short- term (6 months) hormone therapy to dose-escalated radiation therapy for patients with intermediate-risk prostate cancer.

## Leukemia/Lymphomas

**ID Number:** HO10407

**Principal Investigator:** Dr. Patrick Mansky

**Title:** Phase II Study of Velcade and Temsirolimus for Relapsed or Refractory B-cell non-Hodgkin Lymphoma

**Phase:** Phase II

**Purpose:** The purpose of this study is to determine whether Velcade in combination with temsirolimus provides benefit to subjects with relapsed or refractory B-cell non-Hodgkin lymphoma as assessed by overall response rate (ORR) and progression-free survival (PFS).

**ID Number:** E2408

**Principal Investigator:** Dr. Patrick Mansky

**Title:** A 3- Arm Randomized Phase II Trial of Bendamustine-Rituximab (BR) Followed by Rituximab vs. Bortezomib-BR (BVR) Followed by Rituximab vs. BR Followed by Lenalidomide/Rituximab in High Risk Follicular Lymphoma

**Phase:** II

**Purpose:** The purpose of this study is to compare the complete remission (CR) rate of BR versus BVR as induction therapy. And to compare the 1-year post-induction disease-free survival (DFS) rate with rituximab plus lenalidomide to rituximab alone as continuation therapy.

## Lung

**ID Number:** E1505

**Principal Investigator:** Dr. Patrick Mansky

**Title:** Phase III Randomized Trial of Adjuvant Chemotherapy With or Without Bevacizumab for Patients with Completely Resected Stage IB (>4 cm) –IIIA Non-Small Cell Lung Cancer NSCLC)

**Phase:** III

**Purpose:** The purpose of this study is to determine if adding the new drug bevacizumab to chemotherapy improves the chance for cure for patients who have had surgery for the removal of the lung cancer. Researchers will compare the effects (good and bad) of adding bevacizumab to chemotherapy with standard chemotherapy alone on patients and their lung cancer to see which is better at preventing the cancer from coming back.

## Melanoma

**ID Number:** E1609

**Principal Investigator:** Dr. Patrick Mansky

**Title:** A Phase III Randomized Study of Adjuvant Ipilimumab Anti-CTLA4 Therapy Versus High-Dose Interferon a-2b for Resected High-risk Melanoma

**Phase:** III

**Purpose:** The purpose of this study are to evaluate disease recurrence-free survival, and overall survival, between surgically-treated, high risk melanoma patients randomized to receive post-operative ipilimumab versus those randomized to receive high-dose interferon.

## Sarcoma

**ID Number:** USOR 10237

**Principal Investigator:** Dr. Patrick Mansky

**Title:** Soft Tissue Sarcoma (Metastatic) Phase III Multicenter, International Randomized, Double-Blind, Placebo-controlled study of Doxorubicin plus Palifosfamide-Tris Vs. Doxorubicin plus Placebo in Patients with Front-line Metastatic Soft Tissue Sarcoma

**Phase:** III

**Purpose:** The main purpose of this study is to see if a new chemotherapy agent palifosfamide-tris with a standard chemotherapy agent doxorubicin that is used for sarcoma can extend the length of time that a patient's disease is stable and help them live longer, compared to treatment with doxorubicin alone.

## Quality of Life

**ID Number:** RTOG 0433 SC.20

**Principal Investigator:** Dr. Charlie Pan

**Title:** Phase III Trial of Single vs. Multiple Fractions for Re-Irradiation of Painful Bone Metastases

**Phase:** III

**Purpose:** The purpose of this study is to examine the effects of re-irradiation given in a single dose compared to re-irradiation given in multiple smaller doses on people with painful bone metastases. This research is being done because we do not know which of these two commonly-used treatments is better.

**ID Number:** Caris Life Sciences

**Principal Investigator:** Dr. Patrick Mansky

**Title:** CARIS/Target Now™/Registry Trial. Observational Outcomes database for patients utilizing the Caris Target Now™ diagnostic tool for treatment of solid tumor cancer and/or hematopoietic malignancies

**Phase:** N/A

**Purpose:** This is a research registry (a list of information), which will be used for research studies to evaluate how a patient's clinical outcomes relate to tests that they have had. These tests include Caris Target Now™ or diagnostic tests of blood or bone marrow. These research studies will hopefully result in a change in disease treatment and an improvement of care.

**ID Number:** Biodesix Inc

**Principal Investigator:** Dr. Patrick Mansky

**Title:** VIEW-VeriStrat® Observational Study of Patients with Stage IIIB IV Non-small Cell Lung Cancer 2nd line. Observational study to observe EGFR treatment patterns following VeriStrat analysis and reporting of results for all study subjects.

**Phase:** N/A

**Purpose:** The purpose of this study is to correlate a patient's results from a blood serum test called VeriStrat® to a patient's additional cancer treatments that the study doctor prescribes for them. The study will also collect data on which additional cancer treatments a patient receives and how the patient responds to these treatments. VeriStrat is a pre-treatment serum test that will look for certain proteins in a patient's blood serum. VeriStrat is marketed as a test for patients with advanced non-small cell lung cancer (NSCLC) who have already received treatment with chemotherapy, or who are not able to receive chemotherapy.