Brain
No open to accrual studies at this time.

Breast

**DCIS**

<table>
<thead>
<tr>
<th>ID Number:</th>
<th>NSABP B-43</th>
<th>Principal Investigator: Dr. Patrick Mansky</th>
</tr>
</thead>
</table>

**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.

**High Risk Hormone Receptor –Positive /HER2 Negative**

<table>
<thead>
<tr>
<th>ID Number:</th>
<th>S1207</th>
<th>Principal Investigator: Dr. Patrick Mansky</th>
</tr>
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</table>

**Title:** A Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients with High-Risk, Hormone Receptor-Positive and HER2/neu Negative Breast Cancer. e3 Breast Cancer Study- evaluating everolimus with endocrine therapy

**Phase:** III

**Purpose:** The purpose of this study is to compare whether the addition of one year of everolimus to standard adjuvant endocrine therapy improves invasive disease-free survival in patients with high-risk, hormone-receptor (HR) positive and HER2-negative breast cancer.

**Neoadjuvant**

<table>
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<tr>
<th>ID Number:</th>
<th>NSABP B-52</th>
<th>Principal Investigator: Dr. Patrick Mansky</th>
</tr>
</thead>
</table>

**Title:** A Randomized Phase III Trial Evaluating Pathologic Complete Response Rates in Patients with Hormone Receptor-Positive, HER2-Positive, Large Operable and Locally Advanced Breast Cancer Treated with Neoadjuvant Therapy or Docetaxel, Carboplatin, Trastuzumab, and Pertuzumab (TCHP) with or without Estrogen Deprivation

**Phase:** III

**Purpose:** The purpose of this study is to determine whether the addition of estrogen deprivation to neoadjuvant therapy consisting of docetaxel, carboplatin, trastuzumab, and pertuzumab (TCHP) yields a greater rate of pathologic complete response (breast and nodes) than TCHP alone when administered to women with operable, hormone receptor-positive, HER2-positive breast cancer.
**Advanced**

<table>
<thead>
<tr>
<th>ID Number: E2112</th>
<th>Principal Investigator: Dr. Patrick Mansky</th>
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</thead>
</table>

**Title:** A Randomized Phase III Trial of Endocrine Therapy Plus Entinostat/Placebo in Postmenopausal Patients with Hormone Receptor-Positive Advanced Breast Cancer  
**Phase:** III  
**Purpose:** The purpose of this study is find out what effects, both good and bad, an experimental drug called entinostat has on you and your cancer, when given together with the standard hormonal drug treatment, exemestane. Exemestane is an aromatase inhibitor which is used in breast cancer patients to inhibit the growth of the breast cancer.

**Metastatic**

<table>
<thead>
<tr>
<th>ID Number: INCB 18424-268</th>
<th>Principal Investigator: Dr. Patrick Mansky</th>
</tr>
</thead>
</table>

**Title:** A Randomized, Double-Blind, Phase 2 Study of Ruxolitinib or Placebo in Combination with Capecitabine in Subjects with Advanced or Metastatic HER2-Negative Breast Cancer  
**Phase:** II  
**Purpose:** The primary purpose of this study is to compare how long women with advanced or metastatic HER2-negative breast cancer actively take treatment without progression of disease, whether or not the disease responds to the treatment and to assess toxicities and quality of life while being treated.

**Gastrointestinal/Pancreas (Unresectable Disease)**  
**Pancreas Unresectable** Temporarily Suspended due to forthcoming Amendment

<table>
<thead>
<tr>
<th>ID Number: RTOG 1201</th>
<th>Principal Investigator: Dr. Charlie Pan</th>
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**Title:** A Phase II Randomized Trial of High versus Standard Intensity Local or Systemic Therapy for Unresectable Pancreatic Cancer  
**Phase:** II  
**Purpose:** The purpose of this study is to compare the effects, good and/or bad, of three different ways to treat unresectable pancreatic cancer to determine if one increases survival better than another.
Prevention of Adenomas and Second Primary Colorectal Cancers

**ID Number:** S0820  **Principal Investigator:** Dr. Patrick Mansky

**Title:** A Double-Blind Placebo-Controlled Trial of Eflornithine and Sulindac to Prevent Recurrence of High Risk Adenomas and Second Primary Colorectal Cancers in Patients with Stage 0-III Colon Cancer, Phase III – Preventing Adenomas of the Colon with Eflornithine and Sulindac (PACES)

**Phase:** III

**Purpose:** The purpose of this study is to assess whether eflornithine (+/-sulindac), sulindac (+/- eflornithine) or the combination are effective in reducing the three –year event rate (high-risk adenomas and second primary colorectal cancers) in patients with previously treated Stage 0-III colon cancer.

Genitourinary Prostate
Intermediate Risk/Gleason Score 7

**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.

Rising PSA after Prostatectomy

**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.
Clinical trials

Gynecology
Advanced Endometrial

ID Number: GOG 0258  Principal Investigator: Dr. Patrick Mansky

**Title:** A Randomized Phase III Trial of Cisplatin and Tumor Volume Directed Irradiation Followed by Carboplatin and Paclitaxel vs, Carboplatin and Paclitaxel for Optimally Debulked, Advanced Endometrial Carcinoma

**Phase:** III

**Purpose:** The purpose of this study is to determine if treatment with cisplatin and volume-directed radiation followed by carboplatin and paclitaxel for 4 cycles (experimental arm) reduces the rate of recurrence or death when compared to chemotherapy consisting of carboplatin and paclitaxel for 6 cycles in patients with advanced endometrial (uterine) cancer (after optimal surgery).

Leukemia/Lymphomas
Untreated Younger Patients with Chronic Lymphocytic Leukemia

ID Number: E1912  Principal Investigator: Dr. Patrick Mansky

**Title:** A Randomized Phase III Study of Ibrutinib (PCI-32765) - based Therapy vs Standard Fludarabine, Cyclophosphamide, and Rituximab (FCR) Chemoimmunotherapy in Untreated Younger Patients with Chronic Lymphocytic Leukemia (CLL)

**Phase:** III

**Purpose:** The purpose of this study is to evaluate the ability of Ibrutinib-based induction therapy to prolong progression free survival (PFS) compared to standard FCR chemoimmunotherapy for younger patients with CLL.

Companion/Ancillary Study to E1912

ID Number: E3903  Principal Investigator: Dr. Patrick Mansky

**Title:** Ancillary Laboratory Protocol for the Collection of Diagnostic Material on Patients Considered for ECOG Treatment Trials for Leukemia or Related Hematologic Disorders

**Phase:** III

**Purpose:** The purpose of this study is to provide a mechanism for sample collection for diagnostic review to determine eligibility of subjects for accrual to ECOG leukemia trials; 2) to provide umbrella consent for all protocol-embedded laboratory studies both on ECOG-led and intergroup leukemia treatment protocols, and 3) to ensure optimal quality of collected specimens for banking, correlative studies and future research.
Older Patients with Chronic Lymphocytic Leukemia

**Title:** A Randomized Phase III Study of Bendamustine Plus Rituximab Versus Ibrutinib Plus Rituximab Versus Ibrutinib Alone in Untreated Older Patients (≥ 65 Years of Age) with Chronic Lymphocytic Leukemia (CLL)

**Phase:** III

**Purpose:** The purpose of this study is to determine whether progression free survival is improved after therapy with bendamustine in combination with rituximab, ibrutinib alone, or ibrutinib in combination with rituximab in patients age 65 or older with previously untreated Chronic Lymphocytic Leukemia.

High Risk Follicular Lymphoma

**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:** Phase II

**Purpose:** Primary Objectives are 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.

Diffuse B Cell Lymphoma

**Title:** Randomized Phase II Open-Label Study of Lenalidomide R-CHOP (R2CHOP) Vs RCHOP (Rituximab, Cyclophosphamide, Doxorubicin, Vincristine, and Prednisone) in Patients with Newly Diagnosed Diffuse Large B Cell Lymphoma

**Phase:** II

**Purpose:** The purpose of this study is to find out what effects, good and/or bad, the addition of lenalidomide to standard chemotherapy (RCHOP) has on you and your cancer. Everybody in this study will receive standard chemotherapy. In addition to standard chemotherapy randomly chosen half of the patients will receive a medication called lenalidomide. Adding lenalidomide to the standard chemotherapy RCHOP is considered experimental in diffuse large B cell lymphoma, and is not FDA approved.
Newly Diagnosed Symptomatic Multiple Myeloma

**ID Number:** E1A11  
**Principal Investigator:** Dr. Patrick Mansky

**Title:** Randomized Phase III Trial of Bortezomib, LENalidomide and Dexamethasone (VRd) Versus Carfilzomib, Lenalidomide and Dexamethasone (CRd) Followed by Limited or Indefinite DURation Lenalidomide MaintenANCE in Patients with Newly Diagnosed Symptomatic Multiple Myeloma (ENDURANCE)

**Phase:** Phase III  
**Purpose:** Primary Objectives are 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
Advanced Adenocarcinoma

**ID Number:** USOR 12064  
**Principal Investigator:** Dr. Patrick Mansky

**Title:** A Randomized Double-Blind, Phase 3 Study Evaluating the Efficacy and Safety of ABP215 Compared with Bevacizumab in Subjects with Advanced Non-Small Cell Lung Cancer

**Phase:** III  
**Purpose:** The purpose of this study is to compare the effectiveness (how well the drug works) and safety of an experimental drug called ABP 215 against a licensed drug called bevacizumab (also called Avastin®) in subjects with non-small cell lung cancer. ABP 215 has been developed as a ‘biosimilar’ to bevacizumab. A biosimilar medicine is a product which is similar to a biological medicine that has already been authorized (the ‘biological reference medicinal product’).

Melanoma
Unresectable Stage III/IV

**ID Number:** E3612  
**Principal Investigator:** Dr. Patrick Mansky

**Title:** A Randomized Phase II Trial of Ipilimumab with or without Bevacizumab in Patients with Unresectable Stage III or Stage IV Melanoma

**Phase:** Phase II  
**Purpose:** The purpose of this study is to compare the good and bad effects of using the study drug called ipilimumab either alone or in combination with the study drug called bevacizumab. Ipilimumab is approved by the FDA at a dose of 3 mg/kg for a total of 4 doses given 3 weeks apart for metastatic melanoma that is not amenable to surgical resection. Bevacizumab is not approved by the FDA to treat melanoma, and is an experimental treatment.
Quality of Life

**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

**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.

**Neo Adjuvant NBRST (Breast) Registry Trial**

**Number:** Agendia  
**Principal Investigator:** Dr. Patrick Mansky

**Title:** A Prospective neo-adjuvant REGISTRY trial linking MammaPrint, Subtyping and treatment response: Neoadjuvant Breast Registry-Symphony™ Trial (NBRST) (Pronounced “in breast”)

**Purpose:** The purpose of this registry study is to assess information obtained from the Agendia Breast Cancer Suite of diagnostic tests and other clinical information to study ways to assist in breast cancer diagnosis and treatment decisions. The Agendia Breast Cancer Suite includes MammaPrint®, TargetPrint®, BluePrint™ and TheraPrint™ which are tests that help doctors analyze and profile breast cancer tumors.

**Connect ®MDS and AML Registry**

**Number:** Celegene  
**Principal Investigator:** Dr. Patrick Mansky

**Title:** Connect ®MDS and AML: The Myelodysplastic Syndromes (MDS) and Acute Myeloid Leukemia (AML) Disease Registry

**Purpose:** The purpose of this study is to use the information collected to help better understand patterns for diagnosis, treatment and outcomes, including disease progression and survival. To use the information to help better understand patterns for the quality of life in patients newly diagnosed with Lower-Risk, Higher-Risk, or unknown risk MDS or AML. And to use results of this study to provide information to help better understand the effect different treatments have on a patient’s disease and on their quality of life.