

## Breast

NRG-BR003 (NCI CIRB)

A Randomized Phase III Trial of Adjuvant Therapy Comparing Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel with or Without Carboplatin for Node-Positive or High-Risk Node-Negative Triple-Negative Invasive Breast Cancer

**CLOSING SOON**

### **Purpose of the Study:**

Study the effects of the chemotherapy drug, carboplatin, given with the usual chemotherapy drugs after surgery, compared to the usual chemotherapy drugs given without carboplatin. This study will allow the researchers to know whether giving carboplatin with the usual chemotherapy is better, the same, or worse than giving the usual chemotherapy. Carboplatin is FDA-approved for the treatment of cancer and is used for the treatment of breast cancer that has spread, but it has not yet been proven useful in earlier stages of breast cancer.

## Breast

EA1181 (NEW)

Patients must have AJCC 8th Edition stage II or IIIa at diagnosis, ER,PR +/-, Her2 +

(CompassHER2-pCR): Preoperative THP and Postoperative HP in Patients Who Achieve a Pathologic Complete Response Part 1 Component of: The CompassHER2 Trials (COMprehensive Use of Pathologic Response ASSESSment to Optimize Therapy in HER2-Positive Breast Cancer)

### **Purpose of Study**

This trial will determine whether the neoadjuvant combination of a taxane (paclitaxel, docetaxel, or nab-paclitaxel), trastuzumab, and pertuzumab (THP) in patients with stage II and IIIa HER2+ disease allows for omission of additional postoperative chemotherapy in patients who achieve a pathologic complete response (pCR), without compromising long-term survival.

## GI Colon

SWOG S0820 (CTSU)

STAGE 0-III

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 or Rectal Cancer, Phase III - Preventing Adenomas of the Colon with Eflornithine and Sulindac (PACES)

**Purpose of the Study:**

The investigators hypothesize that the combination of eflornithine and sulindac will be effective in reducing a three-year event rate of adenomas and second primary colorectal cancers in patients previously treated for Stages 0 through III colon cancer or rectal cancer.

**GI Colon**

Alliance A021502 (NCI CIRB)

Randomized Trial of Standard Chemotherapy Alone or Combined with Atezolizumab as Adjuvant Therapy for Patients with Stage III Colon Cancer and Deficient DNA Mismatch Repair

**Purpose of the Study:**

This randomized phase III trial studies combination chemotherapy and atezolizumab to see how well it works compared with combination chemotherapy alone in treating patients with stage III colon cancer and deficient deoxyribonucleic acid (DNA) mismatch repair. Drugs used in combination chemotherapy, such as oxaliplatin, leucovorin calcium, and fluorouracil, work in different ways to stop the growth of tumor cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading. Monoclonal antibodies, such as atezolizumab, may interfere with the ability of tumor cells to grow and spread. Giving combination chemotherapy with atezolizumab may work better than combination chemotherapy alone in treating patients with colon cancer.

**GI Lower – Colorectal**

SWOG S1613 (NCI CIRB)

colon or rectum that is metastatic or locally advanced and unresectable

A Randomized Phase II Study of Trastuzumab and Pertuzumab (TP) Compared to Cetuximab and Irinotecan (CETIRI) in Advanced/Metastatic Colorectal Cancer (MCRC) with HER-2 Amplification

**Purpose of the Study:**

This randomized phase II trial studies how well trastuzumab and pertuzumab work compared to cetuximab and irinotecan hydrochloride in treating patients with HER2/neu amplified colorectal cancer that has spread from where it started to other places in the body and cannot be

removed by surgery. Monoclonal antibodies, such as trastuzumab and pertuzumab, may interfere with the ability of tumor cells to grow and spread. Drugs used in chemotherapy, such as cetuximab and irinotecan hydrochloride, work in different ways to stop the growth of tumor cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading. Giving trastuzumab and pertuzumab may work better compared to cetuximab and irinotecan hydrochloride in treating patients with colorectal cancer.

## GU –

### Renal Cell

**A031704** PD-Inhibitor (Nivolumab) and Ipilimumab Followed by Nivolumab Vs. VEGF TKI Cabozantinib with Nivolumab: A Phase III Trial in Metastatic Untreated RENal Cell CancEr [PDIGREE] :

Purpose of study: To compare the overall survival (OS) in patients with metastatic RCC treated with ipilimumabnivolumab followed by either nivolumab versus cabozantinib-nivolumab.

## Hematology – MDS

NHLBI-MDS (NCI CIRB)

The National Myelodysplastic Syndromes (MDS) Natural History Study

### Purpose of the Study:

The goal of the National MDS Study is to establish a publicly available resource to facilitate the study of MDS natural history. This will be accomplished through: 1) Creation of a multi-institutional, longitudinal collection of consistently processed and clinically well-annotated blood and tissue specimens collected prospectively from participants with MDS and participants with idiopathic cytopenia of undetermined significance (ICUS); and 2) Support for investigator-initiated studies of MDS that will have high-impact for MDS patients, including basic science, clinical, health outcomes and epidemiological research.

## Lung, Non-small Cell

ALLIANCE A081105 CIRB - ALCHEMIST - EGFR Tx (NCI CIRB)

Randomized Study of Erlotinib or Observation in Patients with Completely Resected Epidermal Growth Factor Receptor (EGFR) Mutant Non-small Cell Lung Cancer (NSCLC)

**Purpose of the Study:**

ALCHEMIST STUDY (EGFR Treatment Component)

This randomized phase III trial studies how well erlotinib hydrochloride compared to placebo works in treating patients with stage IB-IIIa non-small cell lung cancer that has been completely removed by surgery. Erlotinib hydrochloride may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth.

TEMPORARILY SAUSPENDED 12/22/2020

## **Lung, Non-small Cell**

ALLIANCE A151216 CIRB - ALCHEMIST – Screening (NCI CIRB)

Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST)

**Purpose of the Study:**

This research trial studies genetic testing in screening patients with stage IB-IIIa non-small cell lung cancer that has been or will be removed by surgery. Studying the genes in a patient's tumor cells may help doctors select the best treatment for patients that have certain genetic changes.

## **Lung, Non-small Cell**

ECOG-ACRIN E4512 CIRB - ALCHEMIST - ALK Tx (NCI CIRB)

A Randomized Phase III Trial for Surgically Resected Early Stage Non-Small Cell Lung Cancer: Crizotinib Versus Observation for Patients with Tumors Harboring the Anaplastic Lymphoma Kinase (ALK) Fusion Protein

**Purpose of the Study:**

ALCHEMIST STUDY (ALK Treatment Component)

This randomized phase III trial studies how well crizotinib works and compares it to placebo in treating patients with stage IB-IIIA non-small cell lung cancer that has been removed by surgery and has a mutation in a protein called ALK. Mutations, or changes, in ALK can make it very active and important for tumor cell growth and progression. Tumors with this mutation may respond to treatments that target the mutation, such as crizotinib. Crizotinib may stop the growth of tumor cells by blocking the ALK protein from working. It is not yet known if crizotinib may be an effective treatment for treating non-small cell lung cancer with an ALK fusion mutation.

**Lung, Non-Small Cell****Lung, NSC**

A171901 Older Non-Small Cell Lung Cancer Patients ( $\geq$  70 Years of Age) Treated with First-Line MK-3475 (Pembrolizumab)+/- Chemotherapy (Oncologist's/Patient's Choice) **STAGE IV or RECURRENT**

**Purpose of Study:** To estimate the adverse event profile of MK-3475 (pembrolizumab) over the first six months of treatment, in non-small cell lung cancer patients who are 70 years of age or older and who are treated with MK-3475 (pembrolizumab) +/- chemotherapy in a first-line setting.

**Lung, Non-small Cell**

ECOG-ACRIN EA5163 / S1709 (NCI CIRB)

EA5163/S1709 INSIGNA: A Randomized, Phase III Study of Firstline Immunotherapy Alone or in Combination with Chemotherapy in Induction/Maintenance or Postprogression in Advanced Nonsquamous Non-Small Cell Lung Cancer (NSCLC) with Immunobiomarker SIGNature-Driven Analysis

**Purpose of the Study:**

This phase III trial studies whether pembrolizumab alone as a first-line treatment, followed by pemetrexed and carboplatin with or without pembrolizumab after disease progression is superior to induction with pembrolizumab, pemetrexed and carboplatin followed by pembrolizumab and pemetrexed maintenance in treating patients with stage IV non-squamous non-small cell lung cancer. Immunotherapy with monoclonal antibodies, such as pembrolizumab, may help the body's immune system attack the cancer, and may interfere with the ability of tumor cells to grow and spread. Drugs used in chemotherapy, such as pemetrexed and carboplatin, work in different ways to stop the growth of tumor cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading. It is not yet known whether giving first-line pembrolizumab followed by pemetrexed and carboplatin with or without pembrolizumab works better in treating patients with non-squamous non-small cell cancer.

**SMALL CELL LUNG CANCER**

S1929 Phase II Randomized Study of Maintenance Atezolizumab Versus Atezolizumab in Combination with Talazoparib in Patients with SLFN11 Positive Extensive Stage Small Cell Lung Cancer (ES-SCLC)

**Melanoma**

ECOG-ACRIN EA6134 (NCI CIRB)

A Randomized Phase III Trial of Dabrafenib + Trametinib Followed by Ipilimumab + Nivolumab at Progression vs. Ipilimumab + Nivolumab Followed by Dabrafenib + Trametinib at Progression in Patients with Advanced BRAFV600 Mutant Melanoma

**Purpose of the Study:**

This randomized phase III trial studies how well initial treatment with ipilimumab and nivolumab followed by dabrafenib and trametinib works and compares it to initial treatment with dabrafenib and trametinib followed by ipilimumab and nivolumab in treating patients with stage III-IV melanoma that contains a mutation known as v-raf murine sarcoma viral oncogene homolog B V600 (BRAFV600) and cannot be removed by surgery. Ipilimumab and nivolumab may block tumor growth by targeting certain cells. Dabrafenib and trametinib may block tumor growth by targeting the BRAFV600 gene. It is not yet known whether treating patients with ipilimumab and nivolumab followed by dabrafenib and trametinib is more effective than treatment with dabrafenib and trametinib followed by ipilimumab and nivolumab.

**Purpose of study:** To compare the overall survival (OS) in patients with metastatic RCC treated with ipilimumabnivolumab followed by either nivolumab versus cabozantinib-nivolumab.

**MISC**

**EAZ171 Prospective Validation Trial of Taxane Therapy (Docetaxel or Weekly Paclitaxel) and Risk of Chemotherapy-Induced Peripheral Neuropathy in African American Women**

**A221805 (NEW)**

**Duloxetine to Prevent Oxaliplatin-Induced Chemotherapy-Induced Peripheral Neuropathy: A Randomized, Double-Blind, Placebo-Controlled Phase II to Phase III Study ONLY 6 CYCLES OF FOLFOX ALLOWED**

**Purpose of study:** To determine the dosage of duloxetine (30mg or 60mg daily) that appears most promising in preventing OIPN, To characterize toxicity in each arm, including duloxetine side effects of nausea, dry mouth, dizziness, somnolence, fatigue, and insomnia using CTCAEv5.0