Breast Cancer Studies

Adjuvant therapy after surgery

Triple negative breast cancer

**B-55  Olaparib as Adjuvant Treatment in Patients with Germline BRCA Mutated High Risk HER2 Negative Primary Breast Cancer (olympiA)**

This is a randomized, double-blind, placebo controlled multi-center Phase 111 study to assess the efficacy and safety of *Olaparib* vs placebo as Adjuvant treatment in patients with Germline BRAC 1/2 mutations and high risk HER2 negative primary breast cancer who have completed definitive local treatment and neoadjuvant or adjuvant chemotherapy.

**BR003  Doxorubicin Hydrochloride and Cyclophosphamide Followed by Paclitaxel With or Without Carboplatin in Treating Patients with Triple-Negative Breast Cancer**

This randomized Phase III Trial of studies how well doxorubicin hydrochloride and cyclophosphamide followed by paclitaxel with or without carboplatin work in treating patients with triple-negative breast cancer. Drugs used in chemotherapy, such as doxorubicin hydrochloride, cyclophosphamide, paclitaxel, 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 doxorubicin hydrochloride and cyclophosphamide is more effective when followed by paclitaxel alone or paclitaxel and carboplatin in treating triple negative breast cancer.

Metastatic breast cancer/Triple Negative

**CellDex (CDX-011)  Study of Glembatumumab Vedotin (CDX-011) in Patients with Metastatic, gpNMB Over-Expressing, Triple Negative Breast Cancer (The Metric Study)**

The main purpose of this study is to see whether CDX-011 (glembatumamab Vedotin, an antibody-drug conjugate) is effective in treating patients who have advanced Triple- Negative Breast Center (TNBC; i.e. tumors lacking expression of estrogen, progesterone and HER2 receptors), and whose tumor cells make a protein called glycoprotein NMB (*gpNMB*), which CDX-011 binds to. The study will also further characterize the safety of CDX-011 treatment in the patient population.
**Neoadjuvant Therapy before Surgery/Triple Negative Breast Cancer**

**EA1131** Platinum Based Chemotherapy or Observation in Treating Patients With Residual Triple-Negative Basal-Like Breast Cancer Following Neoadjuvant Chemotherapy

This randomized phase III trial studies how well cisplatin or carboplatin (platinum based chemotherapy) works compared to observation in treating patients with remaining (residual) basal-like triple-negative breast cancer following chemotherapy after surgery (neoadjuvant). Drugs used in chemotherapy, such as cisplatin 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. This study will examine whether cisplatin or carboplatin is more effective than observation in treating patients with residual triple negative basal-like breast cancer.

**Hormone receptor positive breast cancer**

**S1207** Hormone Therapy With or Without Everolimus in Treating Patients with Breast Cancer

Estrogen can cause the growth of breast cancer cells. Hormone therapy using tamoxifen citrate, goserelin acetate, leuprolide acetate, anastrozole, letrozole, and exemestane, may fight breast cancer by lowering the amount of estrogen the body makes. *Everolimus* may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth. On this study, patients will receive an approved endocrine therapy for at least 5 years along with *Everlimous* or placebo for 1 year.

**Kidney Cancer Studies**

**SO931** Everlimous in Treating Patients With Kidney Cancer Who Have Undergone Surgery (EVEREST)

*Everolimus* may stop growth of tumor cells by blocking some of the enzymes needed for cell growth or by blocking blood flow to the tumor. This phase III trial is studying *everolimus* to see how well it works in treating patients with kidney cancer who have undergone surgery. The primary objective of this study is to compare recurrence-free survival in renal carcinoma patients randomly assigned to 54 weeks of *everolimus* versus 54 weeks of placebo after nephrectomy and partial nephrectomy.
**Multiple Myeloma**

**E1A11 Bortezomib or Carfilzomib With Lenalidomide and Dexamethasone in Treating Patients With Newly Diagnosed Multiple Myeloma**

This randomized phase III trial studies bortezomib, lenalidomide, and dexamethasone to see how well it works compared to carfilzomib, lenalidomide, and dexamethasone in treating patients with newly diagnosed multiple myeloma. Bortezomib and carfilzomib may stop the growth of cancer cells by blocking some of the enzymes needed for cell growth. Drugs used in chemotherapy such as lenalidomide and dexamethasone, work in different ways to stop the growth of cancer cell, either by killing the cells for by stopping them from dividing. Giving bortezomib and carfilzomib together with lenalidomide and dexamethasone may kill more cancer cells.

**MMY3008 Study Comparing Daratumumab, Lenalidomide, and Dexamethasone with Lenalidomide and Dexamethasone in Participants with Previously Untreated Multiple Myeloma**

The purpose of this study is to compare the efficacy of daratumumab in combination with lenalidomide and dexamethasone to that of lenalidomide and dexamethasone in terms of progression–free survival (PFS) in participants with newly diagnosed multiple myeloma (a blood cancer of plasma cells) who are not candidates for high dose chemotherapy (treatment of disease, usually cancer, by chemical agents) and autologous stem cell transplant (ASCT).

**LUNG CANCER STUDIES**

**S1400 Biomarker-Targeted Second-Line Therapy in Treating Patients With Recurrent Stage IIIB-IV Squamous Cell Lung Cancer**

This screening and multi-sub study randomized phase II/III trial will establish a method for genomic screening of similar large cancer populations followed by assigning and accruing simultaneously to a multi-sub–study “Master Protocol”. The type of cancer trait (biomarker)
will determine to which sub-study, within this protocol, a participant will be assigned to compare new targeted cancer therapy, designed to block the growth and spread of cancer, or combinations to standard of care therapy with the ultimate goal of being able to approve new targeted therapies in this setting. In addition, the protocol includes a “non-match” sub-study which will include all screened patients not eligible for any of the biomarker-driven sub-studies. This sub-study will compare a non-match therapy to standard of care also with goal of approval.

**G029527 – Study to Assess Safety and Efficacy of Atezolizumab (MPDL3280A) Compared to Best Supportive Care Following Chemotherapy in Patients With Lung Cancer**

This is a phase III, open label, randomized study to investigate the efficacy and safety of *atezolizumab* (anti-PD-L1 antibody) compared with best supportive care following adjuvant cisplatin-based chemotherapy in PD-L1 selected patients with completely resected stage 1b-Ila non-small cell lung cancer.

**NCI MATCH**

**EAY131 – NCI-MATCH: Targeted Therapy Directed by Genetic Testing in Treating Patients With Advanced Refractory solid Tumors or Lymphomas.**

This phase II trial studies how well treatment that is directed by genetic testing works in patients with solid tumors or lymphomas that have progressed following at least one line of standard treatment or for which no agreed upon treatment approach exists. Genetic tests look at the unique material (genes) of patients’ tumor cells. Patients with genetic abnormalities (such as mutations, amplification, or translocations) may benefit more from treatment which targets their tumor’s particular genetic abnormality. Identifying these genetic abnormalities first may help doctors plan better treatment for patients with solid tumors or lymphomas.
MELANOMA

EA6134 – Dabrafenib and Trametinib Followed by Ipilimumab and Nivolumab or Ipilimumab and Nivolumab Followed by Dabrafenib and Trametinib in treating Patients With Stage III-IV BRAFV600 Melanoma

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 patients with dabrafenib and trametinib followed by ipilimumab and nivolumab.

PANCREATIC CANCER


The randomized phase II trial studies how well fluorouracil, irinotecan hydrochloride, and oxaliplatin (combination chemotherapy) works and compares to gemcitabine hydrochloride and paclitaxel albumin-stabilized nanoparticle formulation before surgery in treating patients with pancreatic cancer that can be removed by surgery. Drugs used in chemotherapy, such as fluorouracil, irinotecan hydrochloride, oxaliplatin, gemcitabine hydrochloride, and paclitaxel albumin-stabilized nanoparticle formulation, 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 more than one drug (combination chemotherapy) may kill more tumor cells. It is not yet known whether combination chemotherapy is more effective than gemcitabine hydrochloride and paclitaxel albumin-stabilized nanoparticle formulation before surgery in treating pancreatic cancer.
Registry Studies

Miraca life Science Registry Study
If your physician orders a bone marrow biopsy, you may be eligible participate in this study.

ProMedDx Registry Study
If you have cancer, you can donate blood to be used for cancer research.

City of Hope
There are certain types of cancer that are associated with a genetic predisposition. The City of Hope molecular genetics trial is studying links between genetics environment and behaviors. This study is free of charge and open to anyone who qualifies for genetic assessment.