



**Clinical
Trials-
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FRHS CLINICAL TRIALS

- * **FRHS- James M Stockman Cancer Institute is proud to provide a wide range of clinical trials. Patient treated in clinical trials gain access to therapies for their diagnosis, which would otherwise be unavailable. Patients are able to receive their study treatments conveniently within the Regional Cancer Therapy Center.**
- * **For more information about the clinical trials available at FRHS please call 301-668-7043 or email us at endcancer.net**
- * **Open trials at the James M Stockman Cancer Institute 1562 Opossumtown Pike Frederick, MD 21702 are as follows**

[NCT: 02032823 B-55 \(Breast\) \(SLIDE 5\)](#)

[Click NCT # For More Information](#)

Olaparib as Adjuvant Treatment in Patients with Germline BRCA Mutated High Risk HER 2 Negative Primary Breast Cancer (olympiA)

[NCT:0248896 BR003 \(Breast\) \(SLIDE 6\)](#)

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

[NCT: 02445391 EA1131 \(Breast\) \(SLIDE 7\)](#)

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

[NCT: 01674140 S1207 \(Breast\) \(SLIDE 8\)](#)

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

[NCT: 02513394 B57 \(Breast\) \(SLIDE 9\)](#)

PALbociclib CoLLaborative Adjuvant Study: A Randomized Phase III Trial of Palbociclib With Standard Adjuvant Endocrine Therapy Versus Standard Adjuvant Endocrine Therapy Alone for Hormone Receptor Positive (HR+)/ Human Epidermal Growth Factor Receptor 2 (HER2)- Negative Early Breast Cancer (PALLAS)

[NCT: 03326674 ODO-TE-B301 \(SLIDE 10\)](#)

A Multinational, Multicenter, Randomized, Phase 3 Study of Teseztazel plus a Reduced Dose of Capecitabine Versus Capecitabine Alone in Patients with HER2 Negative, Hormone Receptor Positive, Locally Advanced or Metastatic Breast Cancer Previously Treated with a Taxane

[NCT: 03241810 MM-121-02-02-10 \(SHERBOC\) \(SLIDE 11\)](#)

A Double- Blind, Placebo-controlled, Phase 2 trial of Seribantumab Plus Fulvestrant in Post-Menopausal Women with Hormone Receptor-positive, Heregulin Positive (HRG+), HER2 Negative Metastatic Breast Cancer Whose Disease Progressed After Prior Systemic Therapy

[NCT02492711 CP-MGAH22-04 \(SOPHIA TRIAL\) \(SLIDE 12\)](#)

Margetuzimab Plus Chemotherapy vs Trastuzumab Plus Chemotherapy in the Treatment of HER2 Positive Metastatic Breast Cancer

[NCT: 03025867 Ovarian YO39523 \(SLIDE 13\)](#)

A study of Atezolizumab Versus Placebo In Combination With Paclitaxel, Carboplatin, and Bevacizumab in Participants With Newly-Diagnosed Stage III or Stage IV Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

[NCT: 01863550 E1A11 \(Multiple Myeloma\)](#) (SLIDE 14)

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

[NCT: 02562716 S1505 \(Pancreatic Cancer\)](#) (SLIDE 15)

Combination Chemotherapy or Gemcitabine Hydrochloride and Paclitaxel Albumin-Stabilized Nanoparticle Formulation Before Surgery in Treating Patients With Pancreatic Cancer That Can Be Removed by Surgery

[NCT: 03382899 Cypress 1 / AM0010-201](#) (SLIDE 16)

A Randomized Phase 2 Trial of AM0010 in Combination with Pembrolizumab vs. Pembrolizumab Alone as First-Line Therapy in Patients with Metastatic Non- Small Cell Lung Cancer whose Tumors Have High PD-L1 expression

[NCT: 03382912 Cypress / 2 AM0010-202](#) (SLIDE 17)

A Randomized Phase 2 Trial of AM0010 in Combination With Nivolumab and Nivolumab Alone as Second-Line Therapy in Subjects With Stage IV/ Metastatic Wild Type Non-Small Cell Lung Cancer and Low Tumor Expression of PD-L1

[NCT: 02834013 S1609 Rare Tumors \(DART\)](#) (SLIDE 18)

Nivolumab and Ipilimumab in Treating Patients with Rare Tumors

[NCT: 02224781 EA6134 \(Melanoma\)](#) (SLIDE 19)

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

[NCT: 01349881 S0820 \(PACES\) Colorectal](#) (SLIDE 20)

Adenoma and Second Primary Prevention Trial- A Double Blind Placebo-Controlled Trial of Eflornithine and Sunlindac 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)

[NCT: 02718066 HBI-8000-302](#) (SLIDE 21)

A Phase 1b/2 Study to Assess the Safety and Efficacy of HBI-8000 With Nivolumab in Melanoma, Renal Cell Carcinoma and Non-Small Cell Lung Cancer

[Registry Studies](#) **Miraca life Science Registry Study** (SLIDE 22)

ProMedDx Registry Study

City of Hope

Breast Cancer Studies

Triple negative breast cancer



* B-55

- * Olaparib as Adjuvant Treatment in Patients with Germline BRCA Mutated High Risk HER 2 Negative Primary Breast Cancer (olympiA)r

NCT: 02032823

- * Principal Investigator: Brian O'Connor, M.D.
- * 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.

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Breast Cancer Studies

Triple negative breast cancer



* BR003

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

NCT:0248896

- * Principal Investigator: Brian O'Connor, M.D.

- * 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. Patients with operable node- positive or high- risk node- negative, triple negative breast cancer who have undergone either a mastectomy or lumpectomy are eligible for this trial.

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Breast Cancer Studies



Neoadjuvant Therapy before Surgery
Triple Negative Breast Cancer

* EA1131

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

NCT: 02445391

- * Principal Investigator: Brian O'Connor, M.D.
- * This randomized phase III trial studies how well cisplatin or carboplatin (platinum based chemotherapy) works compared to capecitabine in treating patients with remaining (residual) basal- like triple- negative breast cancer following chemotherapy after surgery (neoadjuvant). Drugs used in chemotherapy, such as cisplatin, carboplatin and capecitabine, 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 cisplatin or carboplatin is more effective than capecitabine in treating patients with residual triple negative basal- like breast cancer.

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Breast Cancer Studies

Hormone receptor positive breast cancer



* S1207

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

NCT: 01674140

- * Principal Investigator: Brian O'Connor, M.D.
- * 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.

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Breast Cancer Studies

Hormone receptor positive breast cancer



* B57

- * PALbociclib CoLLaborative Adjuvant Study: A Randomized Phase III Trial of Palbociclib With Standard Adjuvant Endocrine Therapy Versus Standard Adjuvant Endocrine Therapy Alone for Hormone Receptor Positive (HR+)/ Human Epidermal Growth Factor Receptor 2 (HER2)-Negative Early Breast Cancer (PALLAS)

NCT: 02513394

- * Principal Investigator: Brian O'Connor, M.D.
- * This is a prospective, two arm, international, multicenter, randomized Phase III study evaluating the addition of 2 years of palbociclib to standard adjuvant endocrine therapy for patients with HR+/HER2- early breast cancer. The purpose of the PALLAS study is to determine whether the addition of palbociclib to adjuvant endocrine therapy will improve outcomes over endocrine therapy one for HR+/HER2- early breast cancer. Assessment of a variety of correlative analysis, including evaluation of the effects of palbociclib in genomically defined tumor subgroups, is planned.

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Breast Cancer Studies

Hormone Receptor Positive, HER2 Negative, Metastatic Breast Cancer



* ODO-TE-B301

- * A Multinational, Multicenter, Randomized, Phase 3 Study of TeseTaxel plus a Reduced Dose of Capecitabine Versus Capecitabine Alone in Patients with HER2 Negative, Hormone Receptor Positive, Locally Advanced or Metastatic Breast Cancer Previously Treated

NCT: 03326674

- * Principal Investigator: Brian O'Connor, M.D.

- * This is a research study of an investigational anti-cancer drug called tesseTaxel as a possible treatment for human epidermal growth factor receptor 2 (HER2) negative, hormone receptor (HR) positive breast cancer that is locally advanced or spread to one or more body parts. TeseTaxel has been studied for use in various other cancers. The main purpose of this study is to learn how well the combination of tesseTaxel and a reduced dose of another anti-cancer drug called capecitabine works, compared to the approved higher dose of capecitabine given alone, in patients with the same type and stage of breast cancer.

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Breast Cancer Studies

Hormone Receptor-positive, Heregulin Positive (HRG+), HER2 Negative
Metastatic Breast Cancer Disease Progressed After Prior Systemic Therapy



* [MM-121-02-02-10 \(SHERBOC\)](#)

- * [A Double- Blind, Placebo-controlled, Phase 2 trial of Seribantumab Plus Fulvestrant in Post-Menopausal Women with Hormone Receptor-positive, Heregulin Positive \(HRG+\), HER2 Negative Metastatic Breast Cancer Whose Disease Progressed After Prior Systemic Therapy](#)

[NCT: 03241810](#)

- * [Principal Investigator: Brian O'Connor, M.D.](#)

- * This study is a randomized, double-blind, placebo-controlled international phase 2 trial in patients with HRG+, HR+, HER2- metastatic breast cancer that has progressed following treatment with no more than 2 prior therapies, one of which must have been a CDK inhibitor. All patients will be screened for heregulin using central lab testing, and eligible patients will be randomized to receive seribantumab + fulvestrant or placebo + fulvestrant. Disease status will be assessed according to RECIST v1.1 to support the primary endpoint.

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Breast Cancer Studies

Hormone Receptor Positive, HER2 Negative, Metastatic Breast Cancer



- * **CP-MGAH22-04 (SOPHIA TRIAL)**

- * Margetuximab Plus Chemotherapy vs Trastuzumab Plus Chemotherapy in the Treatment of HER2+ Metastatic Breast Cancer

NCT02492711

- * Principal Investigator: Brian O'Connor, M.D.

- * The purpose of this study is to determine whether patients treated with margetuximab plus chemotherapy have longer progression free survival and overall survival than patients treated with trastuzumab plus chemotherapy.

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Ovarian

Recurrent Ovarian Cancer



* YO39523

- * [Expanded Access Protocol For Niraparib in Patients With Recurrent Ovarian Cancer](#)

[NCT: 03025867](#)

- * [Principal Investigator: Mark Goldstein, M.D.](#)
- * This is an expanded access program (EAP) for eligible patients with Recurrent Ovarian Cancer. This program is designed to provide access to niraparib prior to approval by the US Food and Drug Administration (FDA). To be eligible, patient with Recurrent Ovarian Cancer following a partial (PR) or complete response (CR) to their most recent platinum- based chemotherapy and must have experienced a PR or CR after the penultimate (next to last) platinum-based chemotherapy for at least 6 months without disease progression after this chemotherapy.

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Multiple Myeloma

Newly Diagnosed Multiple Myeloma



* **E1A11**

- * [Bortezomib or Carfilzomib With Lenalidomide and Dexamethasone in Treating Patients With Newly Diagnosed Multiple Myeloma](#)

[NCT: 01863550](#)

- * [Principal Investigator: Mark Goldstein, M.D.](#)
- * 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.

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Pancreatic Cancer

Before surgery in treating patients with pancreatic cancer that can be removed by surgery



* S1505

- * Combination Chemotherapy or Gemcitabine Hydrochloride and Paclitaxel Albumin-Stabilized Nanoparticle Formulation Before Surgery in Treating Patients With Pancreatic Cancer That Can Be Removed by Surgery

NCT-025562716

- * Principal Investigator: Mark Goldstein, M.D.

- * This randomized Phase II trial studies how well fluorouracil, irinotecan hydrochloride, and oxaliplatin (combination therapy) works and compares to gemcitabine hydrochloride and paclitaxel albumin-stabilized nanoparticle formations 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 therapy) 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 treatment pancreatic cancer.

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Lung Cancer

First-Line Metastatic NSC Lung High PD-L1 Expression



* **Cypress 1 / AM0010-201**

- * A Randomized Phase 2 Trial of AM0010 in Combination with Pembrolizumab vs. Pembrolizumab Alone as First-Line Therapy in Patients with Metastatic Non- Small Cell Lung Cancer whose Tumors Have High PD-L1 expression

NCT: 03382899

- * Principal Investigator: Elhamy Eskander, M.D., F.A.C.P
- * The purpose of this study is to compare the efficacy of AM0010 in combination with pembrolizumab versus pembrolizumab alone in patients with Stage IV/metastatic wild type Non-Small Cell Lung Cancer (with high expression of PD- L1) as measured by objective response rate

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Lung Cancer

Second Line Metastatic Wild Type NSCLC Low PD-L1 Expression



* **Cypress 2 AM0010-202**

- * A Randomized Phase 2 Trial of AM0010 in Combination With Nivolumab and Nivolumab Alone as Second-Line Therapy in Subjects With Stage IV/ Metastatic Wild Type Non-Small Cell Lung Cancer and Low Tumor Expression of PD-L1

NCT: 03382912

- * Principal Investigator: Elhamy Eskander, M.D., F.A.C.P
- * This is a Randomized Phase II trial of AM0010 in combination with Nivolumab vs Nivolumab Alone as a second-line therapy in subjects with Stage IV/Metastatic Wild Type Non-Small Cell Lung cancer and low tumor expression of PD-L1. Patients must have received at least one prior systemic therapy that was not an anti-PD-1, anti-PD-L1 and/or anti-CTLA-4 treatment for the advanced stage of the disease.

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Rare Tumors

Multiple rare tumor types

* **S1609 (DART)**

* [Nivolumab and Ipilimumab in Treating Patients With Rare Tumors](#)

[NCT: 02834013](#)

* [Principal Investigator: Patrick Mansky, M.D.](#)

* Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors (DART). This clinical trial studies nivolumab and ipilimumab in treatment patient with rare tumors. Monoclonal antibodies, such as nivolumab and ipilimumab, may interfere with the ability of tumor cells to grow and spread.

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Melanoma

Patients With Stage III-IV BRAFV600 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

NCT: 02224781

- * Principal Investigator: Mark Goldstein, M.D.
- * 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. I albumin-stabilized nanoparticle formulation, work in different ways to stop the growth

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Colorectal

Prevention Trail

* **So820 (PACES)**

- * Adenoma and Second Primary Prevention Trial- A Double Blind Placebo-Controlled Trial of Eflornithine and Sunlindac to Prevent Recurrence of Hight Risk Adenomas and Second Primary Colorectal Cancers in Patients With Stage o-III Colon or Rectal Cancer, Phase III- Preventing Adenomas of the Colon with Eflornithine and Sulindac (PACES)

NCT: 01349881

- * Principal Investigator : Mark Goldstein, MD

- * Colorectal adenomas are tiny growths in the colon or rectum that may eventually lead to cancer. The purpose of this study is to determine if Eflornithine and Sulindac can decrease the risk of high-risk adenomas or second primary colorectal cancer in patients who have been treated for Stage 0, 1, II, III colon or rectal cancer. The study drugs Eflornithine and Sulindac are tablets which are taken orally. Sunlindac is commercially available but is not approved for this indication.

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Melanoma, Renal Cell Carcinoma and Non-Small Cell Lung Cancer

* **HBI-8000-302 (HUYA)**

- * A Phase 1b/2 Study to Assess the Safety and Efficacy of HBI-8000 With Nivolumab in Melanoma, Renal Cell Carcinoma and Non-Small Cell Lung Cancer

NCT:02718066

- * Principal Investigator: Dr Elhamy Eskander
- * The primary objective of this study will be to evaluate the safety and tolerability of HBI-8000 when combined with the standard dose and regimen on nivolumab, to determine Maximum Tolerated Dose (MTD) and/or Recommended Phase 2 Dose to evaluate frequency and severity of toxicities of this combination treatment. This study will try to find out if HBI-8000 at 30 mg administered twice a weekly when combined with nivolumab can be more efficacious to treat cancer. The study is also going to see how the drugs are distributed in your blood and how the drug changes the behavior of cells to fight cancer in your body.

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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.

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