Clinical Trials

OPEN to ENROLLMENT

CNS
- **GAB 101 (CNS THERAPEUTICS INC):** Safety of 3 mg/ml Gablofen (baclofen injection) Delivered by Intrathecal Administration Using the Synchromed II Programmable Infusion System  **Contact person: Kristine Freese Freesek3@oakwood.org**

Cardiac
- **Silver-AMI (Yale):** Risk Stratification in Older Patients with Acute Myocardial Infarction  **Contact person: Jeanne 313.593.8581**
- **Spiration HUD:** IBV Valve System, Humanitarian Use Device for the Control of Prolonged Air Leaks  **Contact person: Marjorie 313.593.8090**
- **USPella (Impella 2.5) Data Registry**  **Contact person: Lynne 313.982.5376**
- **Perceval (Sorin Group USA):** Clinical Investigation of the Perceval Sutureless Heart Valve  **Contact Lynne 313.593.5376**

Skin
- **CAPTURE (Cerexa):** A Multicenter, Retrospective Cohort Study to Characterize the Use of Teflaro® in the Treatment of Patients With Acute Bacterial Skin and Skin Structure Infection or Community-acquired Bacterial Pneumonia  **Contact person: Lama Hsaiky 313.593-3265**

Spine
- **MI-IOM (NOC2 Foundation):** Intraoperative Monitoring Patient Registry  **Contact person: Emily 313.982.5604**
Oncology Clinical Trials

Call 313-593-8090 to enroll patients or for questions

**BRAIN**

- **RTOG0834:** Phase III trial on Concurrent and Adjuvant Temozolomide chemotherapy in non-1p/19q deleted anaplastic glioma. The CATNON Intergroup trial.
- **RTOG 1205:** Randomized Phase II Trial of Concurrent Bevacizumab and Re-Irradiation Versus Bevacizumab Alone as Treatment for Recurrent Glioblastoma
- **A221101:** A Phase III Randomized, Double-Blind Placebo Controlled Study of Armodafinil (Nuvigil?) To Reduce Cancer-Related Fatigue in Patients with Glioblastoma Multiforme
- **A071101:** A Phase II Randomized Trial Comparing The Efficacy Of Heat Shock Protein-Peptide Complex-96 (HSPPC-96) (Nsc #725085, Alliance IND #15380) Vaccine Given With Bevacizumab Versus Bevacizumab Alone In The Treatment Of Surgically Resectable Recurrent Glioblastoma Multiforme (GBM)
- **RTOG 1122:** Phase II Double-Blinded Placebo-Controlled Study of Bevacizumab With or Without AMG 386 in Patients With Recurrent Glioblastoma or Gliosarcoma.

**BREAST**

**DCIS**

- **NSABP B43:** A Phase III Clinical Trial Comparing Trastuzumab Given Concurrently with RT and RT Alone for Women with HER2-Positive DCIS Resected by Lumpectomy

**IBC**

- **Z11102:** Impact of Breast Conservation Surgery on Surgical Outcomes and Cosmesis in Patients with Multiple Ipsilateral Breast Cancers (MIBC)
- **ECOG E2108:** A Randomized Phase III Trial of the Value of Early Local Therapy for the Intact Primary Tumor in Patients with Metastatic Breast Cancer- SWOG
- **SWOG S1007:** A Phase III, Randomized Clinical Trial of Standard Adjuvant Endocrine Therapy +/- Chemotherapy in Patients with 1-3 Positive Nodes, Hormone-responsive and Her2-Negative Breast Cancer according to Recurrence Score (RS)
- **NSABP B47:** A Randomized Phase III Trial of Adjuvant Therapy Comparing Chemotherapy Alone (Six Cycles of Docetaxel Plus Cyclophosphamide or Four Cycles of Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel) to Chemotherapy Plus Trastuzumab in Women with Node Pos or High-Risk Node-Neg HER2-Low Invasive Breast Cancer
- **NSABP B52:** 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 of Docetaxel, Carboplatin, Trastuzumab, and Pertuzumab (TCHP) With or Without Estrogen Deprivation
- **RTOG 1119:** Phase II Randomized Study of Whole Brain Radiotherapy in Combination With Concurrent Lapatinib in Patients with Brain Metastasis From HER2-Positive Breast Cancer a Collaborative Study of RTOG and KROG
- **SWOG S1207:** 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

- **ECOG E1Z11:** A Cohort Study to Evaluate Genetic Predictors of Aromatase Inhibitor Musculoskeletal Symptoms (AIMSS) **OPEN TO ASIAN AND AFRICAN AMERICAN WOMEN ONLY**

- **SWOG S1202:** A Randomized Placebo-Controlled Phase III Study of Duloxetine for Treatment of Aromatase Inhibitor (AI)-Associated Musculoskeletal Symptoms in Women with Early Stage Breast Cancer

**GASTROINTESTINAL**

**Colorectal**

- **A021202:** Prospective Randomized Phase II Trial of Pazopanib Versus Placebo in Patients with Progressive Carcinoid Tumors.

- **CALGB 80702:** A Phase III Trial of 6 Versus 12 Treatments of Adjuvant Folfox Plus Celecoxib or Placebo in Patients with Resected Stage III Colon Cancer

- **SWOG S0820:** A Double Blind Placebo-Controlled Trial of Efornithine 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 Efornithine and Sulindac (PACES)

**Rectal**

- **NCCTG N1048:** A Phase II/III trial of Neoadjuvant FOLFOX, with Selective Use of Combined Modality Chemoradiation versus Preoperative Combined Modality Chemoradiation for Locally Advanced Rectal Cancer Patients Undergoing Low Anterior Resection with Total Mesorectal Excision - requires surgeon credentialing. 1st patient enrolled, if time spec. photos are adequate, they are credentialed

**Gastric**

- **SWOG 1201:** A Randomized Phase II Pilot Study Prospectively Evaluating Treatment for Patients Based on ERCC1 (Excision Repair Cross-Contemplating 1) for Advanced/Metastatic Esophageal, Gastric or Gastroesophageal Junction (GEJ) Cancer

**Esophageal**

- **RTOG 1010:** A Phase III Trial Evaluating the Addition of Trastuzumab to Trimodality Treatment Of HER2-Overexpressing Esophageal Adenocarcinoma — regulatory and credentialing pending for RT

**HCC**

- **CALGB 80802:** Phase III Randomized Study of Sorafenib Plus Doxorubicin Versus Sorafenib in Patients with Advanced Hepatocellular Carcinoma (HCC) - Temp. Closed

- **ECOG E1208:** A Phase III Randomized, Double-Blind Trial of Chemoembolization with or without Sorafenib in Unresectable Hepatocellular - Declaration of Chemoembolization Administration method to be filled out

- **RTOG 1112:** Randomized Phase III Study of Sorafenib versus Stereotactic Body Radiation Therapy followed by Sorafenib in Hepatocellular Carcinoma credentialing needed for RT

- **ECOG E2212:** A Randomized, Double-Blinded, Placebo-Controlled Phase II Study of Adjuvant Everolimus Following the Resection of Metastatic Pancreatic Neuroendocrine Tumors to the Liver
• SWOG S1310: Randomized Phase II Trial of Single Agent MEK Inhibitor Trametinib (GSK1120212) vs 5-Fluorouracil or Capecitabine in Refractory Advanced Biliary Cancer.

**Pancreatic**

• SWOG 1115: Randomized Phase II Clinical Trial of AZD6244 Hydrogen Sulfate (NSC-748727) and MK-2206 (NSC-749607) vs. mFOLFOX in Patients with Metastatic Pancreatic Cancer after Prior Chemotherapy

• ECOG E2211: A Randomized Phase II Study of Temozolomide or Temozolomide and Capecitabine in Patients

• RTOG 1201: A Phase II Randomized Trial of High Versus Standard Intensity Local or Systemic Therapy for Unresectable Pancreatic Cancer—TEMPORARILY CLOSED TO ACCRUAL

**GENITOURINARY**

**Bladder**

• C90601: A Randomized, Double-Blinded, Phase III Study Comparing Gemcitabine, Cisplatin, and Bevacizumab to Gemcitabine, Cisplatin, and Placebo in Patients with Advanced Transitional Cell Carcinoma

**Renal**

• ECOG E1808: A Randomized Phase II Trial of Sunitinib/Gemcitabine or Sunitinib in Advanced Renal Cell Carcinoma with Sarcomatoid Features

• ECOG E2810: Randomized, Double-Blind Phase III Study of Pazopanib vs. Placebo in Patients with Metastatic Renal Cell Carcinoma Who Have No Evidence of Disease Following Metastatectomy

• SWOG S0931: EVEREST: EReroлимus for Renal Cancer Ensuing Surgical Therapy, A Phase III Study

• SWOG 1107: Parallel (Randomized) Phase II Evaluation of ARQ 197 and ARQ 197 in Combination with Erlotinib in Papillary Renal Cell Carcinoma – Temp Closed

• A031203: Randomized Phase II Study Comparing Cabozantinib (NSC #761968 And IND #116059) With Commercially Supplied Sunitinib In Patients With Previously Untreated Locally Advanced Or Metastatic Renal Cell Carcinoma

**Prostate**

• CALGB 90203: A Randomized Phase III Study of Neo-Adjuvant Docetaxel and Androgen Deprivation Prior To Radical Prostatectomy Versus Immediate Radical Prostatectomy in Patients With High-Risk, Clinically Localized Prostate Cancer

• A031201: Phase III Trial Of Enzalutamide (Nsc # 766085) Versus Enzalutamide, Abiraterone And Prednisone For Castration Resistant Metastatic Prostate Cancer

• CALGB 70807: The Men's Eating and Living (MEAL) Study: A Randomized Trial of Diet to Alter Disease Progression in Prostate Cancer Patients on Active Surveillance

• RTOG 0534: A Phase III Trial of Short Term Androgen Deprivation with Pelvic Lymph Node or Prostate Bed Only RT in Prostate Cancer Patients with a Rising PSA after Radical Prostatectomy

• RTOG 0815: 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—regulatory and credentialing pending for RT
• RTOG 1115: Phase III Trial of Dose Escalated Radiation Therapy and Standard Androgen Deprivation Therapy (ADT) with a GnRH Agonist vs. Dose Escalated Radiation Therapy and Enhanced ADT with a GnRH Agonist and TAK-700 for Men with High Risk Prostate Cancer – regulatory and credentialing required for RT. Physician training also needed

• RTOG 0924: Androgen Deprivation Therapy and High Dose Radiotherapy With or Without Whole-Pelvic Radiotherapy in Unfavorable Intermediate or Favorable High Risk Prostate Cancer: A Phase III Randomized Trial -3DCRT credentialed

• S1216: A Phase III Randomized Trial Comparing Androgen Deprivation Therapy + TAK-700 with Androgen Deprivation Therapy + Bicalutamide in Patients with Newly Diagnosed Metastatic Sensitive Prostate Cancer

GYNECOLOGICAL

Cervical
• GOG 0263: Randomized Phase III Clinical Trial of Adjuvant Radiation Versus Chemoradiation in Intermediate Risk, Stage I/IIA Cervical Cancer

• RTOG 0724: Phase III Randomized Study of Concurrent Chemotherapy and Pelvic Radiation Therapy With or Without Adjuvant Chemotherapy in High-Risk Patients With Early-Stage Cervical Carcinoma Following Radical Hysterectomy TEMPORARILY CLOSED TO ACCRUAL

• RTOG 1203: A Randomized Phase III Study of Standard vs. IMRT Pelvic Radiation For Post-Operative Treatment of Endometrial and Cervical Cancer (TIME-C) regulatory and credentialing needed for RT

Endometrial
• GOG 0258: 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

• GOG 026B: A Randomized Phase II/III Study Of Paclitaxel/Carboplatin/Metformin (NSC#91485) Versus Paclitaxel/Carboplatin/Placebo as Initial Therapy for Measurable Stage III Or IVa, Stage IVb, or Recurrent Endometrial Cancer

Ovarian/Peritoneal
• GOG 0213: A Phase III Randomized Controlled Clinical Trial of Carboplatin and Paclitaxel (or Gemcitabine) Alone or in Combination with Bevacizumab (NSC #704865, IND #113912) Followed by Bevacizumab and Secondary Cytoreductive Surgery in Platinum-Sensitive, Recurrent Ovarian, Peritoneal Primary and Fallopian Tube Cancer

• GOG 0260: A Phase II Evaluation Of Elecsclomol Sodium And Weekly Paclitaxel In The Treatment Of Recurrent Or Persistent Platinum-Resistant Ovarian, Fallopian Tube Or Primary Peritoneal Cancer

• GOG 0273: Chemotherapy Toxicity in Elderly Women with Ovarian, Primary Peritoneal or Fallopian Tube Cancer

• GOG 0225: Can Diet and Physical Activity Modulate Ovarian or Primary Peritoneal Cancer \\ Progression-Free Survival?

GYN - all
• GOG 0244: The Lymphedema and Gynecologic Cancer (LEG) Study: Incidence, Risk Factors and Impact in Newly Diagnosed Patients
**HEAD & NECK**

- **ECOG E1305:** A Phase III Randomized Trial of Chemotherapy With or Without Bevacizumab in Patients with Recurrent or Metastatic Head and Neck Cancer
- **RTOG 0920:** A Phase III Study of Postoperative Radiation Therapy (IMRT) +/- Cetuximab for Locally-Advanced Resected Head and Neck Cancer - regulatory and credentialing needed for RT
- **RTOG 1008:** A Randomized Phase II Study of Adjuvant Concurrent Radiation and Chemotherapy Versus Radiation Alone in Resected High-Risk Malignant Salivary Gland Tumors - regulatory and credentialing needed for RT; study specific Investigator questionnaire
- **RTOG 1016:** Phase II Trial Of Radiotherapy Plus Cetuximab Versus Chemoradiotherapy In HPV-Associated Oropharynx Cancer - regulatory and credentialing needed
- **ECOG E1311:** A Randomized, Placebo Controlled Phase II Trial of Afatinib (BIBW2992) as Adjuvant Therapy Following Chemoradiation in Patients with Head and Neck Squamous Cell Carcinoma at High Risk of Recurrence

**LUNG**

**Mesothelioma**

- **CALGB 30901:** Randomized Phase II Study of Maintenance Pemetrexed Versus Observation for Patients with Malignant Pleural Mesothelioma without Progression After First-Line Chemotherapy
- **SWOG S0905:** A Phase I/Randomized Phase II Study of Cediranib (NSC #732208) Versus Placebo in Combination with Cisplatin and Pemetrexed in Chemonaive Patients with Malignant Pleural Mesothelioma – Physician must be registered for MESOMARK testing

**NSCLC**

- **CALGB C140503:** A Phase III Randomized Trial of Lobectomy versus Sublobar Resection for Small (less than or equal to 2 cm) Peripheral Non-small Cell Lung Cancer
- **ECOG E5508:** Randomized Phase III Study of Maintenance Therapy with Bevacizumab, Pemetrexed, or a Combination of Bevacizumab and Pemetrexed Following Carboplatin, Paclitaxel and Bevacizumab for Advanced Non-Squamous NSCLC
- **SWOG 0819:** A Randomized, Phase III Study Comparing Carboplatin/Paclitaxel or Carboplatin/Paclitaxel/Bevacizumab with or without Concurrent Cetuximab in Patients with Advanced Non-Small Cell Lung Cancer (NSCLC)
- **RTOG 0839:** Randomized Phase II Study of Pre-Operative Chemoradiotherapy +/- Panitumumab (IND #110152) Followed by Consolidation Chemotherapy In Potentially Operable Locally Advanced (Stage IIIA, N2+) Non-Small Cell Lung Cancer - regulatory and credentialing needed for RT – Temp. Closed
- **ECOG 1512:** A Randomized Phase II Trial of Erlotinib, Cezbozantanib, or Olotinib plus Cabozantinib as 2nd or 3rd Line Therapy in Patients with EGFR Wild-Type NSCLC
- **RTOG 1306:** Randomized Phase II Study of Individualized Combined Modality Therapy for Stage III Non-Small Cell Lung Cancer (NSCLC)

**SCLC**

- **CALGB C30610:** Phase III Comparison of Thoracic Radiotherapy Regimens in Patients with Limited Small Cell Lung Cancer also receiving Cisplatin and Etoposide
- **RTOG 0937:** Randomized Phase II Study Comparing Prophylactic Cranial Irradiation Alone to Prophylactic Cranial Irradiation and Consolidative Extra-Cranial Irradiation for Extensive Disease Small cell Lung Cancer (ED-SCLC) – 3DCRT credentialed
• **ECOG E2511**: Phase I and Randomized Phase II Double Blind Clinical Trial of Cisplatin and Etoposide in Combination with Veliparib (ABT-888) or Placebo as Frontline Therapy for Extensive Stage Small Cell Lung Cancer

**LEUKEMIA/LYMPHOMA**

**MDS**

• **SWOG 1117**: A Randomized Phase II Study of Azacitidine in Combination with Lenalidomide vs. Azacitidine Alone vs. Azacitidine in Combination with Vorinostat for Higher-Risk Myelodysplastic Syndromes – 2 drug counselors must be trained  TEMPORARILY CLOSED TO ACCRUAL

• **ECOG E2905**: Randomized Phase III Trial Comparing the Frequency of Major Erythroid Response (MER) to Treatment with Lenalidomide (Revlimid) Alone and in Combination with Epoetin Alfa (Procrit) in Subjects with Low-or Intermediate-1 Risk MDS and Symptomatic Anemia

**AML**

• **ECOG E2906**: A Phase III Randomized Trial of Clofarabine as Induction and Post-Remission Therapy vs. Standard Daunorubicin & Cytarabine Induction and Intermediate Dose Cytarabine Post-Remission Therapy, Followed by Decitabine Maintenance vs. Observation in Newly-Diagnosed Acute Myeloid Leukemia in Older Adults (Age > 60 Years)

• **ECOG E3903**: Ancillary Laboratory Protocol For Collecting Diagnostic Material On Patients Considered For ECOG Treatment Trials For Leukemia Or Related Hematologic Disorders

• **SWOG S0919**: A Phase II Study of Idarubicin and ARA-C in Combination with Pravastatin for Poor-Risk Acute Myelogenous Leukemia (AML)

• **SWOG S1203**: A Randomized Phase III Study of Standard Cytarabine Plus Daunomycin (7+3) Therapy versus Idarubicin with High Dose Cytarabine (IA) with or without Vorinostat (IA+V) in Younger Patients with Previously Untreated Acute Myeloid Leukemia (AML)

**CLL**

• **ECOG E1912**: 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)

**Hodgkin’s Lymphoma**

**Follicular Lymphoma**

• **CALGB S0904**: A Randomized Phase II Trial of Ofatumumab and Bendamustine vs. Ofatumumab, Bortezomib and Bendamustine in Patients with Untreated Follicular Lymphoma – imaging core credentialing needed

• **SWOG S1001**: A Phase II Trial of PET-Directed Therapy for Limited Stage Diffuse Large B-cell Lymphoma Submit PET/CT for review

• **ECOG E1412**: Randomized Phase II Study of Lenalidomide R-CHOP (R2CHOP) vs RCHOP (Rituximab,Cyclophosphamide, Doxorubicin, Vincristine and Prednisone) in Patients with Newly Diagnosed Diffuse Large B Cell Lymphoma

• **ECOG E2408**: 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
• RTOG 1114: Phase II Randomized Study of Rituximab, Methotrexate, Procarbazine, Vincristine, and Cytarabine With and Without Low-Dose Whole-Brain Radiotherapy For Primary Central Nervous System Lymphoma- RT credentialing needed

Mantle Cell Lymphoma
• ECOG E1411: Intergroup Randomized Phase II Four Arm Study In Patients >/= 60 with Previously Untreated Mantle Cell Lymphoma of Therapy with: Arm A=Rituximab+Bendamustine Followed by Rituximab Consolidation (RB->R); Arm B= Rituximab+ Bendamustine +Bortezomib Followed by Rituximab Consolidation (RBV->R); Arm C= Rituximab +Bendamustine Followed by Lenalidomide+Rituximab Consolidation (RB->LR), or Arm D= Rituximab+Bendamustine+Bortezomib Followed by Lenalidomide and Rituximab Consolidation (RBV->LR)

Multiple Myeloma
• ECOG E3A06: Randomized Phase III Trial of Lenalidomide Versus Observation Alone in Patients with Asymptomatic High-Risk Smoldering Multiple Myeloma
• SWOG S1211: A Randomized Phase I/II Study of Optimal Induction Therapy of Bortezomib, Dexamethasone and Lenalidomide with or without Elotuzumab (NSC-764479) for Newly Diagnosed High Risk Multiple Myeloma (HRMM)
• SWOG S1304: A Phase II Randomized Study Comparing Two Doses of Carfilzomib (NSC-756640) with Dexamethasone for Multiple Myeloma Patients with Relapsed or Refractory Disease
• ECOG E1A11: 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)

MELANOMA
• ECOG E1609: A Phase III Randomized Study of Adjuvant Ipilimumab Anti-CTLA4 Therapy Versus High-Dose Interferon Alfa-2b for Resected High-risk Melanoma
• ECOG E2607: A Phase II Trial of Dasatinib in Patients with Unresectable Locally Advanced or Stage IV Mucosal, Acral and Solar Melanomas
• ECOG 3611: A Randomized Phase II Study of Ipilimumab at 3 mg/kg or 10 mg/kg Alone or in Combination with High Dose Interferon-a in Advanced Melanoma
• ECOG 3612: A Randomized Phase II Trial of Ipilimumab with or without Bevacizumab in Patients with Unresectable Stage III or Stage IV Melanoma
• NCCTG N0879: A Randomized Phase II Trial of Carboplatin, Paclitaxel, Bevacizumab, with or without Everolimus for Therapy of Metastatic Malignant Melanoma

MISC
• ReCKord: CyberKnife Registry Trial
• CCWF 99211: Feasibility of Delivering a Quitline Based Smoking Cessation Intervention in Lung Cancer Patients Receiving Outpatient Treatment: A Pilot Study
• NCCTG N0392: Assessment of Patient Satisfaction with Participation in Phase II/III NCCTG Clinical Trials
• Cancertype ID: A Database Registry for bioTheranostics Test for tumors with unclear diagnosis/unknown primary

All physicians and staff conducting research at Oakwood MUST complete Human Subjects Training through CITI. Any questions regarding clinical trials at Oakwood, please call: 313.436.2439 or 313.593.8090