
# Trials and Timely Updates

GEORGIA CANCER CENTER
AUGUSTA UNIVERSITY

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## Personalizing Treatment for patients with Small Cell Lung Cancer

Lung cancer constitutes of a group of molecularly and histologically heterogeneous subtypes.[1] Two major histologic subtypes are non–small-cell lung cancer (NSCLC) and small-cell lung cancer (SCLC), which account for 76% and 13%, respectively, of all cases of lung cancer in the United States.[2] Major improvements have been made in NSCLC treatment mainly due to the development of a personalized approach to therapy. There has been great progress in identifying specific subtypes of NSCLC with oncogenic mutations or gene re-arrangements, coupled with Food and Drug Administration (FDA) approval of effective therapies that have contributed to population-level improvement in NSCLC cancer-specific survival.[3] On the basis of the success of these tyrosine kinase inhibitors in selected patients, the National Comprehensive Cancer Network recommended in 2012 that all patients with non-squamous NSCLC undergo genetic testing for EGFR mutations and ALK rearrangements. Currently, NSCLC with EGFR, ALK, ROS, B-raf, RET, NTRK, K-ras G12C and MET exon 14 skipping mutations have FDA-approved targeted therapies available. Furthermore, the development of immunotherapies and the combination of chemo-immunotherapy have further improved clinical outcome of patients with NSCLC. Still, therapy for advanced stage disease aims mostly for disease control and palliation rather than cure. Thus, novel therapies are needed to meet the goal of achieving cure for most patients.

Unlike NSCLC's classification into several sub-types based on specific markers and treatment with oral targeted therapies instead of chemotherapy, patients with SCLC do not yet have such options, subsequently, there has been evolving research in SCLC to identify molecular sub-types and develop therapies targeting specific types of SCLC. For more than 30 years, patients with SCLC have been treated with the same systemic chemotherapies utilizing a platinum/etoposide combination backbone. For these patients, treatment has not been based on selective biomarkers. However, recently, the addition of immunotherapy as atezolizumab[4] or durvalumab to chemotherapy, improved patients' outcome without significant added toxicities.

## Georgia Cancer Center Clinic Locations

Outpatient Services
1411 Laney Walker Boulevard
Augusta, GA 30912
**Office: (706) 721-6744**

Georgia Cancer Center – Downtown
818 St. Sebastian Way
Suite 400
Augusta, GA 30901
**Office: (706) 721-6914**

Georgia Cancer Center Radiation Therapy
821 St. Sebastian Way
Augusta, GA 30912
**Office: (706) 721-2971**

The addition of atezolizumab to platinum doublet therapy in the IMpower133 study led to significant improvement in OS and PFS. The IMpower133 study randomized 403 patients with newly diagnosed ES-SCLC to chemotherapy with atezolizumab or placebo, and met its co-primary endpoints, since it improved OS from 10.3 months in the control arm to 12.3 months in the atezolizumab arm (HR=0.7, 95% CI, 0.54-0.91). The addition of atezolizumab also led to an increase in PFS from 4.3 to 5.2 months (HR=0.77, 95% CI, 0.62-0.96). The combination of carboplatin/etoposide and atezolizumab in the frontline setting for extensive stage SCLC followed by maintenance atezolizumab is currently FDA approved, and has been adopted as standard of care for patients who are eligible to receive immunotherapy [4].

Poly ADP ribose polymerase (PARP) inhibition has shown to potentiate the activity of anti-PD-1/PD-L1 therapy through several mechanisms, including activation of the innate immune system[5]. PD-L1 levels are increased in preclinical models following treatment with PARP inhibitors (PARPi). Several studies have identified DNA damage response (DDR) inhibitors, such as PARP inhibitors, as capable of stimulating increased PD-L1 expression[6] in various tumors, including SCLC. The upregulation of PD-L1 appears to occur via activation of the Stimulator of Interferon Genes (STING) pathway[7]. SCLC has high levels of expression of PARP, making PARP inhibition an attractive and promising target for the treatment of SCLC. Talazoparib is one of the most potent PARP inhibitors and is being investigated in this setting[8,9,10,11].

Several independent preclinical approaches demonstrated that expression of SLFN11 is a predictor of PARP inhibitor sensitivity in SCLC. SLFN11 is a DNA/RNA helicase that, upon DNA damage (e.g., from chemotherapy) engages with the replication fork triggering a replication block and cell death. In a co-clinical trial, SLFN11 was the top biomarker of sensitivity to talazoparib (PARPi) in SCLC PDX models [11]. SLFN11 predicted improved PFS and OS in the cohort receiving the combination of Veliparib (a PARPi inhibitor) and Temozolomide (TMZ) [12]. SLFN11 is currently assessed by immunohistochemistry (IHC) and reported as expressed or not expressed, with the level of expression not yet defined as a predictive factor. (Figure 1)
At the Georgia Cancer Center at Augusta University, we have been developing concepts and clinical trials with the main focus of personalizing therapies in both SCLC and NSCLC. We collaborate with clinicians and scientists from the Southwest Oncology Group (SWOG) and MD Anderson Cancer Center in exploring specific biomarkers that can lead to choosing treatment for small cell lung cancer (SCLC) according to those markers. Patients with SCLC that express SLFN11 (figure 1) have the option of enrolling in a clinical trial that includes the addition of a targeted therapy to their treatment. This approach may offer a significant advance in the outcome of patients with this disease.

There are many benefits from enrolling patients in clinical trials as achieving access to some of the most promising new agents under development. At the Georgia Cancer Center at Augusta University, we offer several clinical trials that aim to improvement of outcome for patients with small cell lung cancer including a frontline therapy trial and second line therapy trial.

# 1. Small Cell Lung Cancer

## 1.1. Frontline Therapy in SCLC

### 1.1.1 *Maintenance Therapy for Small Cell Lung Cancer in Patients with SLFN11 Positive Biomarker*-NCT04334941

S1929 is a Phase II multi-center trial clinical trial led by Dr. Nagla Abdel Karim, MD from Georgia Cancer Center. It is currently enrolling patients in around 200 centers throughout USA through the Southwest Oncology Group (SWOG) co-operative. S1929 is a unique clinical trial in small cell lung cancer that is personalized as it is based on selecting treatment based on the presence of the specific biomarker SLF11. SLFN11 is a predictor marker for PARP inhibitors. Thus, patients who have SLFN11 positive marker on their SCLC, are likely to respond to the oral therapy of talazoparib (one of the PARP inhibitors) when added to their standard of care maintenance treatment. More than half of the patients with SCLC are SLFN11 positive. Mechanistically, PARP inhibitors appear to exert much of their anti-cancer effect in SCLC by trapping PARP1 and PARP2 onto replicating DNA. This phase II trial studies the combination of talazoparib and atezolizumab in SCLC in the maintenance setting compared to the standard of care maintenance therapy alone in patients with SLFN11-positive extensive-stage small cell lung cancer (Figure 3).

The selection of patients for novel agents and the improvement of therapy remains a goal and an area of unmet need. Subsequently, we are looking forward to helping our patients with newly diagnosed small cell lung cancer look into the clinical trials options and consider their eligibility into the currently open clinical trial. The future goal is to improve the clinical outcome of patients with SCLC through personalized therapy (Figure 2).

**PI – Nagla Abdel Karim, MD**
**Research Nurse – Sandra Duncan (706-721-4430 or sduncan@augusta.edu)**

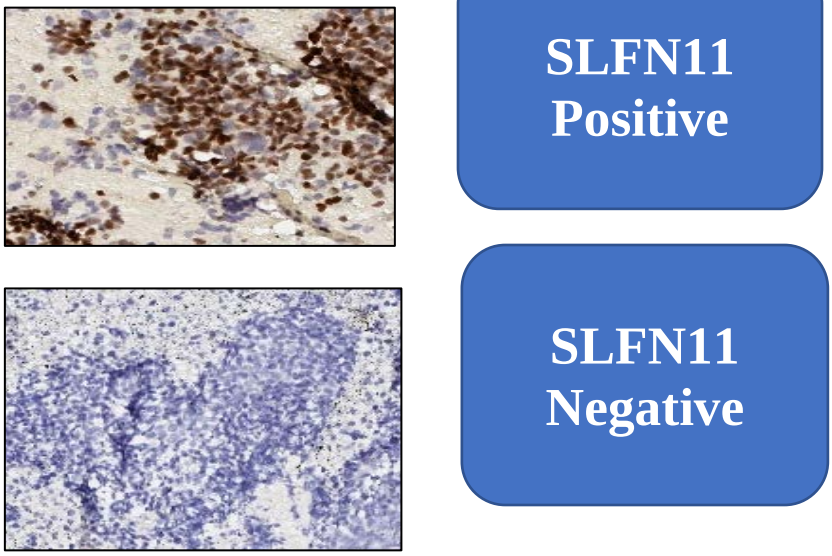


Figure 1. FFPE sections from archival (diagnostic) tumors stained for SLFN11 (>1% = positive) **High SLFN11 (IHC) predicts improved outcome in Veliparib/TMZ arm (PFS, OS)** *(Interaction p-value 0.009)*

Georgia Cancer Center Clinical Trials Office

URL:
https://go.augusta.edu/cancerclinicaltrials

Email:
Cancer_Clinical_Trials@augusta.edu

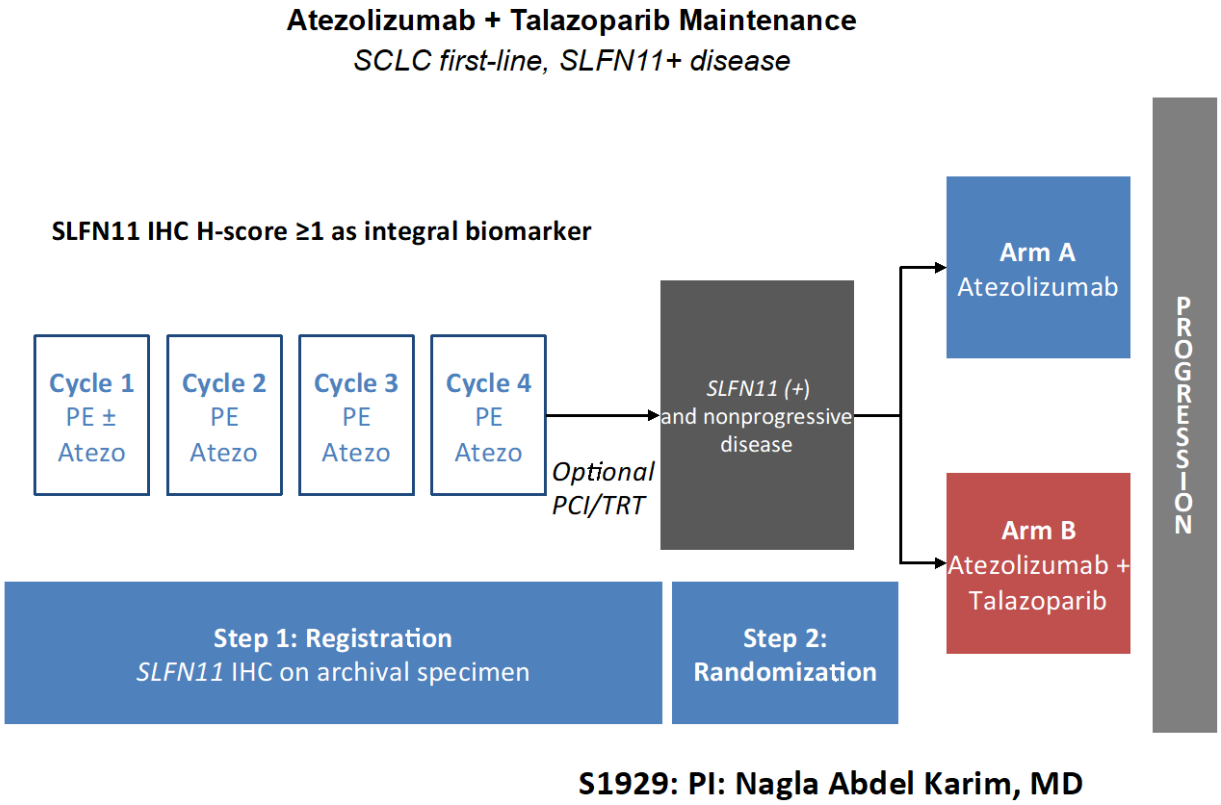


Figure 2: S1929: Testing Maintenance Therapy for Small Cell Lung Cancer in Patients with SLFN11 Positive Biomarker- NCT04334941

## 1.2 Second Line Therapy for SCLC

### *1.2.1. Phase 1 Safety and Feasibility study of Nivolumab in combination with Irinotecan in relapsed or refractory Small Cell Lung Cancer GCC-20-009; NCT04173325*

This is a feasibility study for patients with small cell lung cancer who progress on the first line of therapy. This will offer the combination of immunotherapy and irinotecan. Irinotecan is an active agent against SCLC. The combination of irinotecan and PD-L1 inhibitors has been shown to be synergistic [13] per pre-clinical data, since it significantly decreased tumor volume compared to each agent alone.

Additional experiments showed that 1) combination therapy enhanced proliferation of CD8+ T-cells resulting in an increase in the number of intratumoral tumor-specific CD8+ T–cells, and 2) irinotecan increased MHC class I and PD-L1 expression in tumors and decreased Tregs in tumors, all of which may have contributed to its combination effect with anti-PD-L1. In addition, irinotecan has been utilized in different dosing and schedules in patients with solid tumors and SCLC [14]. Prior clinical trials with PD-1 inhibitors as pembrolizumab plus irinotecan was conducted in patients with solid tumors including SCLC were conducted.

**PI – Nagla Abdel Karim, MD**
**Research Nurse – Sandra Duncan (706-721-4430 or sduncan@augusta.edu)**

Respectfully,

Nagla Abdel Karim, MD
Professor, Department of Medicine - Hematology/Oncology
Director, Thoracic Oncology Program

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# *Featured Clinical Trials*

## Non-Small Cell Lung Cancer (NSCLC)

***Title: Phase III Trial of Induction/Consolidation Atezolizumab + SBRT Versus SBRT Alone in High Risk, Early Stage NSCLC***

Immunotherapy has improved outcomes after chemoradiotherapy in stage III NSCLC and with or without chemotherapy **AND** in stage IV NSCLC. This study is testing whether immunotherapy will improve outcomes in conjunction with stereotactic body radiotherapy (SBRT) for patients who are not surgical candidates or refuse surgery for early stage (T1-T3N0M0) newly diagnosed NSCLC with a higher risk of relapse based on either tumor size ≥2 cm, PET SUV max ≥6.2, and/or moderately differentiated, poorly differentiated, or undifferentiated histology.

**PIs – Dr. William Grubb and Dr. Nagla Karim**
**Research Nurse – Sandra Duncan (706-721-4430 or sduncan@augusta.edu)**

***Title: IST-65: Cabozantinib With Pemetrexed in Advanced Non-small Cell Lung Cancer, Urothelial Cancer and Malignant Mesothelioma***

Cabozantinib is a tyrosine kinase inhibitor that has been approved as an anti-neoplastic agent for several tumor types. Both pemetrexed and cabozantinib are active anti-neoplastic therapies and may have a better outcome when used in combination. In this phase 1 study, patients with non-small cell lung cancer, urothelial cancer and advanced malignant mesothelioma who progress on standard of care therapy are eligible.

**PI – Nagla Abdel Karim, MD**
**Research Nurse – Sandra Duncan (706-721-4430 or sduncan@augusta.edu)**

***Title: A Phase 3, Randomized, Double-blind Study of Neoadjuvant Chemotherapy plus Nivolumab versus Neoadjuvant Chemotherapy plus Placebo, followed by Surgical Resection and Adjuvant Treatment with Nivolumab or Placebo for Participants with Resectable Stage II-IIIB Non-small Cell Lung Cancer (CheckMate 77T, CHECKpoint pathway and nivoluMAb clinical Trial Evaluation 77T)***

Protocol ID: CA209-77T/CheckMate 77T
PI – N. Abdel Karim

***A Phase 3, Randomized, Open Label Study to Compare Nivolumab plus Concurrent Chemoradiotherapy (CCRT) followed by Nivolumab plus Ipilimumab or Nivolumab plus CCRT Followed by Nivolumab vs CCRT followed by Durvalumab in Previously Untreated, Locally Advanced Non-Small Cell Lung Cancer (LA NSCLC) (CheckMate 73L, CHECKpoint pathway and nivoluMAb clinical Trial Evaluation 73L)***

Protocol ID: CA209-73L/CheckMate 73L
PI – N. Abdel Karim

**A Phase 1/2a, Open-Label, Multicenter Study to Investigate the Safety and Preliminary Efficacy of NKTR-214 in Combination with Anti-PD-1 (Pembrolizumab) in Patients with Locally Advanced or Metastatic Solid Tumors**

*Protocol ID: NKTR 16-214-05 ClinicalTrials.gov: NCT03138889*
PI – N. Abdel Karim

# Small Cell Lung Cancer

***Title: Maintenance Therapy for Small Cell Lung Cancer in Patients With SLFN11 Positive Biomarker***

Talazoparib is a novel PARP inhibitor that has shown activity in SCLC and is most potent against SLFN11 positive SCLC. This phase II trial studies the combination of talazoparib and atezolizumab in SCLC in the maintenance setting compared to the standard of care maintenance therapy alone in patients with SLFN11-positive extensive-stage small cell lung cancer.

**PI – Nagla Abdel Karim, MD**
**Research Nurse – Sandra Duncan (706-721-4430 or sduncan@augusta.edu)**

**Title:** ***Phase 1 Safety and Feasibility study of Nivolumab in combination with Irinotecan in relapsed or refractory Small Cell Lung Cancer***

*Protocol ID: GCC-20-009 ClinicalTrials.gov: NCT04173325*

**PI – N. Abdel Karim**
**Research Nurse – Sandra Duncan (706-721-4430 or sduncan@augusta.edu)**

# ***Open Trials by Tumor Type***

# SOLID TUMORS

## Breast Cancer

**Alternate approaches for clinical stage II or III Estrogen Receptor positive breast cancer NeoAdjuvant Treatment (ALTERNATE) in postmenopausal women: a phase III study**

*Protocol ID: A011106 ClinicalTrials.gov #NCT01953588 Phase III*
PI – S. Ghamande

**A Randomized Phase III Trial Comparing Axillary Lymph Node Dissection to Axillary Radiation in Breast Cancer Patients (cT1-3 N1) Who Have Positive Sentinel Lymph Node Disease After Neoadjuvant Chemotherapy**

*Protocol ID: A0111202 ClinicalTrials.gov #NCT01901094 Phase III*
PI – S. Ghamande

**An Open-label, Randomized, Phase 2/3 Study of Olaparib Plus Pembrolizumab Versus Chemotherapy Plus Pembrolizumab After Induction of Clinical Benefit With First-line Chemotherapy Plus Pembrolizumab in Participants With Locally Recurrent Inoperable or Metastatic Triple Negative Breast Cancer (TNBC)**

*Protocol ID: MK7339-009 ClinicalTrials.gov #NCT04191135 Phase II / III*
PI – A. Krutchik

**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**

*Protocol ID: NRG-BR003 ClinicalTrials.gov #NCT02488967 Phase III*
PI – S. Ghamande

**A Randomized, Double-Blind, Parallel Group, Placebo-Controlled Multi-Centre Phase III Study to Assess the Efficacy and Safety of Olaparib Versus Placebo as Adjuvant Treatment in Patients with Germline BRCA1/2 Mutations and High Risk HER2 Negative Primary Breast Cancer Who Have Completed Definitive Local Treatment and Neoadjuvant or Adjuvant Chemotherapy**

*Protocol ID: NSABP-B55 ClinicalTrials.gov #NCT02032823 Phase III*
PI – S. Ghamande

**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**

*Protocol ID: S1207 ClinicalTrials.gov #NCT01674140 Phase III*
PI – S. Ghamande

**Phase II Randomized Placebo-Controlled Trial of Cisplatin with or without ABT-888 (Veliparib) in Metastatic Triple-Negative Breast Cancer and/or BRCA Mutation-Associated Breast Cancer**

*Protocol ID: S1416 ClinicalTrials.gov #NCT02595905 Phase II*
PI – S. Ghamande

**A Randomized Phase III Trial to Evaluate the Efficacy and Safety of MK-3475 (Pembrolizumab) as Adjuvant Therapy for Triple Receptor-Negative Breast Cancer with ≥ 1 cm Residual Invasive Cancer or Positive Lymph Nodes (ypN+) After Neoadjuvant Chemotherapy**

*Protocol ID: S1418 ClinicalTrials.gov #NCT02954874 Phase III*
PI – S. Ghamande

**Randomized, Double-Blind, Phase 3 Study of Tucatinib or Placebo in Combination with Ado-Trastuzumab Emtansine (T DM1) for Subjects with Unresectable Locally-Advanced or Metastatic HER2+ Breast Cancer**

*Protocol ID: SGNTUC-016 ClinicalTrials.gov #NCT03975647 Phase III*
PI – A. Krutchik

**Phase 1/2 Expansion Cohorts Trial of Intravenous Administration of TAEK-VAC-HerBy Vaccine Alone and in Combination With HER2- and PD-1/PD-L1 Antibodies in Patients With Advanced HER2-expressing Cancer**

*Protocol ID: TAEK-VAC-HerBy ClinicalTrials.go #NCT04246671*
PI – P. Raval

**A Phase II Multi-institutional Study of Concurrent Radiotherapy, Palbociclib, and Hormone Therapy for Treatment of Bone Metastasis in Breast Cancer Patients**

*Protocol ID: WCI4472-18 ClinicalTrials.gov #NCT003691493 Phase II*
PI – C. Ferguson

## Gastrointestinal Cancer

**(Poly-ICLC-IM) A Phase I/II Trial of Pembrolizumab and Poly ICLC in Patients with Metastatic Mismatch Repair-Proficient (MRP) Colon Cancer**

*Protocol ID: CC-16047 ClinicalTrials.go # NCT02834052*
PI – A. Nayak

**PRESERVE 1: A Phase 3 Randomized, Double-blind Trial of Trilaciclib versus Placebo in Patients Receiving FOLFOXIRI/Bevacizumab for Metastatic Colorectal Cancer**

*Protocol ID: G1T28-207 ClinicalTrials.go # NCT04607668*
PI – A. Nayak

## Genitourinary Cancer

**A Phase 3, Randomized, Double-blind Trial of Pembrolizumab (MK-3475) Plus Enzalutamide Versus Placebo Plus Enzalutamide in Participants With Metastatic Castration-Resistant Prostate Cancer (mCRPC) (KEYNOTE-641)**

*Protocol ID: MK3475-641 ClinicalTrials.gov #NCT03834493 Phase III*
PI – J. Parikh
Disease Site – Prostate Cancer

**A Phase 3, Randomized, Double-blind Study of Pembrolizumab (MK-3475) Plus Docetaxel Plus Prednisone versus Placebo Plus Docetaxel Plus Prednisone in Participants with Chemotherapy-naïve Metastatic Castration-Resistant Prostate Cancer (mCRPC) who have Progressed on a Next Generation Hormonal Agent (NHA) (KEYNOTE921)**

*Protocol ID: MK3475-921 ClinicalTrials.gov #NCT03834506 Phase III*
PI – J. Parikh
Disease Site – Prostate Cancer

**A Phase 3, Randomized Open-label Study of Pembrolizumab (MK-3475) Plus Olaparib Versus Abiraterone Acetate or Enzalutamide in Participants with Metastatic Castrationresistant Prostate Cancer (mCRPC) Who are Unselected for Homologous Recombination Repair Defects and Have Failed Prior Treatment with One Next-generation Hormonal Agent (NHA) and Chemotherapy (KEYLYNK-010)**

*Protocol ID: MK7339-010 ClinicalTrials.gov #NCT03834519 Phase III*
PI – J. Parikh
Disease Site – Prostate Cancer

# Gynecological Cancer

**Phase 1 Dose Escalation and Cohort Expansion Study of TSR-042, an anti-PD-1 Monoclonal Antibody, in Patients with Advanced Solid Tumors**

*Protocol ID: TESARO 4010-01-001 ClinicalTrials.gov NCT0275284*
PI – S. Ghamande
Disease Site – Advanced solid tumors

**A Multicenter, Open-Label Phase 1/2 Trial Evaluating the Safety, Tolerability, and Efficacy of MORAb-202, a Folate Receptor Alpha (FRa)-Targeting Antibody-Drug Conjugate (ADC) in Subjects with Selected Tumor Types**

*Protocol ID: MORAb-202-G000-201 ClinicalTrials.gov NCT04300556*
PI – S. Ghamande
Disease Site – Endometrial, Ovarian, or Peritoneal Cancer

**A Phase 2 Study to Evaluate the Safety and Efficacy of EP0057 in Combination With Olaparib in Advanced Ovarian Cancer Patients Who Have: Cohort 1 Platinum Resistant Disease and are PARP Inhibitor Naïve; Cohort 2 Had at Least 2 Prior Lines of Therapy Which Must Include at Least 1 Line of Platinum-Based Chemotherapy Followed by PARP Inhibitor Maintenance**

*Protocol ID: EP0057-201 ClinicalTrials.gov NCT04669002*
PI – S. Ghamande
Disease Site – Ovarian Cancer

**A Phase 2, Multicenter Study to Evaluate the Efficacy and Safety Using Autologous Tumor Infiltrating Lymphocytes (LN-145) in Patients with Recurrent, Metastatic or Persistent Cervical Carcinoma**

*Protocol ID: LION C-145-04 ClinicalTrials.gov NCT03108495*
PI – S. Ghamande
Disease Site – Cervical Cancer

**A Phase 1b/2, First-in-Human, Dose Escalation and Expansion Study of XMT-1536 In Patients with Solid Tumors Likely to Express NaPi2b**

*Protocol ID: GOG 3048*
PI – S. Ghamande

**A Phase 3, Randomized, Double-blind, Multicenter Study of TSR-042 plus Carboplatin-Paclitaxel versus Placebo plus Carboplatin-Paclitaxel in Patients with Recurrent or Primary Advanced Endometrial Cancer**

*Protocol ID: GOG-3031/4010-03-001 ClinicalTrials.gov NCT03981796*
PI – S. Ghamande
Disease Site – Endometrial

**A Phase 3, Randomized, Double-Blind, Adaptive, Placebo/Paclitaxel- Controlled study of AVB-S6-500 in Combination with Paclitaxel in Patients with Platinum Resistant Recurrent Ovarian Cancer**

*Protocol ID: GOG 3059 / AVB500-0C-004*
Disease Site – Ovarian Cancer

**A Phase 1 Open-Label, Safety, Pharmacokinetic and Preliminary Efficacy Study of STRO-002, an anti-Folate Receptor alpha (FolRα) Antibody Drug Conjugate (ADC), in Patients with Advanced Epithelial Ovarian Cancer (including Fallopian Tube or Primary Peritoneal Cancers) and Endometrial Cancers**

*Protocol ID: STRO-002-GM1*
Disease Site – Endometrial

**Dragonfly: A Phase 1/2, First-In-Human, Multi-Part, Open-Label, Multiple-Ascending Dose Study to Investigate the Safety, Tolerability, Pharmacokinetics, Biological, and Clinical Activity of DF6002 as a Monotherapy and in Combination with Nivolumab in Patients With Locally Advanced or Metastatic Solid Tumors, and Expansion in Selected Indications**

**Jounce: Phase 1 First-in-Human (FIH) Study of Leukocyte Immunoglobulin-Like Receptor B2 (LILRB2) Inhibitor Monoclonal Antibody (mAb) JTX-8064, as Monotherapy and in Combination with a Programmed Cell Death Receptor-1 (PD-1) Inhibitor, in Adult Subjects with Advanced Refractory Solid Tumor Malignancies**

**A Phase 2 Open-Label, Multicenter Study To Evaluate Efficacy And Safety Of Zn-C3 In Adult Women With Recurrent Or Persistent Uterine Serous Carcinoma**

*Protocol ID: GOG 3065 / Zn-C3-004*
Disease Site – Uterine Cancer

**A Phase 1b/2 Open-Label Trial of Tisotumab Vedotin (HuMax® -TF-ADC) Monotherapy and in Combination with Other Agents in Subjects with Recurrent or Stage IVB Cervical Cancer**

*Protocol ID: GOG 3024*
Disease Site – Cervical Cancer

## Head and Neck Cancer

**A Phase 2 study of lenvatinib (E7080/MK-7902) with or without pembrolizumab (MK-3475) and SOC chemotherapy for R/M HNSCC after platinum therapy and immunotherapy**

*Protocol ID: MK-7902-009 ClinicalTrials.gov: NCT04428151*
PI – A. Guddati
Disease Site – Head and Neck Squamous Cell Carcinoma

**Randomized Phase I/III Trials of Surgery and Postoperative Radiation Delivered with Concurrent Cisplatin versus Docetaxel versus Docetaxel and Cetuximab for High-Risk Squamous Cell Cancer of the Head and Neck**

*Protocol ID: RTOG-1216 ClinicalTrials.gov: NCT01810913*
PI – S. Ghamande
Disease Site – Head and Neck Squamous Cell Cancer

## Melanoma

**Randomized Phase II/III Study of Nivolumab Plus Ipilimumab Plus Sargramostim Versus Nivolumab Plus Ipilimumab in Patients With Unresectable Stage III or Stage IV Melanoma**

*Protocol ID: EA6141 ClinicalTrials.gov: NCT02339571*
PI – S. Ghamande
Disease Site – Melanoma

**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**

*Protocol ID: EA6134 ClinicalTrials.gov: NCT02224781*
PI – S. Ghamande
Disease Site – Melanoma

## Neuro-Oncology

**A Phase 1, Open-Label, Multicenter, Dose Escalation and Expansion Study of PRT811 in Subjects with Advanced Solid Tumors, CNS Lymphoma, and Recurrent High-Grade Gliomas**

*Protocol ID: PRT811-01 ClinicalTrials.gov NCT04089449*
PI – A. Krutchik
Disease Site – Gliomas

## Thoracic Oncology

**ASCO Survey on COVID-19 in Oncology Registry**

*Protocol ID: GCC-20-066A*
PI – N. Abdel Karim

**PrOspective Non-interventional study in patients with locally advanced or metastatic TRK fusion cancer treated with Larotrectinib**

Protocol ID: ON-TRK
PI – N. Abdel Karim

**A Phase III Double-Blind Trial for Surgically Resected Early Stage Non-Small Cell Lung Cancer: Crizotinib versus Placebo for Patients with Tumors Harboring the Anaplastic Lymphoma Kinase (ALK) Fusion Protein**

*Protocol ID: E4512 (ALCHEMIST) ClinicalTrials.gov: NCT02201992*
PI – N. Abdel Karim
Disease Site – Non-Small Cell Lung Cancer

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**

Protocol No. EA5163
PI – N. Abdel Karim

**A Pilot Study of Hypofractionated Radiotherapy Followed by Atezolizumab Consolidation in Stage II or III NSCLC Patients with Borderline Performance Status**

Protocol ID: S1933
PI – N. Abdel Karim

**A Master Protocol to Evaluate Biomarker-Driven Therapies and Immunotherapies in Previously-Treated Non-Small Cell Lung Cancer (Lung-MAP Screening Study)**
(LUNG-MAP)

**Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial**

Protocol ID: S1827
PI – N. Abdel Karim

# HEMATOLOGIC MALIGNANCIES

## Acute Lymphoblastic Leukemia

**A Phase 3, Randomized, Open-label, Multicenter Study Comparing Ponatinib versus Imatinib, Administered in Combination with Reduced-intensity Chemotherapy, in Patients with Newly Diagnosed Philadelphia Chromosome-positive Acute Lymphoblastic Leukemia (Ph+ ALL) Protocol**

*Protocol ID: Ponatinib-3001 ClinicalTrials.gov: NCT03589326*
PI – V. Kota
Disease Site – Acute Lymphoblastic Leukemia

## Acute Myeloid Leukemia

**Randomized Trial of Gilteritinib vs. Midostaurin in FLT3 Mutated Acute Myeloid Leukemia (AML)**

*Protocol ID: PrE0905 ClinicalTrials.gov: NCT03836209*
PI – V. Kota
Disease Site – Acute Myeloid Leukemia

**Phase III Randomized Trial of DFP-10917 vs. Non-Intensive Reinduction (LoDAC, Azacitidine, Decitabine) or Intensive Reinduction (High and Intermediate Dose Cytarabine Regimens) for Acute Myelogenous Leukemia Patients in Second or Third Salvage**

*Protocol ID: D18-11141 ClinicalTrials.gov: NCT03926624*
PI – J. Cortes
Disease Site – Acute Myelogenous Leukemia

**Randomized, Open-Label Study of the Efficacy and Safety of Galinpepimut-S Maintenance Therapy Compared to Best Available Therapy in Acute Myeloid Leukemia Patients Who Have Achieved Complete Remission After Second-Line Salvage Therapy**

*Protocol ID: SLSG18-301 ClinicalTrials.gov: NCT04229979*
PI – J. Cortes
Disease Site – Acute Myelogenous Leukemia

**A Phase I, Open-Label, Multicenter, Dose Escalation, Dose Expansion Study of PRT543 in Patients with Advanced Solid Tumors and Hematologic Malignancies**

*Protocol ID: PRT543-01 ClinicalTrials.gov: NCT03886831*
PI – J. Cortes
Disease Site – Large B-cell Lymphoma, Myelodysplasia, Myelofibrosis, Mantle Cell Lymphoma, Acute Myeloid Leukemia, and Myelomonocytic Leukemia

## Chronic Lymphocytic Leukemia

**A Randomized Phase III Study of Ibrutinib Plus Obinutuzumab Versus Ibrutinib Plus Venetoclax and Obinutuzumab in Untreated Older Patients (>/= 70 Years of Age) with Chronic Lymphocytic Leukemia**

*Protocol ID: A041702 Clinicaltrials.gov: NCT03737981*
PI – L. Bryan
Disease Site – Chronic Lymphocytic Leukemia

## Chronic Myeloid Leukemia

**A Two-Part Phase 1/2 Study to Determine Safety, Tolerability, Pharmacokinetics, and Activity of K0706, a Novel Tyrosine Kinase Inhibitor (TKI), in Healthy Subjects and in Subjects with Chronic Myeloid Leukemia (CML) or Philadelphia Chromosome Positive Acute Lymphoblastic Leukemia (Ph+ ALL)**

*Protocol ID: CLR-15-03 ClinicalTrials.gov: NCT02629692*
PI – J. Cortes
Disease Site – Chronic Myeloid Leukemia or Acute Lymphoblastc Leukemia

**An Open-Label, Multicenter, Phase 1b/2 Study of the Safety and Efficacy of KRT-232 Combined with a Tyrosine Kinase Inhibitor (TKI) in Patients with Relapsed or Refractory Ph+ Chronic Myeloid Leukemia (CML)**

*Protocol ID: KRT-232-117 ClinicalTrials.gov: NCT04835584*
PI – J. Cortes
Disease Site – Chronic Myeloid Leukemia

## Lymphoma

**A Phase I Clinical Trial to Study the Safety, Pharmacokinetics, and Efficacy of BP1002 (L-Bcl-2) Antisense Oligonucleotide in Patients with Advanced Lymphoid Malignancies**

*Protocol ID: BP1002-101-Lymph ClinicalTrials.gov: NCT04072458*
PI – L. Bryan
Disease Site – Lymphomas and Leukemias

**A Randomized Double-Blind Phase III Study of Ibrutinib During and Following Autologous Stem Cell Transplantation Versus Placebo in Patients with Relapsed or Refractory Diffuse Large B-cell Lymphoma of the Activated B-cell Subtype**

*Protocol ID: A051301 ClinicalTrials.gov: NCT02443077*
PI – L. Bryan
Disease Site – Large B-Cell Lymphoma

**A Randomized Phase III Trial of Consolidation with Autologous Hematopoietic Cell Transplantation Followed by Maintenance Rituximab vs. Maintenance Rituximab Alone for Patients with Mantle Cell Lymphoma In Minimal Residual Disease-Negative First Complete Remission**

*Protocol ID: EA4151 ClinicalTrials.gov: NCT03267433*
PI – L. Bryan
Disease Site – Mantle Cell Lymphoma

**A Phase III, Randomized Study of Nivolumab (Opdivo) Plus AVD or Brentuximab Vedotin (Adcetris) Plus AVD in Patients (Age >/= 12 Years) with Newly Diagnosed Advanced Stage Classical Hodgkin Lymphoma**

*Protocol ID: S1826 ClinicalTrials.gov: NCT03907488*
PI – L. Bryan
Disease Site – Advanced Stage Classical Hodgkin Lymphoma

**A Phase 1b Open-Label Study to Evaluate the Safety and Antitumor Activity of Loncastuximab Tesirine and Ibrutinib in Patients with Advanced Diffuse Large B-Cell Lymphoma or Mantle Cell Lymphoma**

*Protocol ID: ADCT-402-103 ClinicalTrials.gov: NCT03684694*
PI – L. Bryan
Disease Site – Large B-Cell Lymphoma and Mantle Cell Lymphoma

**A Phase 1b/2 Trial of Hu5F9-G4 in Combination with Rituximab in Patients with Relapsed/Refractory B-cell Non-Hodgkin's Lymphoma**

*Protocol ID: 5F9003 ClinicalTrials.gov: NCT02953509*
PI – L. Bryan
Disease Site – Relapsed/Refractory B-cell Non-Hodgkin's Lymphoma

## MPN

**Phase 2 study of 9-ING-41, a Glycogen Synthase Kinase-3 Beta (GSK-3β) inhibitor, as a single agent or combined with Ruxolitinib, in patients with myelofibrosis**

*Protocol ID: Actuate 1901 ClinicalTrials.gov: NCT04218071*
PI – J. Cortes
Disease Site – Myelofibrosis

**A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study of Navitoclax in Combination with Ruxolitinib Versus Ruxolitinib in Subjects with Myelofibrosis (TRANSFORM-1)**

*Protocol ID: M16-191 ClinicalTrials.gov: NCT04472598*
PI – J. Cortes
Disease Site – Myelofibrosis

**A Randomized, Open-Label, Phase 3 Study Evaluating Efficacy and Safety of Navitoclax in Combination with Ruxolitinib Versus Best Available Therapy in Subjects with Relapsed/Refractory Myelofibrosis (TRANSFORM-2)**

*Protocol ID: M20-178 ClinicalTrials.gov: NCT04468984*
PI – J. Cortes
Disease Site – Myelofibrosis

## Stem-Cell Transplant

**A Phase 3 Study of Itacitinib or Placebo in Combination With Corticosteroids as Initial Treatment for Chronic Graft-Versus-Host Disease**

*Protocol ID: INCB-39110-309 ClinicalTrials.gov: NCT03584516*
PI – V. Kota
Disease Site – Chronic Graft-Versus-Host Disease

# PEDIATRIC ONCOLOGY

**Phase 2 Trial of Indoximod with Chemotherapy and Radiation for Children with Progressive Brain Tumors or Newly Diagnosed DIPG**

*Protocol ID: GCC-19-049 ClinicalTrials.gov: NCT04049669*
PI – T. Johnson
Disease Site – Glioblastoma, Medulloblastoma, Ependymoma, Diffuse Intrinsic Pontine Glioma

**Pediatric Precision Laboratory Advanced Neuroblastoma Therapy- A Study Using Molecular Guided Therapy with Induction Chemotherapy followed by a Randomized Controlled Trial of standard immunotherapy with or without DFMO followed by DFMO maintenance for Subjects with Newly Diagnosed High-Risk Neuroblastoma**

*Protocol ID: NMTRC012 ClinicalTrials.gov: NCT02559778*
PI – C. McDonough
Disease Site – Neuroblastoma

**NMTT - Neuroblastoma Maintenance Therapy Trial Using Difluoromethylornithine (DFMO); NMTRC014**

*Protocol ID: NMTRC014 ClinicalTrials.gov: NCT02679144*
PI – C. McDonough
Disease Site – Neuroblastoma

# Georgia Cancer Center Physicians

## Hematologic Malignancies

Dr. Locke Bryan
802-338-1808

Dr. Ayushi Chauhan
914-414-3775

Dr. Jorge Cortes
706-833-6476

Dr. Anand Jillella
706-951-5144

Dr. Amany Keruakous
216-571-3654

Dr. Vamsi Kota
706-825-4091

## General Oncology Care

Dr. Germame Ajebo
615-788-0747

Dr. Vaishalli Doshi
423-883-0821

Dr. Jigarkumar Parikh
404-993-2491

## Breast Cancer

Dr. Alicia Arnold (Vinyard)
704-860-3523

Dr. Tania Arora
434-825-0670

Dr. Caprice Greenberg
706-721-4651

Dr. Allan Krutchik
201-788-1795

Dr. Priyanka Raval
501-766-8875

## Gastrointestinal Cancer

Dr. Tania Arora
434-825-0670

Dr. Edward Kruse
706-627-0685

Dr. Asha Nayak
706-589-0075

## Genitourinary Oncology

Dr. Zachary Klaassen
706-469-0090

Dr. Martha Terris
706-830-8585

## Gynecologic Oncology

Dr. Sharad Ghamande
706-951-8718

Dr. Robert Higgins
704-726-1330

Dr. Marian Symmes Johnson
864-376-4977

Dr. Bunja Rungruang
205-542-0253

## Head and Neck Cancer

Dr. William Albergotti
706-721-6100

Dr. Kenneth Byrd
843-819-6392

Dr. Michael Groves
706-721-6100

Dr. Achuta Guddati
312-404-8928

Dr. Patrick Morgan
757-621-8975

## Melanoma and Skin Cancer

Dr. Tania Arora
434-825-0670

Dr. Achuta Guddati
312-404-8928

## Neuro-Oncology

Dr. John Henson
706-721-2505

Dr. Allan Krutchik
201-788-1795

## Pediatric Hematology/Oncology

Dr. Afshin Ameri
706-836-4442

Dr. Theodore Johnson
706-910-4718

Dr. Colleen McDonough
706-414-4619

Dr. Amir Mian
501-213-5228

Dr. David Munn
706-721-7141

Dr. Eric Ring
864-546-1965

## Psycho-Oncology

Dr. Lauren Bigham
706-825-4154

## Thoracic Cancer Care

Dr. Nagla Abdel Karim
513-375-2554

Dr. Girindra Raval
501-766-8875

## Radiation Oncology

Dr. John Barrett
706-231-3050

Dr. Catherine Ferguson
706-691-2275

Dr. William Grubb
724-889-7767

## Center for Blood Disorders

Dr. Nnenna Badamosi (Pediatrics)
301-385-6649

Dr. Abdullah Kutlar (Adult)
706-231-7099

Dr. Betty Pace (Pediatrics)
972-824-9615

Dr. Girindra Raval (Adult)
501-766-8875

*If you would like to be added to our mailing list, please email your contact info to cancer@augusta.edu*