Trials and Timely Updates

GEORGIA CANCER CENTER
AUGUSTA UNIVERSITY

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Clinical Trials at the Georgia Cancer Center

Greetings to all our colleagues. We are introducing this Newsletter from the Georgia Cancer Center where we want to provide you with information on some of the latest developments in the various cancers and provide information on the clinical trials we are conducting at the Georgia Cancer Center. The progress made in the outcome of many cancers is remarkable. This progress has been made possible by the deeper understanding of the molecular biology of the disease, the interplay of various elements including the immune system, the microenvironment, the molecular abnormalities, various host characteristics and many others. Those of us who have been working in cancer for many years have witnessed the rapid transformation in oncology. We have come to understand that each cancer type has many subtypes, and we have at our disposal many more treatment options of various mechanisms of action that allow us to be more selective and rational in our treatments. This has led to better outcomes in many cancers manifested in improved response rates, improved patient reported outcomes, safer therapies and longer overall survival. The most recent statistics from the Annual Report to the Nation from the National Institute of Health Surveillance, Epidemiology and End Result Program (SEER) show that for the decade of 2007 to 2017, cancer death rates decreased 15% overall. If we look back to 1991, the decline from 1991 to 2018 in cancer death rate has been 31%, including an 2.4% decline from 2017 to 2018, the largest one-year decline recorded in history.[1] Much work remains ahead of us but this trend is very encouraging.

Clinical trials have a central part in the treatment of patients with cancer and have been a major contributor to the progress over the past years. A growing number of trials are being conducted in hematology and medical oncology investigating new drugs, new approaches, new combinations, new devices and many other concepts, many of which will become standard practice in the near future. Unfortunately, participation in clinical trials for adult patients with cancer is less than 5%. In children it is more than 50%. At the same time, cancer mortality has been declining much faster in children with cancer than in adults. It is suggested that greater enrollment in clinical trials not only leads to faster advances in treatments, but may also lead to improved outcomes and decreased cancer mortality. An analysis of the Cancer Therapy Evaluation Program (CTEP) of NCI's Division of Cancer Therapy and Diagnosis looking at the correlation between accrual to cancer treatment clinical trials between 2001 and 2006 and 5-year survival rates by age groups shows a near 1:1 correlation between these two variables.[2]

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

There are many benefits from enrolling patients in clinical trials. These include the access to some of the most promising new agents under development at all stages of the cancer journey from the newly diagnosed to the multi-refractory settings; the opportunity to give additional treatment options when standard therapies are exhausted; the close and standardized approach that is so valuable in improving outcomes; the ability, in many instances, to have access at no cost to some or all of the drugs being administered; and the contribution to advance the knowledge and development of new therapies. Cancer clinical trials also have limitations, including a somehow difficult to meet eligibility criteria, high demands for frequent visits to the study site, regulatory and administrative burden to investigators and, frequently, to participants, and lack of information of available trials. One potentially positive outcome from the COVID-19 crisis we all experienced is that it taught us that in many instances some aspects of clinical trials could be simplified and made more patient-friendly. Although there is much more work to be done on this, we are starting to see some positive trends from sponsors and regulatory authorities in making changes to make trials more accessible and patient-friendly.

At the Georgia Cancer Center, we have a large offering of clinical trials for all tumor types, for all stages and for all steps of the journey, including studies for newly diagnosed patients where improvements in outcomes are still needed, to advanced stages where patients have experienced failure of many treatment options. Our intent with this Newsletter is to bring to you information of available clinical trials. We plan to bring this Newsletter to you periodically with each focusing on a specific tumor type, with a brief outlook of what we see as the most important advances and upcoming trends in the management of patients with these tumors, with information on the available clinical trials available for that tumor type, and with the contact information where you can obtain additional details in case a you may want to consider one of these clinical trials for one of your patients. I hope this Newsletter becomes a valuable tool for you. We want this to be a useful instrument for you in the management of your cancer patients and welcome any feedback you may have to make this Newsletter more valuable and informative. In this first edition we provide a select list of trials from various tumors that might be of interest, but any of the faculty at the Georgia Cancer Center will be happy to provide information on the availability of additional trials in their area of expertise.

With our combined efforts, we will see the outcome of cancer patients continue to improve over the next years.

Respectfully,

Jorge Cortes

References

1. Society AC. Cancer Facts & Figures 2021. Atlanta: American Cancer Society, 2021.
2. Unger JM, Cook E, Tai E, Bleyer A. The Role of Clinical Trial Participation in Cancer Research: Barriers, Evidence, and Strategies. Am Soc Clin Oncol Educ Book 2016; 35: 185-98.

Featured Clinical Trials

Acute Myeloid Leukemia (AML)

Title: Phase III Trial of DFP-10917 vs. Non-Intensive Reinduction (LoDAC, Azacitidine, Decitabine) or Intensive Reinduction (High and Intermediate Dose Cytarabine Regimens) for AML Patients in 2nd or 3rd Salvage

DFP-10917 is a nucleoside analog that induces DNA strand breakage that has shown significant activity in relapsed and refractory AML, with an overall response rate of 48% in heavily treated patients. The study offers a treatment option to patients with AML who are resistant or refractory to 2 or 3 prior therapies, a setting where few treatment options are available.

PI – Dr. Jorge Cortes (jorge.cortes@augusta.edu)
Research Nurse – Kelly Jenkins (706-721-1204 or kejenkins@augusta.edu)

Title: CPX-351 Combined with Various Targeted Agents in Subjects with Previously Untreated Acute Myeloid Leukemia

CPX-351 is a liposomally encapsulated combination of daunorubicin and cytarabine approved for treatment of secondary AML where it improved survival significantly compared to standard therapy. In this study, patients with newly diagnosed AML are eligible if they have FLT3 or IDH mutations. The study combines CPX-351 with either midostaurin (if FLT3 mutated) or enasidenib (if IDH2 mutated).

PI – Dr. Jorge Cortes (jorge.cortes@augusta.edu)
Research Nurse – Kelly Jenkins (706-721-1204 or kejenkins@augusta.edu)

Chronic Lymphocytic Leukemia

Title: A Randomized Phase III Study of Ibrutinib Plus Obinutuzumab Versus Ibrutinib Plus Venetoclax and Obinutuzumab in Untreated Older Patients with CLL

The trial explores the combination of active oral CLL agents, ibrutinib (a BTK inhibitor) and venetoclax (a BCL-2 inhibitor), in elderly patients with CLL/SLL. The study is for patient age ≥70 years with limited exclusion criteria so most all patients in this age group will be eligible. The protocol will determine if triple therapy using ibrutinib, venetoclax, and obinutuzumab (anti-CD20 monoclonal antibody) may obtain deep remissions using a defined time course of treatment rather than indefinite therapy until disease progression. All agents provided by the study.

PI – Dr. Locke Bryan (lbryan@augusta.edu)
Research Nurse – Heather Rosier (706-729-2459 or herosier@augusta.edu)

Georgia Cancer Center Clinical Trials Office

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

Email: Cancer_Clinical_Trials@augusta.edu

Chronic Myeloid Leukemia (CML)

Title: Phase 1/2 Study of Vodobatinib (K0706) patients with CML or Philadelphia Chromosome Positive Acute Lymphoblastic Leukemia (Ph+ ALL)

Vodobatinib is a novel TKI that has shown activity in patients who have received multiple prior therapies, including ponatinib. This study is aimed to patients who have experienced failure to at least 3 prior 3 TKIs, one of which should be ponatinib. The drug has no activity against T315I so patients with this mutation are not eligible.

PI – Dr. Jorge Cortes (jorge.cortes@augusta.edu)
Research Nurse – Kelly Jenkins (706-721-1206 or kejenkins@augusta.edu)

Colorectal Cancer

Title: Pembrolizumab + Poly-ICLC in MRP Colon Cancer Phase II.

In this study, pembrolizumab, and anti-PD1 antibody, is combined with a novel immuno-stimulant aimed at enhancing the anti-tumor effect of pembrolizumab. The study is aimed at patients with stage 4 colorectal cancer who have progressed on two or more lines of therapy

PI – Dr. Asha Nayak-Kapoor
Research Nurse – Ashlyn Stevenson (706-721-0660 or asstevenson@augusta.edu)

Follicular Lymphoma

Title: A Phase II/III randomized study of R-miniCHOP with or without oral azacitidine (CC-486) in participants age 75 years or older with newly diagnosed diffuse large B cell lymphoma, Grade IIIb Follicular Lymphoma

CC-486 is a newly approved oral form of azacitadine, a hypomethylating agent. The protocol will enroll elderly / frail patients with newly diagnosed DLBCL (all subtypes). CC-468 is given in combination with mini-R-CHOP x 6 cycles. The protocol is built on the concept that priming with azacitidine can chemosensitize DLBCL patients thus improving therapeutic benefit of a well-tolerated regimen in this population.

PI – Dr. Locke Bryan (lbryan@augusta.edu)
Research Nurse – Heather Rosier (706-729-2459 or herosier@augusta.edu)

Glioblastoma

Title: Phase I Study of PRT811 in Progressive GBM

PRT811 is a potent, oral protein Arginine Methyl Transferase 5 (PRMT5) inhibitor, a protein associated with progression of CNS lymphomas and glioblastomas. This study is aimed at patients with progressive glioblastoma after prior radiotherapy and temoxolamide.

PIs – Drs. Allan Krutchik and John Henson
Research Nurse – Joanne Huff (706-446-5177 or johuff@augusta.edu)

Hodgkin's Lymphoma

Title: A Phase III, Randomized Study of Nivolumab Plus AVD or Brentuximab Vedotin Plus AVD in Patients with Newly Diagnosed Advanced Stage Classical Hodgkin Lymphoma

The trial investigates the use of chemoimmunotherapy for newly diagnosed advanced stage Hodgkin lymphoma. Protocol uses standard AVD chemotherapy in combination with either brentuximab (an anti-CD30 antibody-drug conjugate) or nivolumab, a PD-1 inhibitor. This is a large cooperative group study enrolling patients age ≥12 years that will likely determine the best front-line treatment for Hodgkin lymphoma.

PI – Dr. Locke Bryan (lbryan@augusta.edu)
Research Nurse – Heather Rosier (706-729-2459 or herosier@augusta.edu)

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 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
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: Bosutinib in Combination With Pemetrexed in Patients With Selected Metastatic Solid Tumors

Pemetrexed single-agent is standard therapy in the second line setting for patients with non-squamous non-small cell lung cancer. Patients with high SRC expression may have lower response to Pemetrexed. The addition of Bosutinib, a potent SRC inhibitor, may result in an improved clinical outcome. Patients with advanced non-small cell lung cancer, ovarian, peritoneal, urothelial cancer and malignant mesothelioma are eligible.

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

Pediatric

Title: Phase 2 trial of indoximod with chemotherapy and radiation for children with progressive brain tumors or newly diagnosed DIPG

Indoximod blocks the IDO (indoleamine 2,3-dioxygenase) pathway, thereby reversing IDO-mediated immune suppression in the tumor microenvironment. This is a phase 2 study for pediatric patients 3 to 21 years of age with newly diagnosed DIPG or progressive ependymoma, medulloblastoma, or glioblastoma. The Core Regimen is comprised continuous oral indoximod with cyclic temozolomide.

PI – Dr. Theodore Johnson (thjohnson@augusta.edu)
Research Nurse – Taylor King (tayking@augusta.edu)

Title: Expanded access for indoximod in combination with chemotherapy for pediatric patients with relapsed brain cancer

Indoximod blocks the IDO (indoleamine 2,3-dioxygenase) pathway, thereby reversing IDO-mediated immune suppression in the tumor microenvironment. This is a multi-patient expanded-access protocol to provide compassionate access to indoximod for patients who do not qualify for the open GCC1949 phase 2 trial.

PI – Dr. Theodore Johnson (thjohnson@augusta.edu)
Research Nurse – Taylor King (tayking@augusta.edu)

Sickle Cell

Title: Voxelotor Expanded Access for Pediatric Patients With Sickle Cell Disease

Voxelotor is a polymerization inhibitor of deoxygenated sickle hemoglobin that increases oxygen affinity and relative concentration of oxygenated hemoglobin. This study provides early access to treatment with voxelotor prior to market authorization for pediatric patients age 4 to 11 years with sickle cell disease who have no alternative treatment options.

PI – Nnenna Badamosi
Research Associate – Mutsa Seremwe, PhD (706-721-9682 or mseremwe@augusta.edu)

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)

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

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

Genitourinary Cancer

A Phase 2, Fast Real-time Assessment of Combination Therapies in Immuno-Oncology Study of Participants with Advanced Renal Cell Carcinoma

Protocol ID: CA01800f (Fraction-RCC) ClinicalTrials.gov: NCT02996110 Phase II
PI – J. Parikh
Disease Site – Renal Cell Carcinoma

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 Phase 1b Study of ASP1951, a GITR Agonistic Antibody, as a Single Agent and in Combination with Pembrolizumab in Subjects with Advanced Solid Tumors

Protocol ID: 1951-CL-0101 ClinicalTrials.gov NCT03799003
PI – S. Ghamande
Disease Site – Advanced solid tumors

Safety Study of Bintrafusp alfa in Combination with Other Anti-cancer Therapies in Participants with Locally Advanced or Advanced Cervical Cancer Protocol

Protocol ID: MS200647-0046 ClinicalTrials.gov NCT04551950
PI – S. Ghamande
Disease Site – Cervical Cancer

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 Two-arm, Randomized, Non-comparative, Phase 2 Trial of AGEN2034 (Anti-PD-1) as a Monotherapy or Combination Therapy With AGEN1884 (Anti-CTLA4) or With Placebo in Women With Recurrent Cervical Cancer (Second Line) – RaPiDS

Protocol ID: GOG-3028/C-750-01 ClinicalTrials.gov NCT03894215
PI – S. Ghamande
Disease Site – Cervical 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 Randomized, Phase II/III Study of Pegylated Liposomal Doxorubicin and CTEP-Supplied Atezolizumab versus Pegylated Liposomal Doxorubicin/Bevacizumab and CTEP-Supplied Atezolizumab versus Pegylated Liposomal Doxorubicin/Bevacizumab in Platinum Resistant Ovarian Cancer

Protocol ID: NRG-GY009 ClinicalTrials.gov NCT02839707
PI – S. Ghamande
Disease Site – Ovarian 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 Randomized, Double-Blind, Phase 3 Trial of Maintenance With Selinexor/Placebo After Combination Chemotherapy for Patients With Advanced or Recurrent Endometrial Cancer Protocol

Protocol ID: GOG-3055/KCP-330-024 ClinicalTrials.gov NCT03555422
PI – S. Ghamande
Disease Site – Endometrial

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 Randomized, Open-Label, Phase 3 Trial of Tisotumab Vedotin vs Investigator's Choice Chemotherapy in Second- or Third-Line Recurrent or Metastatic Cervical Cancer

Protocol ID: GOG-3057/SGNTV-003 ClinicalTrials.gov: NCT04697628
PI – S. Ghamande
Disease Site – Cervical

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

A Phase 3, randomized, placebo-controlled, double-blind clinical study of pembrolizumab (MK3475) with or without lenvatinib (E7080/MK-7902) to evaluate the safety and efficacy of pembrolizumab and lenvatinib as 1L intervention in a PD-L1 selected population of participants with recurrent or metastatic head and neck squamous cell carcinoma (R/M HNSCC)

Protocol ID: MK-7902-010 ClinicalTrials.gov: NCT04199104
PI – A. Guddati
Disease Site – Head and Neck Squamous Cell Carcinoma

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

Phase I Study of the Non-receptor Kinase Inhibitor Bosutinib in Combination with Pemetrexed in Patients with Selected Metastatic Solid Tumors

Protocol ID: EXP-16-01 ClinicalTrials.gov: NCT03023319
PI – N. Abdel Karim
Disease Site – Non-Small Cell Lung Cancer

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
Disease Site – Small Cell Lung Cancer

Phase I study of cabozantinib in combination with pemetrexed in advanced non-squamous non-small cell lung cancer (NSCLC), urothelial cancer and advanced solid tumors

Protocol ID: IST 65 ClinicalTrials.gov: NCT04173338
PI – N. Abdel Karim
Disease Site – Non-Small Cell Lung Cancer

Phase I Trial of Accelerated or Conventionally Fractionated Radiotherapy Combined With MEDI4736 (durvalumab) in PD-L1 High Locally Advanced Non-Small Cell Lung Cancer (NSCLC) (ARCHON-1)

Protocol ID: NRG-LU004 ClinicalTrials.gov: NCT03801902
PI – N. Abdel Karim
Disease Site – Non-Small Cell Lung Cancer

A Phase 1 Dose Escalation and Cohort Expansion Study of TSR-022, an anti-TIM-3 Monoclonal Antibody, in Patients with Advanced Solid Tumors

Protocol ID: TESARO 4020-01-001 ClinicalTrials.gov: NCT02817633
PI – N. Abdel Karim
Disease Site – Non-Small Cell Lung Cancer

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
Disease Site – Non-Small Cell Lung Cancer

Maintenance Systemic Therapy Versus Local Consolidative Therapy (LCT) Plus Maintenance Systemic Therapy for Limited Metastatic Non-Small Cell Lung Cancer (NSCLC): A Randomized Phase II/III Trial

Protocol ID: NRG-LU002 ClinicalTrials.gov: NCT03137771
PI – N. Abdel Karim
Disease Site – Non-Small Cell Lung Cancer

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 – S. Ghamande
Disease Site – 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

A Randomized Phase III Trial of Induction/Consolidation Atezolizumab (NSC #783608) + SBRT Versus SBRT Alone in High Risk, Early Stage NSCLC
S1914

A Pilot Study of Hypofractionated Radiotherapy Followed by Atezolizumab Consolidation in Stage II or III NSCLC Patients with Borderline Performance Status
S1933

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

A Phase II Study of Rucaparib in Patients with Genomic LOH High And/Or Deleterious BRCA1/2 Mutation Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Sub-Study)
S1900A

HEMATOLOGIC MALIGNANCIES

Acute Lymphocytic 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

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 Phase 1 Study of CDX-1140, a Fully Human Agonist anti-CD40 Monoclonal Antibody, as Monotherapy or in Combination in Patients with Advanced Malignancies

Protocol ID: CDX1140-01 ClinicalTrials.gov: NCT03329950
PI – V. Kota
Disease Site – Lymphomas

A Phase I/II Study of Ixazomib and Ibrutinib in Relapsed/Refractory Mantle Cell Lymphoma

Protocol ID: PrE0404 ClinicalTrials.gov: NCT03323151
PI – L. Bryan
Disease Site – Mantle Cell Lymphoma

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

A Phase 1b/2 Open-Label, Dose Escalation and Expansion Study of Orally Administered VRx3996 and Valganciclovir in Subjects with Epstein-Barr Virus-Associated Lymphoid Malignancies Protocol Type: Treatment

Protocol ID: VT3996-201 ClinicalTrials.gov: NCT03397706
PI – L. Bryan
Disease Site – Epstein-Barr Virus Associated Lymphoid Malignancies

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

Breast Cancer

Dr. Tania Arora
434-825-0670

Dr. Caprice Greenberg
706-721-4651

Dr. Allan Krutchik
201-788-1795

Dr. Priyanka Raval
501-766-8875

Dr. Alicia Vinyard
704-860-3523

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. Jigarkumar Parikh
404-993-2491

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

Melanoma and Skin Cancer

Dr. Germame Ajebo
615-788-0747

Dr. Tania Arora
434-825-0670

Neuro-Oncology

Dr. John Henson
706-721-2505

Dr. Allan Krutchik
201-788-1795

Pediatric Hematology/ Oncology

Dr. Afshin Ameri
706-836-4442

Dr. Nnenna Badamosi
301-385-6649

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. Betty Pace
972-824-9615

Dr. Eric Ring
864-546-1965

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