
# Trials *and* Timely Updates

**Volume 3, Summer 2022**

## Lymphoma Updates

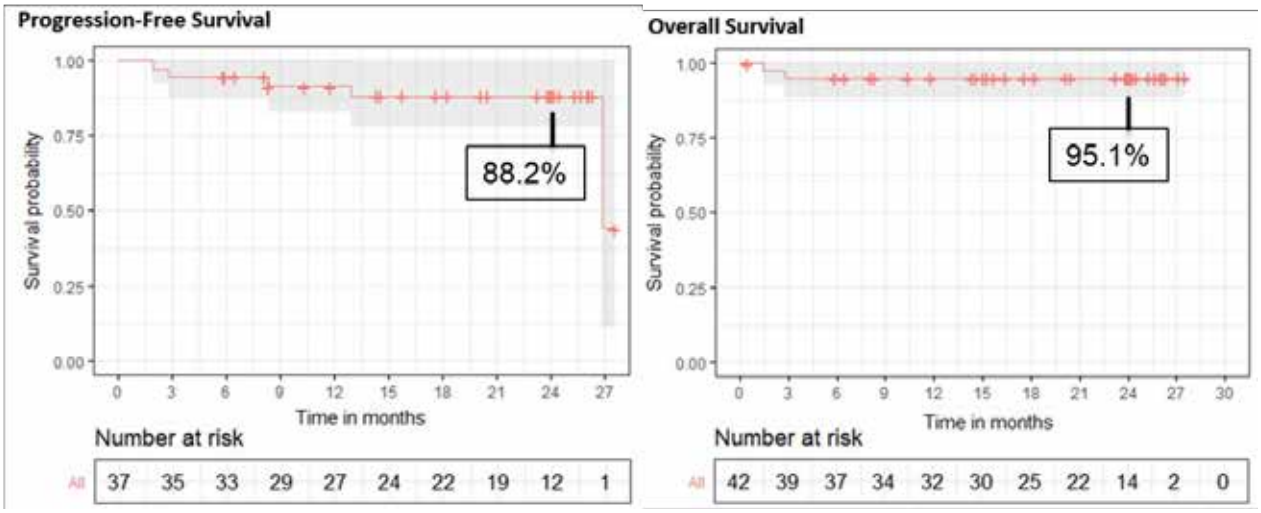
Lymphomas are uncommon blood cancers and make up approximately 5% of all new cancers diagnosed in the US annually[1]. Fortunately, we have increasingly effective treatment options to offer and survival outcomes are excellent for a majority of patients. The lymphoid neoplasms include a heterogenous group of diseases with over 60 subtypes listed in the most recent iteration of the WHO classification[2]. Proper diagnosis is crucial to select the best treatment plan for patients. Our multidisciplinary approach includes closely working with our excellent hematopathologist, Dr Natasha Savage, on every patient. Second pathology review and discussion in our weekly tumor board offer a great resource for complex cases. The lymphoma program welcomes a new hematologist, Dr. Ayushi Chauhan. Dr. Chauhan completed her fellowship training at Georgetown University focusing on lymphoid neoplasms. She adds a breadth of knowledge on the subject and will be involved in our clinical trial and transplant programs.

Our CAR-T program opened in May 2021 and we currently have commercial products including Yescarta, Kymriah, and Tecartus (using the brand names for easy pronunciation). We are one of only three centers with immune effector cell (IEC) therapy available in Georgia. Delivery of CAR-T requires collaboration with numerous subspecialties for safe and effective treatment. With scrutinized certification, the Georgia Cancer Center meets those requirements. Exciting updates from the recent ASH Annual Meeting in December 2021 showed excellent outcomes when utilizing CAR-T earlier in the treatment algorithms for diffuse large B-cell lymphoma (DLBCL). Updated results were presented

from the three Phase III CAR-T studies: BELINDA, TRANSFORM, and ZUMA-7[3-5]. Briefly, TRANSFORM compared Breyanzi to standard of care (SOC = salvage chemotherapy followed by autologous stem cell transplant (autoSCT)) for relapsed DLBCL and enrolled 184 patients. Results showed improvement in event-free survival (EFS) (10.1 months vs 2.3 months), complete remission (CR) rate (61% vs 36%), progression-free survival (PFS) (14.8 months vs 5.7 months), and overall survival (OS) (not reached (NR) vs 16.4 months)[4]. For the ZUMA-7 trial, Yescarta was compared to SOC in 359 patients. Results confirmed an improvement in EFS (8.3 months vs 2 months), PFS (14.7 months vs 3.7 months), and OS (NR vs 35.1 months)[5]. In the BELINDA trial, Kymriah was compared to SOC enrolling 322 patients. The EFS was similar at 3 months. CR and partial response (PR) rates showed a slight advantage (75% vs 68%)[3]. It is important to note that patients on these three key studies had short remissions, with relapse within 12 months, or refractory disease indicative of chemo-resistance. Shadman et al published a recent retrospective review of the CIBMTR database comparing SOC vs CAR-T therapy in 410 patients. In short, when looking at a broader population of DLBCL patients, those with chemosensitive disease had similar PFS (52% vs 42%) with a lower rate of relapse (40% vs 55%) and improved 2 year OS (69% vs 47%) when receiving CAR-T6. Recently, CAR-T therapy was approved in the second line for DLBCL that is refractory or relapsed within 1 year from initial treatment[7]. Standard salvage chemotherapy followed by autoSCT remains a reliable approach to relapsed DLBCL patients. Having both options available at the Georgia Cancer Center allows us to offer the best treatment on an individualized basis. Additionally, CAR-T currently has FDA approval for relapsed mantle cell lymphoma (MCL), follicular lymphoma (FL), and B-ALL.

Current advances in classic Hodgkin lymphoma (cHL) include the use of targeted therapy including brentuximab and the checkpoint inhibitors, nivolumab and pembrolizumab, prior to autoSCT. We are currently enrolling on the cooperative group study, S1826, which randomizes patients with cHL to either Brentuximab-AVD vs Nivolumab-AVD[8]. The study will likely define front-line therapy for advanced stage cHL. We recently presented data from our Pembrolizumab-ICE salvage protocol at the 2021 ASH Annual Meeting. We found an improvement in CR rates using this regimen at 86.5% compared to <60% in historical controls[9]. The 2yr PFS was 88.2% and OS was 95.1% (Figure 1). As the data matures, we continue to see improvement of outcomes with durable remissions following consolidative autoSCT. The Pembrolizumab-ICE regimen will be used as a comparator arm in an upcoming large cooperative group study for relapsed cHL – stay tuned!

**Figure 1**: Outcomes from PEM+ICE trial for relapsed / refractory classic Hodgkin lymphoma.




For chronic lymphocytic leukemia (CLL/SLL), results from the CAPTIVATE trial were presented at the ASCO Annual Meeting and published in Blood[10]. This phase II study in patients ≤70 years with previously untreated CLL/SLL evaluated the use of ibrutinib for 3 months followed by the combination of ibrutinib plus venetoclax for 12 months. The rate of undetectable measurable residual disease on peripheral blood was 77% with excellent 2 year PFS and OS at 95% and 98%, respectively. The combination is a well-tolerated and effective all-oral, fixed-duration, chemotherapy-free regimen. We participated in the two cooperative group studies (A041702 for patients ≥65 years and EA9161 for patients ≤ 70 years) for front-line CLL/SLL therapies randomizing ibrutinib/obinutuzumab +/- venetoclax. Both studies have completed accrual and we await final analysis. The landscape of CLL/SLL continues to evolve to well-tolerated oral agents and improved quality of life using fixed-duration treatment for our patients.

The primary results for an emerging agent, epcoritamab, were presented at the EHA2022 conference. Epcoritamab is a novel subcutaneous CD3/CD20 bispecific antibody that has shown potent activity across several B-cell lymphoma subtypes[11]. The phase 2 results of monotherapy in relapsed/refractory DLBCL showed 63% ORR including 39% with CR in patients with a median of 3 (range, 2-11) prior lines of therapy. Patients had high-risk disease including double/triple-hit lymphoma, histologic transformation, and patients previously treated with CAR-T cell therapy. We are currently pursuing trials using epcoritamab in combination with several chemotherapy options for DLBCL, FL, and MCL including both untreated and relapsed/refractory disease. We anticipate these trials opening at the Georgia Cancer Center in late 2022.

We have a robust clinical trial portfolio to provide options to patients even with rare lymphoma subtypes. We participated in phase 1 trials for nanatinostat (recently given orphan drug approval for EBV+ lymphomas) and loncatuzumab (now approved for relapsed DLBCL). The loncatuzumab protocol has expansion cohorts with available slots for both DLBCL and follicular lymphoma[12]. We saw clinical responses with magrolimab, a novel CD47 mAb, in the phase I/II study and await plans to incorporate this agent in combination with standard regimens. A currently available phase 1 trial offering treatment for a broad range of hematologic malignancies is BP-1002-101[13]. This novel liposomally encapsulated BCL-2 oligonucleotide provides a novel approach to inhibit BCL-2 and is expected to have a minimal toxicity profile. To date, there are only 2 patients worldwide that have received BP1002 and both are here at the Georgia Cancer Center.

We welcome referrals for discussion and guidance with these uncommon cancers. Please reach out with any questions.

Sincerely,

Locke J. Bryan, MD
Associate Professor of Medicine; Medical College of Georgia
Fellowship Program Director – Hematology/Oncology
Blood and Marrow Transplantation and Cellular Therapies

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# Featured Clinical Trials

## LYMPHOMA

**S1826: 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 (NCT03907488)**

Description: This phase III trial compares immunotherapy drugs (nivolumab or brentuximab vedotin) when given with combination chemotherapy in treating patients with newly diagnosed Stage III/IV classic Hodgkin lymphoma. The combination with the checkpoint inhibitor Nivolumab is an exciting concept. We expect this protocol will likely define the standard of care for initial treatment of classic Hodgkin lymphoma.

Principal Investigator – Dr. Locke J. Bryan
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**BP1002-101-Lymph: 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 (NCT04072458)**

Description: This study evaluates the safety, pharmacokinetics, and efficacy of BP1002 (L-Bcl-2) antisense oligonucleotide in patients with advanced lymphoid malignancies. Enrollment covers a broad range of lymphoma subtypes. The novel agent is a promising therapy targeting a common pathway, BCL-2, in hematologic malignancies. Preclinical studies for the drug delivery compound has shown a very low toxicity profile.

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**EA4151: Rituximab with or without Stem Cell Transplant in Treating Patients with Minimal Residual Disease-Negative Mantle Cell Lymphoma in First Complete Remission (NCT03267433)**

Description: This randomized phase III trial studies the utility of CloneSeq to assess MRD status in patients with mantle cell lymphoma following induction chemotherapy. CloneSeq is a blood test to detect circulating tumor DNA. The trial is intended for patients eligible for a consolidative autologous stem cell transplant. Patients that are MRD negative are randomized to transplant with rituximab maintenance vs rituximab maintenance alone. All treatment except the autologous stem cell transplant can be performed locally in collaboration with the referring physician.

Principal Investigator – Dr. Locke J. Bryan
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**S1918: 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, Transformed Lymphoma, and High-grade B-cell Lymphomas with MYC and BCL2 and/or BCL6 Rearrangements (NCT04799275)**

Description: This phase II/III trial compares the side effects and activity of oral azacitidine in combination with R-miniCHOP versus R-miniCHOP alone in treating patients 75 years or older with newly diagnosed aggressive B cell non-Hodgkin lymphoma. The goal is to improve outcomes in older patients that are unfit for intense induction chemotherapy while avoiding excessive toxicity.

Principal Investigator – Dr. Locke J. Bryan
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**ADCT-402-103: 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 (NCT03684694)**

Description: This Phase ½ study is to evaluate the safety and efficacy of Loncastuximab Tesirine (ADCT-402) in combination with Ibrutinib in participants with Diffuse Large B-Cell Lymphoma or Mantle Cell Lymphoma. The trial has completed the toxicity assessment with encouraging antitumor activity and a manageable toxicity profile. There are current expansion cohorts to further evaluate improvement in treatment outcomes.

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# Open Trials by Tumor Type

## Solid Tumors

### BREAST CANCER

**The COMPASSHER2 Trials (COMprehensive Use of Pathologic Response ASSessment to Optimize Therapy in HER2-Positive Breast Cancer): COMPASSHER2 Residual Disease (RD), A Double-Blinded, Phase III Randomized Trial of T-DM1 and Placebo Compared with T-DM1 and Tucatinib**

*Protocol ID: A011801 – ClinicalTrials.gov # – NCT04457596*
Principal Investigator – Dr. Sharad Ghamande
Clinical Research Coordinator – Kelly Adams (803) 292-6885 or keadams@augusta.edu

**Phase ½ 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.gov # – NCT04246671*
Principal Investigator – Dr. Priyanka Raval
Clinical Research Coordinator – Ashlyn Stevenson (706) 721-0660 or asstevenson@augusta.edu

### GYNECOLOGICAL 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 – Ovarian Cancer**
Principal Investigator – Dr. Sharad Ghamande
Clinical Research Coordinator – Sara Mobley (706) 721-4394 or smobley@augusta.edu

**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*
**Disease Site – Advanced Solid Tumors**
Principal Investigator – Dr. Sharad Ghamande
Clinical Research Coordinator – Ashlyn Stevenson (706) 721-0660 or asstevenson@augusta.edu

**A Multicenter, Open-Label Phase ½ 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*
**Disease Site – Endometrial, Ovarian, or Peritoneal Cancers**
Principal Investigator – Dr. Sharad Ghamande
Clinical Research Coordinator – Sara Mobley (706) 721-4394 or smobley@augusta.edu

**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*
**Disease Site – Ovarian Cancer**
Principal Investigator – Dr. Sharad Ghamande
Clinical Research Coordinator – Sara Mobley (706) 721-4394 or smobley@augusta.edu

**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*
**Disease Site – Cervical Cancer**
Principal Investigator – Dr. Sharad Ghamande
Clinical Research Coordinator – Katie Dorr (706) 721-3460 or kdoor@augusta.edu

**A Randomized Phase II Trial of Radiation Therapy and Cisplatin Alone or in Combination with Intravenous Triapine in Women with Newly Diagnosed Bulky Stage IB2, Stage II, IIIB, or IVA Cancer of the Uterine Cervix or Stage II-IVA Vaginal Cancer**

Protocol ID: NRG-GY006 – ClinicalTrials.gov # – NCT02466971
**Disease Site – Uterine, Cerivcal, Vaginal Cancers**
Principal Investigator – Dr. Sharad Ghamande
Clinical Research Coordinator – Sara Mobley (706) 721-4394 or smobley@augusta.edu

### 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*
**Disease Site – Cervical Cancer**
Principal Investigator – Dr. Sharad Ghamande
Clinical Research Coordinator – Katie Dorr (706) 721-3460 or kdoor@augusta.edu

### 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**
Principal Investigator – Dr. Sharad Ghamande
Clinical Research Coordinator –Amanda Spires (706) 721-8981 or amspires@augusta.edu

**NRG-GY019:** A Randomized Phase III, Two-Arm Trial of Paclitaxel/Carboplatin/Maintenance Letrozole Versus Letrozole Monotherapy in Patients with Stage II-IV, Primary Low-Grade Serous Carcinoma of the ovary or Peritoneum
Clinical Research Coordinator – Gwen Stanley (706) 721-3473 or gstanley@augusta.edu

**GOG 3024:** A Phase 2 Open-Label Trial of Tisotumab Vedotin (HuMax®-TF-ADC) alone or in Combination in First Line Recurrent or Stage IVB Cervical Cancer
Clinical Research Coordinator – Melissa Berry (706) 721-4880 or melberry@augusta.edu

**MER-XMT-1536- Mersana: GOG 3048:** "A Phase 1b, First-in-Human, Dose Escalation and Expansion Study of XMT-1536 In Patients with Solid Tumors Likely to Express NaPi2b"
Clinical Research Coordinator – Katie Dorr – (706) 721-3460 or kdorr@augusta.edu

## 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*
**Disease Site – Gliomas**
Principal Investigator – Dr. John Henson
Clinical Research Coordinator – Ashlyn Stevenson (706) 721-0660 or asstevenson@augusta.edu

## THORACIC ONCOLOGY

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

Protocol ID: S1933
**Disease Site – Non-Small Cell Lung Cancer**
Principal Investigator – Dr. Sharad Ghamande
Clinical Research Coordinator – Kelly Jenkins (706) 721-1206 or kejenkins@augusta.edu

### 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*
**Disease Site – Non-Small Cell Lung Cancer**
Principal Investigator – Dr. Sharad Ghamande
Clinical Research Coordinator – Kelly Jenkins (706) 721-1206 or kejenkins@augusta.edu

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

*Protocol ID: S1914 – ClinicalTrials.gov # – NCT04214262*
**Disease Site – Non-Small Cell Lung Cancer**
Principal Investigator – Dr. Sharad Ghamande
Clinical Research Coordinator – Kelly Jenkins (706) 721-1206 or kejenkins@augusta.edu

### 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 (18-MAY-2018)

*Protocol ID: NRG-LU002 – ClinicalTrials.gov# – NCT03137771*
**Disease Site – Non-Small Cell Lung Cancer**
Principal Investigator – Dr. Sharad Ghamande
Clinical Research Coordinator – Kelly Jenkins (706) 721-1206 or kejenkins@augusta.edu

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

*Protocol ID: LUNGMAP – ClinicalTrials.gov# – NCT03851445*
**Disease Site – Non-Small Cell Lung Cancer**
Principal Investigator – Dr. Sharad Ghamande
Clinical Research Coordinator – Kelly Jenkins (706) 721-1206 or kejenkins@augusta.edu

### 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 ID: EA5163 – ClinicalTrials.gov# – NCT03793179*
Disease Site – Non-Small Cell Lung Cancer
Principal Investigator – Dr. Sharad Ghamande
Clinical Research Coordinator – Kelly Jenkins (706) 721-1206 or kejenkins@augusta.edu

### Phase II Randomized Study of Maintenance Atezolizumab Versus Atezolizumab in Combination with Talazoparib in Patients with SLFN11 Positive Extensive Stage Small Cell Lung Cancer (ES-SCLC)

*Protocol ID: S1929 – ClinicalTrials.gov# – NCT04334941*
**Disease Site – Extensive Stage Small Cell Lung Cancer**
Principal Investigator – Dr. Sharad Ghamande
Clinical Research Coordinator – Kelly Jenkins (706) 721-1206 or kejenkins@augusta.edu

### MRI Brain Surveillance Alone Versus MRI Surveillance and Prophylactic Cranial Irradiation (PCI): A Randomized Phase III Trial in Small-Cell Lung Cancer (MAVERICK)

*Protocol ID: S1827 – ClinicalTrials.gov# – NCT04155034*
**Disease Site –Small Cell Lung Cancer**
Principal Investigator – Dr. Sharad Ghamande
Clinical Research Coordinator – Kelly Jenkins (706) 721-1206 or kejenkins@augusta.edu

### 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*
**Disease Site – Non-Small Cell Lung Cancer**
Principal Investigator – Dr. Giri Raval
Clinical Research Coordinator – Kelly Jenkins (706) 721-1206 or kejenkins@augusta.edu


# Hematologic Malignancies

## ACUTE LYMPHOBLASTIC LEUKEMIA

**A Phase III Trial to Evaluate the Efficacy of the Addition of Inotuzumab Ozogamicin (a Conjugated Anti-CD22 Monoclonal Antibody) to Frontline Therapy in Young Adults (Ages 18-39 Years) with Newly Diagnosed Precursor B-Cell ALL**

*Protocol ID: A041501 – ClinicalTrials.gov # – NCT04049669*
Principal Investigator – Dr. Vamsi Kota
Clinical Research Coordinator – Patricia Loveday (706) 721-5095 or ploveday@augusta.edu

**A Phase III Randomized Trial of Steroids +Tyrosine Kinase Inhibitor Induction with Chemotherapy or Blinatumomab for Newly Diagnosed BCR-ABL-positive Acute Lymphoblastic Leukemia in Adults**

*Protocol ID: EA9181 – ClinicalTrials.gov # – NCT04530565*
Principal Investigator – Dr. Vamsi Kota
Clinical Research Coordinator – Patricia Loveday (706) 721-5095 or ploveday@augusta.edu

## CHRONIC LYMPHOBLASTIC 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 (CLL)**

*Protocol ID: A041702 – ClinicalTrials.gov # – NCT03737981*
Principal Investigator – Dr. Locke Bryan
Clinical Research Coordinator – Savannah Crews – (706) 729-2459 or sacrews@augusta.edu

## DIFFUSE LARGE B-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*
Principal Investigator – Dr. Locke Bryan
Clinical Research Coordinator – Savannah Crews – (706) 729-2459 or sacrews@augusta.edu

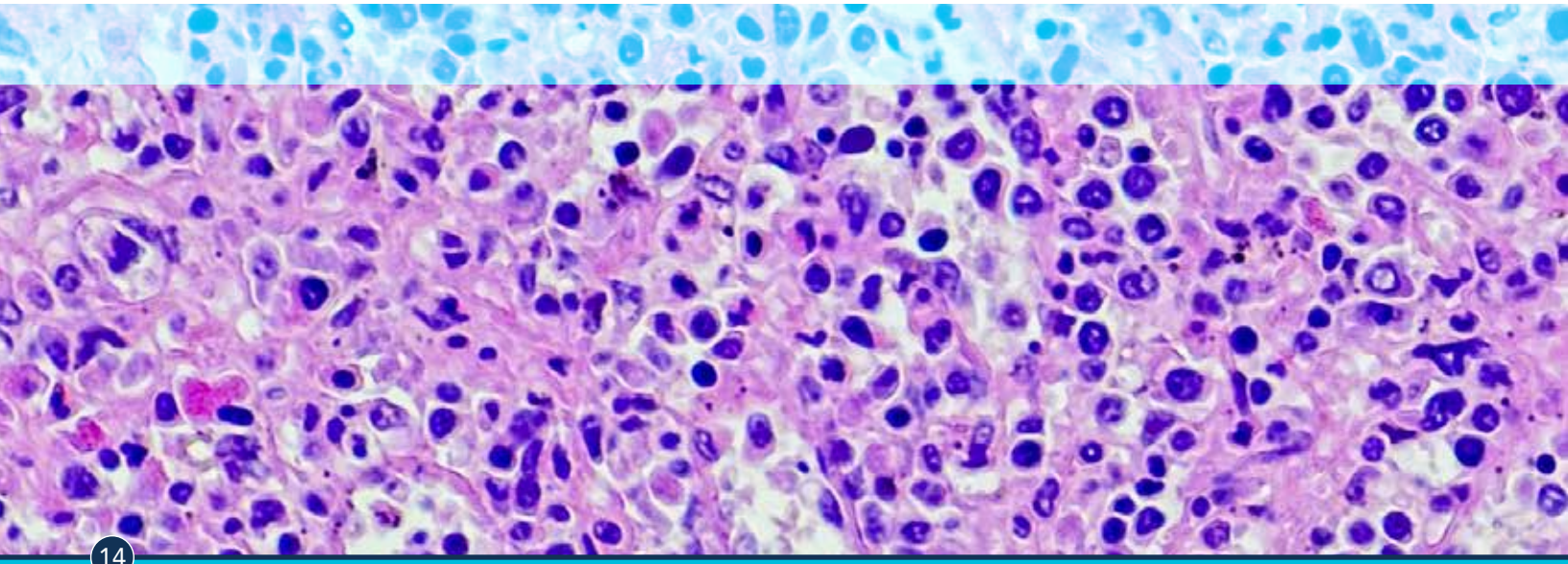
**A Phase II/III Randomized Study of R-miniCHOP with or without Oral Azacitidine (CC-486) in Participants Age 75 Years or Older With Newly Diagnosed Diffuse Large B Cell Lymphoma, Grade IIIb Follicular Lymphoma, Transformed Lymphoma, and High-grade B-cell Lymphomas With MYC and BCL2 and/or BCL6 Rearrangements**

*Protocol ID: S1918 – ClinicalTrials.gov # – NCT04799275*
Principal Investigator – Dr. Locke Bryan
Clinical Research Coordinator – Savannah Crews – (706) 729-2459 or sacrews@augusta.edu

## GRAFT VERSUS HOST DISEASE

**GRAVITAS-309: A Phase $^{2}/_{3}$ Study of Itacitinib and Corticosteroids as Initial Treatment for Chronic Graft-Versus-Host Disease**

*Protocol ID: INCB-39110-309 – ClinicalTrials.gov # – NCT03584516*
Principal Investigator – Dr. Vamsi Kota
Clinical Research Coordinator – Sarah Leathers – (706) 721-1556 or sleathers@augusta.edu



## MYELOFIBROSIS

**Actuate 1901: Phase 2 Study of 9-ING-41, a Glycogen Synthase Kinase-3 Beta (GSK-3B) Inhibitor, as a Single Agent or Combined with Ruxolitinib, in Patients with Myelofibrosis**

*Protocol ID: Actuate 1901 – ClinicalTrials.gov # – NCT04218071*
Principal Investigator – Dr. Jorge Cortes
Clinical Research Coordinator – Thalyta DeMedeiros – (706) 721-6487 or tdemedeiros@augusta.edu

**M16-191: A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study of Navitoclax in Combination with Ruxolitinib Versus Ruxolitinib in Subjects with Myelofibrosis (TRANSFORM-1)**

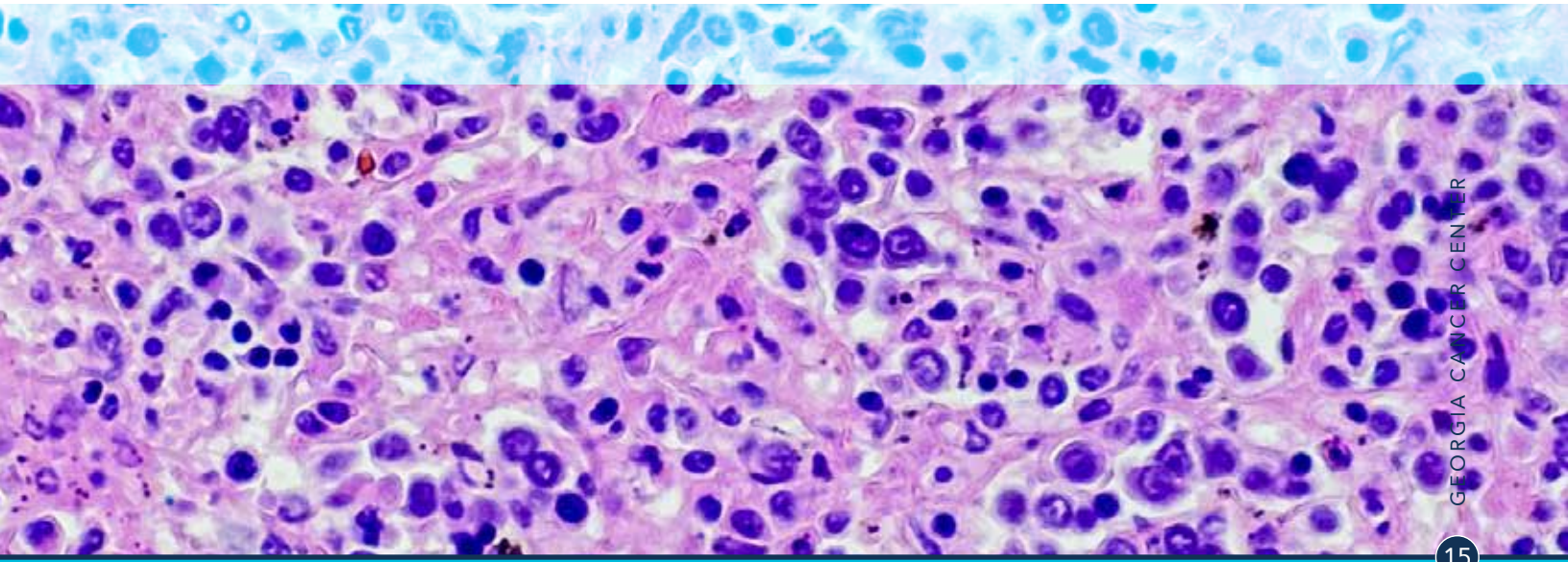
*Protocol ID: M16-191 – ClinicalTrials.gov # – NCT04472598*
Principal Investigator – Dr. Jorge Cortes
Clinical Research Coordinator – Thalyta DeMedeiros – (706) 721-6487 or tdemedeiros@augusta.edu

**M20-178: 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 # – NCT044468984*
Principal Investigator – Dr. Jorge Cortes
Clinical Research Coordinator – Thalyta DeMedeiros – (706) 721-6487 or tdemedeiros@augusta.edu

**STML-401-0314: Tagraxofusp (SL-401) in Patients with Chronic Myelomonocytic Leukemia (CMML) or Myelofibrosis (MF)**

*Protocol ID: STML-401-0314 – ClinicalTrials.gov # – NCT02268253*
Principal Investigator – Dr. Jorge Cortes
Clinical Research Coordinator – Thalyta DeMedeiros – (706) 721-6487 or tdemedeiros@augusta.edu



## ACUTE MYELOID LEUKEMIA

**A Phase IIa, Open-label, Clinical Trial to Evaluate the Safety, Pharmacokinetics, Pharmacodynamics, and Efficacy of BP1001 (a Liposomal Grb2 Antisense Oligonucleotide) in Combination with Venetoclax plus Decitabine in Patients with Acute Myeloid Leukemia (AML) or High Risk Myelodysplastic Syndrome (MDS) Who Are Ineligible for Intensive Induction Therapy**

*Protocol ID: BP1001-201-AML – ClinicalTrials.gov # – NCT02781883*
Principal Investigator – Dr. Vamsi Kota
Clinical Research Coordinator – Patricia Loveday – (706) 721-5095 or ploveday@augusta.edu

**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*
Principal Investigator – Dr. Jorge Cortes
Clinical Research Coordinator – Thalyta DeMedeiros – (706) 721-6487 or tdemedeiros@augusta.edu

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

*Protocol ID: PrE0905 – ClinicalTrials.gov # – NCT03836209*
Principal Investigator – Dr. Vamsi Kota
Clinical Research Coordinator – Patricia Loveday – (706) 721-5095 or ploveday@augusta.edu

**A Randomized, Open-Label Study of the Efficacy and Safety of Galinpepimut-S (GPS) Maintenance Monotherapy Compared to Investigator's Choice of Best Available Therapy in Subjects with Acute Myeloid Leukemia Who Have Achieved Complete Remission After Second-Line Salvage Therapy**

*Protocol ID: SLSG18-301 – ClinicalTrials.gov # – NCT04229979*
Principal Investigator – Dr. Jorge Cortes
Clinical Research Coordinator – Thalyta DeMedeiros – (706) 721-6487 or tdemedeiros@augusta.edu

**A Phase 1 Study of Safety, Pharmacokinetics and Preliminary Activity of TAS1553 in Subjects with Relapsed or Refractory (R/R) Acute Myeloid Leukemia (AML) and Other Myeloid Neoplasms**

*Protocol ID: TAS1553-01 – ClinicalTrials.gov # – NCT4637009*
Principal Investigator – Dr. Jorge Cortes
Clinical Research Coordinator – Thalyta DeMedeiros – (706) 721-6487 or tdemedeiros@augusta.edu

## CHRONIC MYELOID 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*
Principal Investigator – Dr. Jorge Cortes
Clinical Research Coordinator – Thalyta DeMedeiros – (706) 721-6487 or tdemedeiros@augusta.edu

**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*
Principal Investigator – Dr. Jorge Cortes
Clinical Research Coordinator – Thalyta DeMedeiros – (706) 721-6487 or tdemedeiros@augusta.edu

# Phase 1

## MYELODYSPLASTIC SYNDROMES

**FGCL-4592-082: A Phase 3 Randomized Double-Blind Placebo-Controlled Study Investigating the Efficacy and Safety of Roxadustat (FG-4592) for Treatment of Anemia in Patients with Lower Risk Myelodysplastic Syndrome (MDS) with Low Red Blood Cell (RBC) Transfusion Burden (LTB)**

*Protocol ID: FGCL-4592-082 – ClinicalTrials.gov # – NCT03263091*
Principal Investigator – Dr. Jorge Cortes
Clinical Research Coordinator – Thalyta DeMedeiros – (706) 721-6487 or tdemedeiros@augusta.edu

## 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*
**Disease Site – Glioblastoma, Medulloblastoma, Ependymoma, Diffuse Intrinsic Pontine Glioma**
Principal Investigator – Dr. Theodore (Ted) Johnson
Clinical Research Coordinator – Taylor King – (706) 721-2949 or tayking@augusta.edu

**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*
**Disease Site – Neuroblastoma**
Principal Investigator – Dr. Colleen McDonough
Clinical Research Coordinator – Kimberly Gray – (706) 721-1870 or kigray@augusta.edu

**NMTT – Neuroblastoma Maintenance Therapy Trial using Difluoromethylornithine (DFMO)**

*Protocol ID: NMTRC014 – ClinicalTrials.gov # – NCT02679144*
**Disease Site – Neuroblastoma**
Principal Investigator – Dr. Colleen McDonough
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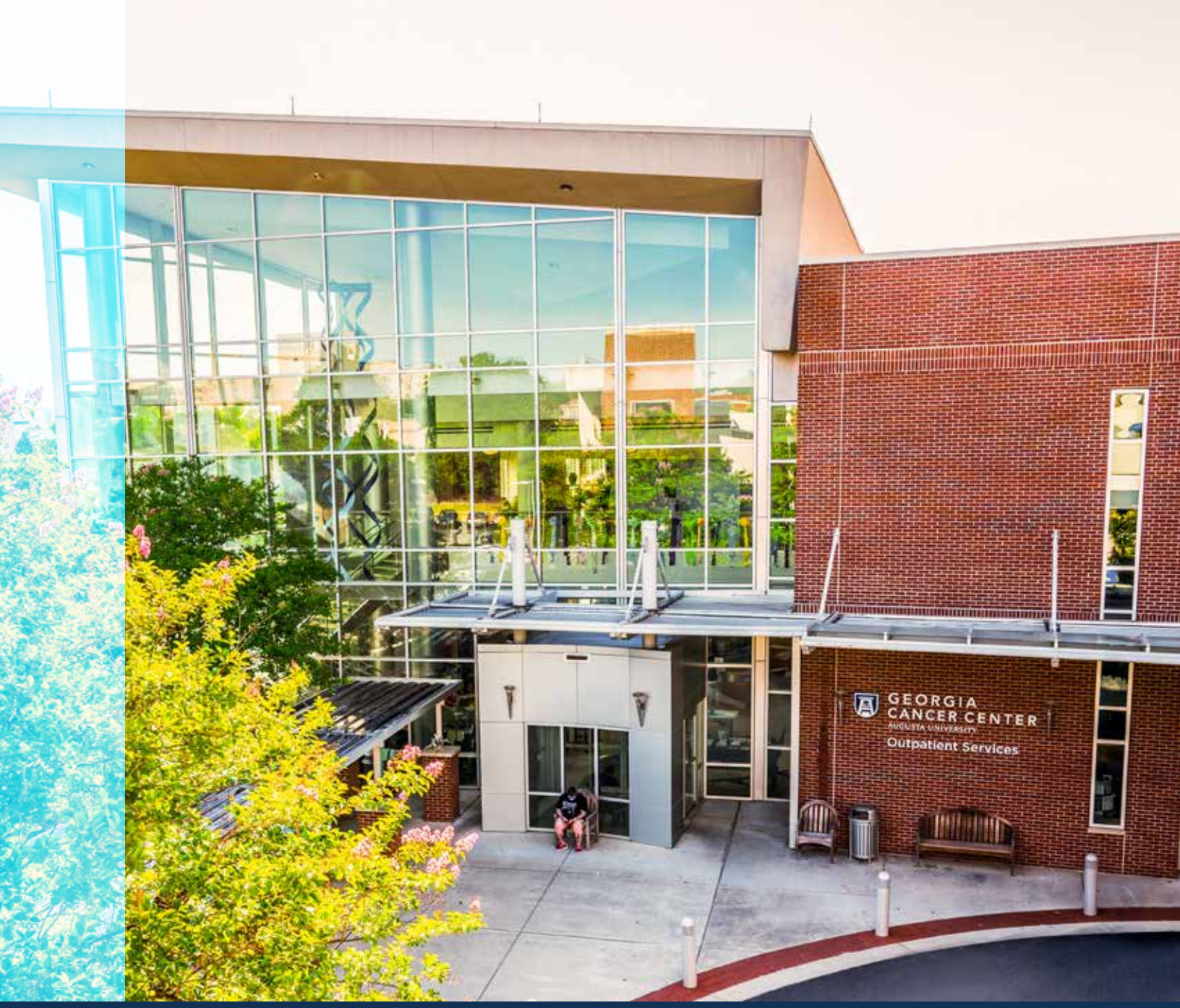


GEORGIA CANCER CENTER
AUGUSTA UNIVERSITY

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