CHARLESTON
ONCOLOGY

COMPASSIONATE CARE FOR CANCER
AND BLOOD DISORDERS

Clinical Trial Open Enrollment Master List

Clinical Research Department

REVISED: 19NOV2021 AM

CHARLESTON ONCOLOGY
CLINICAL TRIALS AT A GLANCE

BREAST: (6)

1) Up to 3 lines of post-adjuvant or neoadjuvant therapy for TNBC/AYALA: AL-TNBC-01: A Phase 2, Multicenter, Open-label study of AL101 Monotherapy in Patients with Notch Activated Recurrent or Metastatic Triple Negative Breast Cancer

2) First line for locally advanced/ metastatic ER+ HER2 Neg/ BO41843: A Phase III Randomized, Double-Blind, Placebo-Controlled, Multicenter Study Evaluating the Efficacy and Safety of GD9545 Combined with Palbociclib Compared with Letrozole Combined with Palbociclib in Patients with ER+, HER2 Neg Locally Advanced or Metastatic Breast Cancer

3) First and Second line of therapy (dependent upon monotherapy or combination therapy/Zeno 001: A Phase 1/2 Open Label, Multicenter Study to Assess the Safety, Tolerability, Pharmacokinetics, and Anti-Tumor Activity of ZN-c5 Alone and in Combination with Palbociclib in Subjects with Estrogen-Receptor Positive, Human Epidermal Growth Factor Receptor-2 Negative Advanced Breast Cancer.

4) First line advanced/metastatic ER+ HER2 Neg ZENO 003 (ON HOLD): A Phase 1B Study of ZN-c5 in Combination with Abemaciclib in Patients with Estrogen-Receptor Positive, Human Epidermal Growth Factor Receptor-2 Negative Advanced Breast Cancer

5) WO42633: A Phase 3, Randomized, Double Blind, Placebo Controlled Clinical Trail To Evaluate The Efficacy And Safety Of Adjuvant Atezolizumab OR Placebo And Trastuzumab Emtansine For HER2-Postive Breast Cancer At High Risk Of Recurrence Following Preoperative Therapy.

6) eMonoarch I3Y-MC-JPCW USO#20364: A Randomized, Double Blind, Placebo-Controlled Phase 3 Study of Abemaciclib plus Standard Adjuvant Endocrine Therapy in patients with High-Risk, Node-Positive, HR+, HER2+ Early Breast Cancer Who Have Completed Adjuvant HER2 Targeted Therapy

CENTRAL VENOUS ACCESS DEVICES: (1)

1) Supportive Care for Dysfunctional CVADs/ READY 1 CUSA-081-HEM-01: A Phase 3, Randomized, Double-Blind, Active and Placebo-Controlled Study on the use of CUSA-081 for Dysfunctional Central Venous Access Devices (CVADs)

CHRONIC LYMPHOCYTIC LEU Lymphocytic Leukemia: (1)

1) **ULTRA-V U2-VEN-207:** Phase 2/3 Randomized Study to Assess the Efficacy and Safety of Ublituximab in Combination with Umbralisib and Venetoclax (U2-V) Compared to Ublituximab and Umbralisib (U2) in Subjects with Chronic Lymphocytic Leukemia (CLL)

BASAL CELL CARCINOMA: (1- Observational)

1) Metastatic or Locally Advanced and not candidates for curative surgery or curative radiation/ R2810-ONC-1806: CemiplimAb (Libtayo) Survivorship Epidemiology (CASE) Study.

CUTANEOUS SQUAMOUS CELL CARCINOMA: (1- Observational)

1) Metastatic or Locally Advanced and not candidates for curative surgery or curative radiation/ R2810-ONC-1806: CemiplimAb (Libtayo) Survivorship Epidemiology (CASE) Study

CHOLANGIOCARCINOMA: (1)

1) First Line Metastatic/ QBGJ398-301: A Phase 3 Multicenter, Open-Label, Randomized, Controlled Study of Oral Infigratinib versus Gemcitabine with Cisplatin in Subjects with Advanced/Metastatic or Inoperable Cholangiocarcinoma with FGFR2 Gene Fusions/Translocations: The PROOF Trial

COLORECTAL: (1)

1) Phase 1B single agent cohort part of Mirati 849-001/USO 19151: Cohort F - A Phase 1/2 Multiple Expansion Cohort Trial of MRTX849 in Patients with Advanced Solid Tumors with KRAS G12C Mutation CRC with KRAS G12C mutation - **21** SLOTS AVAILABLE! USOR will NOT participate in the cohort sub-studies nor the fed state (food effect) cohort.

DIFFUSE LARGE B-CELL LYMPHOMA: (4)

1) 2ND line or greater/ SGN35-031: A Randomized, Double-blind, Placebo-Controlled, Active-Comparator, Multicenter, Phase 3 Study of Brentuximab Vedotin or Placebo in Combination with Lenalidomide and Rituximab in Subjects with Relapsed or Refractory Diffuse Large B-cell Lymphoma (DLBCL)

2) CTMX-M-2029-001 (CytomX) A Phase 1-2, First-in-Human Study of CX-2029 in Adults with Metastatic or Locally Advanced Unresectable Solid Tumors or Diffuse Large B-cell Lymphomas.

3) MOR208C310 frontMIND: A Phase 3, multicenter, randomized, double-blind, placebo-controlled trial comparing the efficacy and safety of Tafasitamab plus lenalidomide in addition to R-CHOP versus R-CHOP in previously untreated, high-intermediate, and high-risk patients with newly diagnosed diffuse large B-cell lymphoma (DLBCL)

4)NDS-DLBCL-003 Connect® Lymphoma Disease Registry: A US-Based Prospective Observational Cohort Study: The Connect® Lymphoma Disease Registry is a US-based, multicenter, prospective observational (non-interventional) cohort study designed to collect real-world, patient-level data longitudinally in patients diagnosed with various subtypes of NHL. The study will consist of **4 cohorts**, as described in detail below: **1)** patients with first R/R DLBCL who have initiated second-line **(2L)** systemic treatment; **2)** patients with second R/R DLBCL who have initiated third line (**3L**) systemic treatment; **3)** patients with first R/R FL who have initiated 2L systemic treatment; and 4) patients with first R/R PMBCL who have initiated 2L systemic treatment.

FOLLICULAR LYMPHOMA Grade 1 to 3a or R/R Marginal Zone Lymphoma (2)

1) INCMOR 0208-301 inMIND: A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Tafasitamab Plus Lenalidomide in Addition to Rituximab Versus Lenalidomide in Addition to Rituximab in Patients With Relapsed/Refractory (R/R) Follicular Lymphoma Grade 1 to 3a or R/R Marginal Zone Lymphoma.

2) NDS-DLBCL-003 Connect® Lymphoma Disease Registry: A US-Based Prospective Observational Cohort Study: The Connect® Lymphoma Disease Registry is a US-based, multicenter, prospective observational (non-interventional) cohort study designed to collect real-world, patient-level data longitudinally in patients diagnosed with various subtypes of NHL. The study will consist of **4 cohorts**, as described in detail below: **1)** patients with first R/R DLBCL who have initiated second-line **(2L)** systemic treatment; **2)** patients with second R/R DLBCL who have initiated third line (**3L**) systemic treatment; **3)** patients with first R/R FL who have initiated 2L systemic treatment; and 4) patients with first R/R PMBCL who have initiated 2L systemic treatment.

HEAD AND NECK: (1)

1) **MNPR-301-001/Monopar:** A Phase 2b/3, multicenter, randomized, double-blind, placebo-controlled study comparing the efficacy and safety of clonidine mucoadhesive buccal tablet to placebo to prevent chemoradiotherapy-induced severe oral mucositis in patients with oropharyngeal cancer.

HEPATOCELLULAR CARCINOMA: (1)

1)MK-1308A-004: Phase 2, Multicenter, Clinical Study to Evaluate the Safety and Efficacy of MK-1308A (Coformulated MK-1308/MK-3475) in Combination with Lenvatinib (E7080/MK-7902) in First-line Therapy of Participants with Advanced Hepatocellular Carcinoma

LUNG CANCER* OBSERVATIONAL*: (1)

***SMALL CELL LUNG CANCER**

1) JAZZ/ EMERGE 402: Phase IV Observational Study to Collect Safety and Outcome Data in Real-World Setting in Adult Patients with Extensive Stage Small Cell Lung Cancer (SCLC) Receiving Zepzelca.

LUNG CANCER: (5)

***NON-SMALL CELL LUNG CANCER**

1) Neoadjuvant Setting for Resectable patients Stage IIA to select Stage IIIB/ USO#19211 AEGEAN: A Phase III, Double-blind, Placebo-controlled, Multi-center International Study of Neoadjuvant/Adjuvant Durvalumab for the Treatment of Patients with Resectable Stages II and III Non-small Cell Lung Cancer

2) Untreated Locally Advanced (Stage 3A, 3B, or 3C) Amendable to CCRT/ BMS CA209-73L: 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)

3) USO#19151 MRTX891-0001: A Phase ½ Multiple Expansion Cohort Trial of MRTX849 in Patients with Advanced Solid Tumors with **KRAS G12C Mutation**- Multiple cohorts

4) USO #19118 CARMEN-LC03 Randomized, Open Label Phase 3 study of SAR408701 versus Docetaxel in Previously Treated metastatic non-squamous Non-Small Cell Lung Cancer patients with CEACAM5 positive tumors

5) RMC-4630-03- A Phase 2, Open-Label, Mulitcenter Study of the Combination of RMC-4630 and Sotorasib for Non-Small Cell Lung Cancer Subjects with KRAS(G12C) Mutation After Failure of Prior Standard Therapies. Evaluate the antitumor effects of RMC-4630 and Sotorasib as assessed by objective response rate per RECIST v1.1 in locally advanced or metastatic NSCLC subjects with KRASG12C mutation with and without co-existing genetic aberrations in specific genes such as STK11/LKB1, KEAP1, and PIK3CA after failure of prior standard therapy. **(No more than 3 prior lines of therapy)**

Multiple Myeloma: (1-Observational)

1)Relapsed/Refractory MM/ IONA: A prospective, non-interventional, multinational, observational study with Isatuximab in patients with relapsed and/or refractory multiple myeloma (RRMM)

MDS: (2)

1)First Line/ ASTX727-03: **Phase 2 is open** (Two Arms)A Randomized, Open-Label, phase 1-2 Study of ASTX727 Low Dose (ASTX727) Extended Schedule in Subjects with Lower Risk Myelodysplastic Syndrome (MDS)

2) FGCL-4592-082/FibroGen: 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).

PROSTATE CANCER: (2)

1) First Line Metastatic mCRPC: USO #19191: BMS CA209-7DX: A Phase 3 Randomized, Double-Blind Study of Nivolumab or Placebo in Combination with Docetaxel, in Men with Metastatic Castration-resistant Prostate Cancer (Check-Mate 7DX: CHECKpoint pathway and nivoluMAB clinical Trial Evaluation 7DX)

2) Cohort 21 and 23 part of XL184-021 EXELIXIS: A Phase Ib Dose-Escalation Study of Cabozantinib (XL184) Administered Alone or in Combination with Atezolizumab to Subjects with Locally Advanced or Metastatic Solid Tumors (More information under Prostate Cancer/Solid Tumors Section)

SOLID TUMORS: (2)

1) CTMX-M-2029-001 (CytomX) A Phase 1-2, First-in-Human Study of CX-2029 in Adults with Metastatic or Locally Advanced Unresectable Solid Tumors or Diffuse Large B-cell Lymphomas

2) USO#19151 MRTX891-0001: A Phase ½ Multiple Expansion Cohort Trial of MRTX849 in Patients with Advanced Solid Tumors with **KRAS G12C Mutation**- Multiple cohorts

CHOLANGIOCARCINOMA:

<table>
<tr><td colspan="2">QBGJ398-301: A Phase 3 Multicenter, Open-Label, Randomized, Controlled Study of Oral Infigratinib versus Gemcitabine with Cisplatin in Subjects with Advanced/Metastatic or Inoperable Cholangiocarcinoma with FGFR2 Gene Fusions/Translocations: The PROOF Trial</td></tr>
<tr><td>Sponsor: QED Therapeutics

Foundation One for Tissue Blocks (14+ day TAT) or Mayo Clinic – 10 slides (7+ day TAT)

Prescreening Tissue Consent Now Available
Site receives report of results

Liquid Biopsy not accepted</td><td>Therapy Line: 1st Line Metastatic
Drug Classification: Selective pan-FGFR kinase inhibitor

**Cisplatin and Gemzar SOC –
Not provided by Sponsor**

Randomization is 2 - Infigratinib: 1 - Gemzar/Cisplatin)</td></tr>
<tr><td>Principal Investigator: James M. Orcutt, MD</td><td>CRC: Ashley Morrill ext. 291</td></tr>
<tr><td colspan="2">Location Clinical Trial Offered: West Ashley, Mount Pleasant & North Charleston</td></tr>
<tr><td colspan="2">Basic Enrollment Information Criteria: Have written documentation of local or central laboratory determination of FGFR2 gene fusions/translocations from tumor tissue collected before treatment. Note: All enrolled subjects must have determination of FGFR2 gene fusions/translocations by the central laboratory as confirmation of local laboratory testing, but this central confirmation is not required prior to enrollment in the. Have a representative tumor sample available for central FGFR2 fusion/translocation molecular testing. An archival tumor sample and associated pathology report may be submitted. However, if not available, a newly obtained tumor biopsy may be submitted instead. (ECOG) performance status ≤ 1. Have a life expectancy > 3 months. Subject must be approved by the Sponsor for eligibility. Ophthalmology EXAM is REQUIRED.

Exclusion Criteria: Have received treatment with any systemic anti-cancer therapy for unresectable, recurrent, or metastatic cholangiocarcinoma. Prior neoadjuvant or adjuvant therapy is permitted if documented disease recurrence occurred > 6 months after the last date of neoadjuvant or adjuvant therapy. Have a history of liver transplant. Have received prior or current treatment with a MEK or selective FGFR inhibitor. Have insufficient hepatic and renal function.</td></tr>
</table>

BREAST CANCER (TNBC):

<table>
<tr><td colspan="2">AL-TNBC-01 AYALA: A Phase 2, Multicenter, Open-label Study of AL101 Monotherapy in Patients with Notch Activated Recurrent or Metastatic Triple Negative Breast Cancer</td></tr>
<tr><td>Sponsor: Ayala

Single arm AL101 Monotherapy

Patients may sign prescreening consent to have tissue sent to central lab, Tempus, for NGS testing. This may be performed while patients are on other therapies</td><td>Therapy Line: Three or fewer lines of post-adjuvant or neo-adjuvant therapy

Drug Classification: Gamma secretase-mediated Notch signaling

Patients must have FFPE tissue available; a tumor block or 25 unstained slides from an archived (within 1.5 years) or fresh tumor samples (core or punch needle biopsy) are acceptable</td></tr>
<tr><td>Principal Investigator: David Ellison, MD</td><td>CRC: Ashley Morrill ext. 291</td></tr>
<tr><td colspan="2">Location Clinical Trial Offered: West Ashley, Mt. Pleasant & N. Charleston</td></tr>
<tr><td colspan="2">Inclusion Criteria: Radiographic or clinical disease progression within 6 months. Patients must have NGS results from tumor biopsy that shows Notch GOF+. Patients cannot have more than 3 lines of systemic chemo or immunotherapy for metastatic disease. TNBC subjects must have confirmed diagnosis of inoperable locally advanced or metastatic TNBC defined as ER and progesterone receptor staining <10% and HER2-negative. Non-TNBC subjects must also have confirmed diagnosis of inoperable locally advanced or metastatic hormone receptor positive breast cancer defined as ER and/or progesterone receptor staining ≥10% and HER2-negative.

Exclusion Criteria: An additional malignancy. Exclusions include basal cell carcinoma of the skin or squamous cell carcinoma of the skin. CNS Metastases. Current or recent GI disease or disorders. Peripheral neuropathy ≥ Grade 2 for at least 14 days prior to first dose of investigational product. Developed immune-mediated colitis with immunotherapy unless resolved to G1 or lower and without requirement of steroid treatment for at least 14 days prior to first dose of investigational product. Evidence of uncontrolled, active infection, requiring systemic anti-bacterial, anti-viral or anti-fungal therapy ≤7 days prior to administration of investigational product such as known active infection with hepatitis B, hepatitis C, or human immunodeficiency virus (HIV) at Screening. Unstable or severe uncontrolled medical condition (e.g., unstable cardiac or pulmonary function or uncontrolled diabetes) or any important medical illness or abnormal laboratory finding that would, in the investigator's judgment, increase the risk to the subject associated with his or her participation in the study. Myocardial infarction within 6 months prior to enrollment. Completed palliative radiation therapy < 7 days prior to initiating investigational product. Prior treatment with gamma secretase inhibitors. Subjects treated with a nucleoside analogue within 6 months prior to administration of investigational product.</td></tr>
</table>

BREAST CANCER (HR+ HER2+)

eMonarcHER USO #20364: A Randomized, Double Blind, Placebo-Controlled Phase 3 Study of Abemaciclib plus Standard Adjuvant Endocrine Therapy in patients with High-Risk, Node-Positive, HR+, HER2+ Early Breast Cancer Who Have Completed Adjuvant HER2 Targeted Therapy	
Sponsor: Eli Lilly	Drug Classification: **Kinase Inhibitor**
Principal Investigator: Brian Lingerfelt, MD	**CRC:** Ashley Morrill ext. 291
Location Clinical Trial Offered: West Ashley	

Inclusion Criteria: ECOG of 0 or 1. Have tumor tissue from breast or lymph node for exploratory biomarker analysis available prior to randomization. Confirmed HR+, HER2+ in initial diagnostic tissue, early invasive breast cancer without evidence of disease recurrence of distant metastases, per STEEP criteria. Participants must have high-risk disease as defined by one of the following 2 criteria: a) For participants who were treated with neoadjuvant chemotherapy administered with HER2-targeted therapy; the presence of axillary nodal disease detected pathologically in the surgical specimen; the presence of residual disease in the breast surgical specimen may also be detected pathologically but is not required b.) For participants who were not treated with neoadjuvant therapy**:** Participant's cancer must be axillary node positive (microscopic and macroscopic tumor involvement are allowed; ipsilateral internal mammary and supraclavicular lymph nodes are allowed but will not count toward the number of positive lymph nodes) and fulfill one of the following criteria: i. Pathological tumor involvement in ≥4 ipsilateral axillary lymph nodes OR ii. Pathological tumor involvement in 1 to 3 ipsilateral axillary lymph node(s) and at least 1 of the following criteria: 1. Histological Grade 3 as defined by a combined score per the modified Bloom-Richardson grading system (Elston and Ellis 1991), also known as the Nottingham scale, or equivalent following discussion with the Lilly CRP/CRS 2. primary invasive tumor size ≥5 cm determined pathologically. Must have undergone definitive surgery of the primary breast tumor(s). **Participants must be randomized within 18 months of primary breast cancer surgery.** Participants have completed approximately 9 months to one year of standard HER2-targeted therapy without evidence of disease recurrence. The total duration of HER2 directed therapy may include combination of neoadjuvant and adjuvant treatments. **Participants must be randomized within 12 weeks of completion of standard adjuvant HER2-targeted therapy.** Have received a minimum of 4 cycles of chemotherapy in either the neoadjuvant or adjuvant setting per standard of care therapy. Participants must have discontinued previous treatments for cancer and recovered from the acute effects of therapy (i.e., Grade ≤1), except for residual alopecia or Grade ≤2 peripheral neuropathy.

Exclusion Criteria: Breast cancer with any of the following features: Disease recurrence of distant metastatic disease (including axillary lymph nodes), Lymph node-negative status, Pathological complete response from any prior systemic treatments for early breast cancer, Inflammatory carcinoma, Participants with a history of previous breast cancer, with the exception of ipsilateral DIC treated by local regional therapy alone >5 years ago **(contralateral DCIS treated by local regional therapy at any time may be eligible)** History of VTE (DVT of the leg or arm and/or PE). **Previously received treatment with any CDK4 and 6 inhibitors. Received adjuvant prior treatment with immunotherapy, tucatinib, neratinib, investigational HER2 directed therapy, or DS8201 for treatment of breast cancer (Prior exposure with these agents during neoadjuvant treatment is allowed) Previously received ET (tamoxifen, raloxifene or AI) for breast cancer prevention.** Significant clinical cardiac abnormalities.

BREAST CANCER (ER+ HER2 Neg):

<table>
<tr><td colspan="2">ZENO 001: A Phase 1/2 Open Label, Multicenter Study to Assess the Safety, Tolerability, Pharmacokinetics, and Anti-Tumor Activity of ZN-c5 Alone and in Combination with Palbociclib in Subjects with Estrogen-Receptor Positive, Human Epidermal Growth Factor Receptor-2 Negative Advanced Breast Cancer</td></tr>
<tr><td>Sponsor: Zeno Alpha, Inc.

Monotherapy Phase 2: Three dose levels of Single agent ZN-c5 (QD or BID dosing)</td><td>Therapy Line: 1st line chemotherapy and 2nd line hormonal-based therapy for advanced/metastatic disease – Up to 3rd line

Drug Classification:
Palbociclib: CDK 4/6 inhibitor
ZN-c5: Selective Estrogen Receptor Degrader (SERD)

Palbociclib AND ZN-c5 will be provided by sponsor</td></tr>
<tr><td>Principal Investigator: George Keogh, MD</td><td>CRC: Ashley Morrill ext. 291</td></tr>
<tr><td colspan="2">Location Clinical Trial Offered: West Ashley and Mt. Pleasant</td></tr>
<tr><td colspan="2">Inclusion Criteria: Histologically or cytologically confirmed diagnosis of advanced adenocarcinoma of the breast not amenable to any potential curative intervention; ER positive / HER2 negative; Up to 2 prior lines of endocrine therapy for advanced or metastatic breast cancer in the monotherapy cohort and up to 1 prior line of endocrine therapy for advanced or metastatic breast cancer in the combination phase; Documented prior response to endocrine therapy for advanced or metastatic disease lasting > 6 months or disease recurrence after at least 24 months of adjuvant endocrine treatment; Subjects who will undergo a FES-PET must have discontinued all prior ER blocking therapy for ≥ 60 days before the day of the examination at baseline; In the monotherapy dose escalation cohort, up to 2 prior lines of chemotherapy for advanced breast cancer; for the monotherapy phase 2 cohort no prior chemotherapy regimens are allowed; for the monotherapy expansion, combination dose escalation and combination phase 2 cohorts, up to 1 prior line of chemotherapy; Evaluable or measurable disease per RECIST v1.1.; ECOG Performance Status of ≤ 2;

Exclusion Criteria: Tamoxifen, AI, fulvestrant or other anti-cancer endocrine therapy < 14 days; Any chemotherapy or investigational drug therapy < 28 days (or 5 half-lives, whichever is shorter); Prior radiotherapy < 14 days (except for palliative radiotherapy to peripheral sites without residual toxicity); Major surgery < 28 days; Prior hematopoietic stem cell or bone marrow transplantation; Brain metastases that require immediate treatment or are clinically or radiologically unstable; Leptomeningeal disease that requires or is anticipated to require immediate treatment; Other known active cancers; Unexplained symptomatic endometrial disorders; Uncontrolled symptomatic thyroid dysfunction; Myocardial infarction, symptomatic congestive heart failure (NYHA > Class II), unstable angina, or serious uncontrolled cardiac arrhythmia within the last 6 months;</td></tr>
</table>

REVISED: 19NOV2021 AM

BREAST CANCER (ER+ HER2 Neg):

<table>
<tr><td colspan="2">ZENO 003: A Phase 1B Study of ZN-c5 in Combination with Abemaciclib in Patients with Estrogen-Receptor Positive, Human Epidermal Growth Factor Receptor-2 Negative Advanced Breast Cancer</td></tr>
<tr><td>Sponsor: Zeno Alpha, Inc.

ENROLLMENT ON HOLD</td><td>Therapy Line: 1st line chemotherapy and 2nd line hormonal-based therapy for advanced/metastatic disease

Drug Classification:
Abemaciclib: Cyclin-Dependent Kinase Inhibitor
ZN-c5: Selective Estrogen Receptor Degrader (SERD)</td></tr>
<tr><td>Principal Investigator: George Keogh, MD</td><td>CRC: Ashley Morrill ext. 291</td></tr>
<tr><td colspan="2">Location Clinical Trial Offered: West Ashley and Mt. Pleasant</td></tr>
<tr><td colspan="2">Inclusion Criteria: Histologically or cytologically confirmed diagnosis of advanced adenocarcinoma of the breast. ER+ breast cancer (>10% positive stained cells by IHC) and HER2-negative breast cancer based on the most recent tumor biopsy and documented by a local laboratory or medical record. Postmenopausal; Patients can be pre- or peri-menopausal, who must receive a gonadotropin-releasing hormone agonist beginning at least 4 weeks prior to first dose of study medication. Received no prior chemotherapy for the treatment for advanced/metastatic disease; Received up to 1 prior hormonal-based therapy for the treatment of advanced/metastatic disease.

Exclusion Criteria: Timing for discontinuation of prior therapy versus Cycle 1 Day 1 (Tamoxifen, AI, fulvestrant or other anti-cancer endocrine therapy < 14 days, any investigational drug therapy < 28 days or 5 half-lives (whichever is shorter), prior radiotherapy < 28 days (except for palliative radiotherapy to peripheral sites without residual toxicity)), prior hematopoietic stem cell or bone marrow transplantation, prior radiotherapy to > 25% of bone marrow, brain metastases that require immediate treatment or are clinically or radiologically unstable, other known active cancer(s), concurrent use of food or drugs known to be moderate or strong CYP3A4 or CYP2C9 inhibitors, including grapefruit and grapefruit juice, history of interstitial lung disease, non-infectious interstitial pneumonitis that required steroids, current pneumonitis or pulmonary fibrosis, or severe dyspnea at rest or requiring oxygen therapy, unexplained symptomatic endometrial disorders.</td></tr>
</table>

BREAST CANCER (ER+ HER2 Neg):

<table>
<tr><td colspan="2">BO41843: A PHASE III RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER STUDY EVALUATING THE EFFICACY AND SAFETY OF GDC-9545 COMBINED WITH PALBOCICLIB COMPARED WITH LETROZOLE COMBINED WITH PALBOCICLIB IN PATIENTS WITH ESTROGEN RECEPTOR-POSITIVE, HER2-NEGATIVE LOCALLY ADVANCED OR METASTATIC BREAST CANCER</td></tr>
<tr><td>Sponsor: F. Hoffmann-La Roche

Arm A: GDC-9545 30mg PO QD + Letrozole-matched placebo PO QD + Palbociclib 125mg PO Days 1-21 of 28 day cycle

Arm B: GDC-9545/ Placebo PO QD + Letrozole 2.5mg QD + Palbociclib 125mg PO Days 1-21 of 28 day cycle</td><td>Therapy Line: First line for locally advanced/ metastatic disease

Drug Classification: ER antagonist

GDC-8545/Letrozole/Placebo and Palbociclib provided by sponsor</td></tr>
<tr><td>Principal Investigator: Dr. Gene Saylors</td><td>CRC: Ashley Morrill ext. 291</td></tr>
<tr><td colspan="2">Location Clinical Trial Offered: West Ashley, Mt. Pleasant & N. Charleston</td></tr>
<tr><td colspan="2">Inclusion Criteria: ECOG 0-1; Locally advanced (recurrent or progressed) or metastatic adenocarcinoma of the breast, not amenable to treatment with curative intent; Documented ER-positive tumor according to American Society of Clinical Oncology/College of American Pathologists (ASCO/CAP) guidelines assessed locally and defined as ≥ 1% of tumor cells stained positive based on the most recent tumor biopsy (or archived tumor sample); Patient must be considered appropriate for endocrine therapy; Documented HER2-negative tumor assessed locally and defined as meeting one of the following sets of criteria: HER2 immunohistochemistry (IHC) score of 0 or 1, HER2 IHC score of 2 accompanied by a negative fluorescence, chromogenic, or silver in situ hybridization test indicating the absence of HER2 gene amplification, HER2/CEP17 ratio of 2.0 based on the most recent tumor biopsy (or archived tumor sample); No history of systemic anti-cancer therapy for locally advanced (recurrent or progressed) or metastatic disease; Measurable disease as defined per RECIST v1.1; Patients with only bone disease must have at least one predominantly lytic bone lesion confirmed by CT or MRI; Tumor lesions previously irradiated or subjected to other locoregional therapy will be deemed measurable only if disease progression at the treated site after completion of therapy is clearly documented. Disease recurrence from eBC after standard adjuvant endocrine therapy: at least 24 months of AI treatment in (neo)adjuvant setting, at least 24 months of tamoxifen treatment in (neo)adjuvant setting, at least 24 consecutive months of either AI or tamoxifen if both AI and tamoxifen received in (neo)adjuvant setting Without disease progression during treatment and disease free interval since the last treatment must be greater than 12 months. Bilateral breast cancers Both ER+/HER2-, Proof of ER+/HER2- metastases, if different ER+/HER2- status.

Exclusion Criteria: Disease recurrence during or within 12 months of completing prior neoadjuvant or adjuvant treatment with an AI (i.e., anastrozole, letrozole, or exemestane); Disease recurrence during or within 12 months of completing prior neoadjuvant or adjuvant treatment with any CDK4/6 inhibitor; Prior treatment with a SERD (e.g., fulvestrant); Prior treatment with tamoxifen is permitted, provided the patient did not experience disease recurrence within the first 24 months of treatment with tamoxifen; Treatment with any investigational therapy within 28 days prior to study treatment; Major surgery, chemotherapy, radiotherapy, or other anti-cancer therapy within 14 days prior to randomization; History of other malignancy within 5 years prior to screening, except for appropriately treated carcinoma in situ of the cervix, non-melanoma skin carcinoma, or Stage I endometrial cancer; Serious infection requiring oral or IV antibiotics within 14 days prior to randomization. Advanced, symptomatic, visceral spread that is at risk of life-threatening complications. Active uncontrolled or symptomatic CNS metastases, carcinomatous meningitis, or leptomeningeal disease. Active cardiac disease or history of cardiac dysfunction. Serious infection requiring oral or IV antibiotics, or other clinically significant infection within 14 days prior to randomization. Patients fully recovered from serious or clinically significant infections at least 14 days prior to screening are eligible.</td></tr>
</table>

BREAST CANCER (ER+ HER2 Neg):

WO42633: A Phase 3, Randomized, Double Blind, Placebo Controlled Clinical Trail To Evaluate The Efficacy And Safety Of Adjuvant Atezolizumab OR Placebo And Trastuzumab Emtansine For HER2-Postive Breast Cancer At High Risk Of Recurrence Following Preoperative Therapy.

Sponsor: F. Hoffmann-La Roche **Patients will be randomized to one of the following treatment arms in a 1:1 ratio:** **Arm A: Atezolizumab placebo 1200 mg IV Q3W and trastuzumab emtansine 3.6 mg/kg IV Q3W for 14 cycles** **Arm B: Atezolizumab 1200 mg IV Q3W and trastuzumab emtansine 3.6 mg/kg IV Q3W for 14 cycles**	Drug Classification: humanized IgG1 monoclonal antibody, antibody drug conjugate (ADC). **** Atezolizumab OR Placebo And Trastuzumab Emtansine (Kadcyla), and Herceptin are provided by Sponsor**** Patients must have completed preoperative systemic treatment consisting of at least 6 cycles with a total duration of at least 16 weeks, including at least 9 weeks of trastuzumab and at least 9 weeks of taxane-based chemotherapy (or, if receiving dose-dense chemotherapy regimens, at least 6 weeks of taxane-based therapy and at least 8 weeks of trastuzumab). Patients may have received more than one HER2-directed therapy. Patients may have received an anthracycline as part of preoperative therapy.
Principal Investigator: Dr. Gene Saylors	**CRC:** Ashley Morrill ext. 291

Location Clinical Trial Offered: West Ashley, Mt. Pleasant & N. Charleston

Inclusion Criteria: ECOG performance status of 0 or 1 Histologically confirmed invasive breast carcinoma. Preferably, pretreatment breast biopsy material will be assessed centrally to confirm diagnosis of HER2-positive breast cancer and evaluation of hormone receptor and PD-L1 status. Tumor staging requirements: Patients with cT1-3/N0-1/M0 disease at presentation (patients with cT1mi/T1a/T1b/N0 are not eligible) must have pathologic evidence of residual invasive carcinoma in axillary lymph node(s) at surgery (with or without residual invasive disease in the breast). Patients with cT4/anyN/M0 or any cT/N2–3/M0 disease at presentation must have pathologic evidence of residual invasive carcinoma in the breast and/or axillary lymph node(s) at surgery. Completion of all preoperative systemic chemotherapy and HER2-directed treatment: Systemic therapy of at least 6 cycles with a total duration of at least 16 weeks, including: at least 9 weeks of trastuzumab and at least 9 weeks of Taxane based chemotherapy. Patients with dose-dense chemotherapy regimens are eligible: at least 6 weeks of Taxane based therapy and at least 8 weeks of trastuzumab.
Patients may have used more than one HER2 directed therapy. Adequate excision of all clinically evident disease, including axillary lymph node surgery and partial or total mastectomy, after completion of neoadjuvant treatment. An interval of ≤ 12 weeks between date of primary surgery and randomization. Inclusion of an exploratory Ovarian Function Biomarker Objective: to evaluate and validate the ability of fertility biomarkers to diagnose and predict permanent loss of ovarian function after therapy.

Exclusion Criteria: Stage IV (metastatic) breast cancer. Disease progression at the conclusion of preoperative systemic therapy. Inadequate surgery. Patients for whom radiotherapy is indicated but cannot receive it due to medical contraindications. History of cumulative exposure of anthracyclines (doxorubicin > 240mg/m2, Epirubicin>480mg/m2, for other anthracyclines, exposure equivalent to doxorubicin). Prior treatment with Trastuzumab Emtansine or Atezolizumab History of other malignancy within 5 years prior to screening, with the exception of appropriately treated Carcinoma in situ of the cervix, non melanoma skin cancer, Stage 1 uterine cancer or DCIS. Live, attenuated vaccine within 4 weeks prior to initiation of study treatment, or anticipation during atezolizumab/placebo treatment or within 5 months after the final dose Investigational therapy within 28 days prior to initiation of study treatment. Prior CD137 agonists or immune checkpoint blockade therapies. Systemic immunostimulatory agents within 4 weeks or 5 half-lives of the drug (whichever is longer). Treatment with systemic immunosuppressive medication within 2 weeks prior to initiation of study treatment

CENTRAL VENOUS ACCESS DEVICES:

READY 1 CUSA-081-HEM-01: A Phase 3, Randomized, Double-Blind, Active and Placebo-Controlled Study on the use of CUSA-081 for Dysfunctional Central Venous Access Devices (CVADs)	
Sponsor: Chiesi **Randomization is 9:1:6 (CUSA-081: Placebo: Alteplase)**	Therapy Line: **Supportive** Drug Classification: **Fibrinolytic agent**
Principal Investigator: David Ellison, MD	**CRC:** Ashley Morrill ext. 291
Location Clinical Trial Offered: West Ashley Only	
Basic Enrollment Criteria: Male and non-pregnant female subjects 18 years or older. Inability to have 3mL of blood withdrawn from selected study catheter; A single or multi-lumen CVAD, implanted port and PICC in place >24 hours and documented as previously being patent and functional; Ability to designate one dysfunctional lumen of a multi-lumen catheter to be used throughout the study for both study drug instillation and assessment of CVAD function; Able to have fluids infused at the volume necessary to instill study drug into the CVAD A urine pregnancy test is required for all females of childbearing potential. Women in natural or surgical post-menopause do not need to be tested for pregnancy. Natural menopause is defined as the permanent cessation of menstrual periods, determined retrospectively after a woman has experienced 12 consecutive months of lack of menstruation (amenorrhea) without any other obvious pathological or physiological cause. Surgical menopause is defined as the removal of both ovaries (bilateral oophorectomy) before the natural menopause**. Blood pressure and heart rate will be measured at screening in supine position after 5-min rest. If blood pressure and heart rate are collected as part of Standard of Care on the same day of informed consent signing, then assessment taken prior to consent can be used.** **Exclusion Criteria:** CVAD (any type) used for hemodialysis; **CVAD known to be dysfunctional for more than 48 hours**; Reasonable evidence of mechanical or non-thrombotic occlusion in the selected study catheter; Known or suspected catheter related bloodstream infection; Uncontrolled hypertension at screening (systolic BP ≥ 160 or diastolic BP ≥ 110 mmHg) Use of any intravenously administered fibrinolytic agent or anticoagulant (e.g., alteplase, tenecteplase, reteplase, urokinase or heparin) within 24 hours prior to the treatment period (first instillation of study drug). Use of subcutaneous LMWH for prophylaxis of thromboembolic events is allowed); Known to be at high risk for bleeding events or embolic complications in the opinion of the investigator, or has a known condition for which bleeding constitutes a significant hazard (e.g. recent stroke, recent intracranial or intraspinal surgery or serious head trauma, intracranial neoplasm, arteriovenous malformation or aneurysm, known bleeding diathesis); History of allergic reaction to reteplase, alteplase or vial ingredients (excipients or diluents); Previously treated in READY 1 or READY 2 **Oral anticoagulants are allowed (e.g., dabigatran, rivaroxaban, warfarin).** **Antiplatelet medications are allowed (e.g., aspirin, clopidogrel, prasugrel,**	

BASAL CELL CARCINOMA:

R2810-ONC-1806: CemiplimAb (Libtayo) Survivorship Epidemiology (CASE) Study	
Sponsor: Regeneron Pharmaceuticals ***A registry/observational study***	Therapy Line: **Metastatic or Locally Advanced and not candidates for curative surgery or curative radiation** Drug Classification: **Programmed Death Receptor – 1 (PD-1) blocking antibody**
Principal Investigator: David M. Ellison, MD	**CRC:** Ashley Morrill ext. 291
Location Clinical Trial Offered: West Ashley, Mount Pleasant & North Charleston	
Basic Inclusion Criteria: 18 years of age. Receiving treatment with cemiplimab for CSCC or initiating treatment with CemiplimAb for CSCC. Patients who are continuing treatment with cemiplimab after completing cemiplimab treatment on the R2810-ONC-1540 clinical trial are eligible to participate in this study at the time that they initiate treatment with cemiplimab in a real-world setting. For completeness and ease of prospective data collection, it is recommended that patients be enrolled prior to administration of their third dose of cemiplimab. Willing and able to comply with standard clinical care for CSCC. Able to understand and complete study-related questionnaires. Provide signed informed consent. Group 1: Eligible for treatment with and prescribed cemiplimab for advanced CSCC in accordance with approved prescribing information For completeness and ease of prospective data collection, patients should be enrolled before their second dose of cemiplimab. Group 2: Eligible for treatment with and prescribed cemiplimab for advanced BCC in accordance with approved prescribing information. **Exclusion Criteria:** Receiving cemiplimab for an indication other than advanced CSCC or advanced BCC. Any condition that, in the opinion of the investigator, may interfere with patient's ability to participate in the study, (eg, unstable social situation such as homelessness or psychiatric conditions making follow-up unreliable such as schizophrenia, advanced depression, active substance abuse, or severe cognitive impairment or other comorbidities) that would, in the opinion of the investigator, predictably limit compliance with the intended treatment plan, or prevent the patient from adequately completing QOL assessments treatment plan or prevent the patient from adequately completing QOL assessments.Patients concurrently participating in any study including administration of any investigational drug (including cemiplimab) or procedure (including survival follow up).	

CUTANEOUS SQUAMOUS CELL CARCINOMA:

R2810-ONC-1806: CemiplimAb (Libtayo) Survivorship Epidemiology (CASE) Study	
Sponsor: Regeneron Pharmaceuticals ***A registry/observational study***	Therapy Line: **Metastatic or Locally Advanced and not candidates for curative surgery or curative radiation** Drug Classification: **Programmed Death Receptor – 1 (PD-1) blocking antibody**
Principal Investigator: David M. Ellison, MD	**CRC:** Ashley Morrill ext. 291
Location Clinical Trial Offered: West Ashley, Mount Pleasant & North Charleston	
Basic Inclusion Criteria: 18 years of age. Receiving treatment with cemiplimab for CSCC or initiating treatment with CemiplimAb for CSCC. Patients who are continuing treatment with cemiplimab after completing cemiplimab treatment on the R2810-ONC-1540 clinical trial are eligible to participate in this study at the time that they initiate treatment with cemiplimab in a real-world setting. For completeness and ease of prospective data collection, it is recommended that patients be enrolled prior to administration of their third dose of cemiplimab. Willing and able to comply with standard clinical care for CSCC. Able to understand and complete study-related questionnaires. Provide signed informed consent. Group 1: Eligible for treatment with and prescribed cemiplimab for advanced CSCC in accordance with approved prescribing information For completeness and ease of prospective data collection, patients should be enrolled before their second dose of cemiplimab. Group 2: Eligible for treatment with and prescribed cemiplimab for advanced BCC in accordance with approved prescribing information. **Exclusion Criteria:** Receiving cemiplimab for an indication other than advanced CSCC or advanced BCC. Any condition that, in the opinion of the investigator, may interfere with patient's ability to participate in the study, (eg, unstable social situation such as homelessness or psychiatric conditions making follow-up unreliable such as schizophrenia, advanced depression, active substance abuse, or severe cognitive impairment or other comorbidities) that would, in the opinion of the investigator, predictably limit compliance with the intended treatment plan, or prevent the patient from adequately completing QOL assessments treatment plan or prevent the patient from adequately completing QOL assessments.Patients concurrently participating in any study including administration of any investigational drug (including cemiplimab) or procedure (including survival follow up).	

Diffuse Large B-cell Lymphoma (DLBCL):

SGN35-031: A Randomized, Double-blind, Placebo-Controlled, Active-Comparator, Multicenter, Phase 3 Study of Brentuximab Vedotin or Placebo in Combination with Lenalidomide and Rituximab in Subjects with Relapsed or Refractory Diffuse Large B-cell Lymphoma (DLBCL)	
Sponsor: Seattle Genetics, Inc. **Brentuximab vedotin/ Placebo + Lenalidomide *Provided by Sponsor) + Rituximab (Not provided by Sponsor)**	Therapy Line: **≥2 lines of prior systemic therapy** Drug Classification: **CD30-directed Antibody Drug conjugate (ADC); targeted therapy monoclonal antibody and an antineoplastic agent** **Tumor tissue (≤4 weeks before Day 1) to be submitted to central lab for determination of CD30 expression**
Principal Investigator: Dr. James Orcutt	**CRC:** Ashley Morrill ext. 291
Location: West Ashley, Mt. Pleasant and N. Charleston	
Basic Inclusion Criteria: ECOG 0-2; Subjects must have R/R disease following ≥2 lines of prior systemic therapy; Subjects with relapsed or refractory diffuse and transformed large B-cell lymphoma (R/R DLBCL). DLBCL and cell of origin (GCB versus non-GCB) will be histologically determined by the most recent local pathology assessment for the purposes of study eligibility and stratification. **The following subtypes of DLBCL are eligible for enrollment:** a. Not otherwise specified (NOS), b. Intravascular large B-cell lymphoma, c. DLBCL associated with chronic inflammation, d. EBV-positive NOS and/or BCL6 (double-/triple-hit lymphoma), e. ALK-positive, f. T-cell-/histiocyte-rich large B-cell lymphoma, g. Primary mediastinal large B-cell lymphoma, h. High-grade B-cell lymphoma with translocations of MYC and BCL2, i. High-grade NOS B-cell lymphomas, j. Primary cutaneous DLBCL (leg type), k. DLBCL arising from transformed indolent lymphomas/leukemias; Subjects must have fluorodeoxyglucose (FDG)-avid disease PET and bidimensional measurable disease of at least 1.5 cm by CT, as assessed by the site radiologist within 28 days of Day 1; Subjects must be registered into the mandatory lenalidomide REMS®/risk minimization programs and be willing to comply with its requirements **Basic Exclusion Criteria: Chemotherapy, radiotherapy, biologics, and/or other antitumor treatment with immunotherapy that is not completed 3 weeks prior to first dose of study drug, unless underlying disease has progressed on treatment;** History of another malignancy within 2 years before the first dose of study drug or any evidence of residual disease from a previously diagnosed malignancy. Exceptions are malignancies with a negligible risk of metastasis or death (e.g., 5-year OS ≥90%), such as carcinoma in situ of the cervix, non-melanoma skin carcinoma, localized prostate cancer, ductal carcinoma in situ, or Stage I uterine cancer; History of progressive multifocal leukoencephalopathy (PML); Active cerebral/meningeal disease related to the underlying malignancy. Subjects with a history of cerebral/meningeal disease related to the underlying malignancy are allowed if prior CNS disease has been effectively treated and without progression for at least 3 months; Any uncontrolled Grade 3 or higher (per NCI CTCAE version 5.0) viral, bacterial, or fungal infection within 2 weeks prior to the first dose of study drug. Routine antimicrobial prophylaxis is permitted	

Diffuse Large B-cell Lymphoma (DLBCL):

<table>
<tr><td colspan="2">CytomX (PROCLAIM-CX-2029): A Phase 1-2, First-in-Human Study of CX-2029 in Adults with Metastatic or Locally Advanced Unresectable Solid Tumors or Diffuse Large B-cell Lymphomas</td></tr>
<tr><td>Part C: Histologically or cytologically confirmed metastatic or locally advanced unresectable HNSCC, DLBCL, NSCLC (squamous cell histology only), or esophageal (EAC, ESCC, or GE junction) cancer</td><td>Therapy Line: Metastatic, Locally Advanced, or Unresectable. Patients must have exhausted available life prolonging therapies

Drug Classification: Humanized anti-CD71 Probody-drug conjugate (PDC)</td></tr>
<tr><td>Principal Investigator: Dr. James Orcutt</td><td>CRC: Ashley Morrill ext. 291</td></tr>
<tr><td colspan="2">Location: N. Charleston, West Ashley, and Mt. Pleasant</td></tr>
<tr><td colspan="2">Basic Inclusion Criteria: ECOG 0 to 1, Agree to provide tumor tissue; archival, new, or recent acquisition confirmed to be available prior to initiation of study drug for performance of correlative tissue and cellular studies from a tumor site not previously irradiated. Subjects with advanced or metastatic stage IV NSCLC with known EGFR or ALK genomic alterations are eligible if they have progressed on treatment or did not tolerate appropriate targeted therapy. Subjects with known NSCLC with known ROS1 rearrangement must have received prior treatment with crizotinib. Subjects with known B-RAF mutations must have received prior treatment with a B-RAF inhibitor. Subjects with HNSCC and esophageal (EAC, ESCC, or GE junction) cancer must have received a platinum-containing regimen (unless intolerant or not suitable) and a PD-1 inhibitor if approved for subject's indication in their locality. Relapsed or refractory DLBCL after 2 lines of systemic therapy. At least 1 line should contain anti-CD20 based immunochemotherapy, and subjects should not be candidates for autologous hematopoietic stem cell transplantation. Subjects with EAC, ESCC, or GE junction cancer should have received at least 1 line of systemic chemotherapy or chemoradiation, unless intolerant or not suitable. Subjects with known HER2 overexpressing tumors should have received treatment with HER2-targeted therapy. Documented progression or relapse after at least 1 prior systemic therapy. Moreover, subjects must have exhausted available life prolonging therapies

Basic Exclusion Criteria: Serious concurrent illness. History of another malignancy within 2 years. Current anticoagulation with Warfarin. Transfusion dependent anemia. Inability to discontinue treatment with a strong CYP3A4 inhibitor or inducer prior to start of treatment. Neuropathy >Grade 1. History of severe allergy or anaphylactic reaction to previous monoclonal antibodies or known hypersensitivity to auristatins. Clinically significant iron metabolism disorders. Use of iron chelators. Major surgery within 3 months prior to study enrollment. Live vaccine within 28 days prior to planned dose. Participation in any clinical study involving medications, radiation, or surgery. Women who are pregnant or breast-feeding.</td></tr>
</table>

Diffuse Large B-cell Lymphoma (DLBCL):

MOR208C310 frontMIND: A Phase **3, multicenter, randomized, double-blind, placebo-controlled study is designed to investigate whether Tafasitamab plus lenalidomide as add-on therapy to R-CHOP provides improved clinical benefit compared to R-CHOP in patients with newly-diagnosed high-intermediate and high-risk DLBCL.**	
Sponsor: MorphoSys AG	Therapy Line: **First Line** Drug Classification: **Tafasitamab** anti-CD20 monoclonal antibody (mAb) rituximab plus CHOP (cyclophosphamide, doxorubicin, vincristine, and prednisone) chemotherapy (R-CHOP) is the current standard of care for the treatment of patients with newly diagnosed DLBCL.
Principal Investigator: Dr. James Orcutt	**CRC:** Ashley Morrill ext. 291
Location: N. Charleston, West Ashley	

Basic Inclusion Criteria: ECOG performance status of 0, 1, or 2. Previously untreated patients with local biopsy proven, CD20 positive DLBCL, including one of the following diagnoses by High grade BCL with MYC and B cell lymphoma 2 (BCL2) and/or B cell lymphoma 6 (BCL6) rearrangements (double hit or triple hit lymphoma). Please note : Patients must be appropriate candidates for R CHOP. If an investigator deems a patient with a known double or triple hit lymphoma (HGBL) should be treated more aggressively (e.g. dose adjusted etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin and rituximab [DA EPOCH R] or cyclophosphamide, vincristine, doxorubicin and dexamethasone (CVAD) followed by methotrexate and cytarabine [Hyper CVAD]), this patient would not be considered eligible for this study DLBCL coexistent with either follicular lymphoma (FL) of any grade, gastric MALT lymphoma or non gastric MALT lymphoma. FL grade 3b. Availability of archival or freshly collected tumor tissue sent for retrospective central pathology review. Please note: neither receipt of tumor samples nor central review of diagnosis is necessary prior to study enrollment. Up to six of the largest target nodes, nodal masses, or other lymphomatous lesions that are measurable in two diameters should be identified by local assessment from different body regions representative of the patient's overall disease burden and include mediastinal and retroperitoneal disease, if involved. At baseline, a measurable node must be greater than 15 mm in longest diameter (LDi). Measurable extranodal disease may be included in the six representative, measured lesions. At baseline, measurable extranodal lesions should be greater than 10 mm LDi . All other lesions (including nodal, extranodal, and assessable disease) should be followed as nonmeasured disease as non target lesions (e.g. cutaneous, GI, bone, spleen, liver, kidneys, pleural or pericardial effusions, ascites, bone, bone marrow). At least one measurable lesion must be confirmed to be PET positive (Deauville score of 4 or 5) at the time of randomization by local assessment.

Basic Exclusion Criteria: Any other histological type of lymphoma according to WHO 2016 classification of lymphoid neoplasms, e.g. primary mediastinal (thymic) large B cell lymphoma, Burkitt's lymphoma, BCL, unclassifiable, with features intermediate between DLBCL and classical Hodgkin lymphoma (grey zone lymphoma); primary effusion lymphoma; primary cutaneous DLBCL, leg type; primary DLBCL of the CNS; DLBCL arising from CLL or indolent lymphoma. History of radiation therapy to ≥ 25% of the bone marrow for other diseases History of prior non hematologic malignancy except for the following: Malignancy treated with curative intent and with no evidence of active disease present for more than 2 years before screening. Adequately treated lentigo malignant melanoma without current evidence of disease or adequately controlled non melanomatous skin cancer. Adequately treated carcinoma in situ without current evidence of disease Known active systemic bacterial, viral, fungal, or other infection at screening, including patients with suspected active or latent tuberculosis (as confirmed by a positive interferon gamma release assay) Any systemic anti lymphoma and/or investigational therapy prior to the start of C1D1, except for permitted pre phase treatment defined in Section 9.6. Contraindication to any of the individual components of R CHOP, including prior receipt of anthracyclines. Pregnancy or lactation. History of hypersensitivity to any component of R CHOP, to lenalidomide , to compounds of similar biological or chemical composition to Tafasitamab , IMiDs ® and/or the excipients contained in the study drug formulations. History or evidence of rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose galactose malabsorption. Vaccination with live vaccine within 21 days prior to study randomization.
Major surgery within up to 21 days prior to signing the ICF, unless the patient is recovered at the time of signing the ICF

Follicular Lymphoma Grade 1 to 3a or R/R Marginal Zone Lymphoma (1)

INCMOR 0208-301: A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Tafasitamab Plus Lenalidomide in Addition to Rituximab Versus Lenalidomide in Addition to Rituximab in Patients With Relapsed/Refractory (R/R) Follicular Lymphoma Grade 1 to 3a or R/R Marginal Zone Lymphoma	
Sponsor: Incyte Corporation	Therapy Line: **Relapsed/Refractory** Drug Classification: Tafasitamab (MOR00208/MOR208/XmAb5574/Tafasitamab-cxix) is an Fc-modified, humanized mAb
Principal Investigator: Gene Saylors, MD	**CRC:** Ashley Morrill ext. 291
Location Clinical Trial Offered: West Ashley, Mt. Pleasant & N. Charleston	
Basic Enrollment Criteria: Histologically confirmed Grade 1, 2, or 3a FL or histologically confirmed nodal MZL, splenic MZL, or extranodal MZL of the MALT; Tumor tissue sufficient for retrospective central pathology review and correlative studies (fresh biopsy is preferred); Must have been previously treated with at least 1 prior systemic anti-CD20 immunotherapy or chemo-immunotherapy. This includes treatments such as rituximab monotherapy or chemotherapy plus immunotherapy with rituximab or Obinutuzumab, with or without maintenance; Must have documented relapsed, refractory, or PD after treatment with systemic therapy; Relapsed lymphoma: relapsed after initial response of CR to prior therapy; Refractory lymphoma: achieved less than PR to the last treatment or achieved a CR or PR that lasted less than 6 months before lymphoma progression; Progressive lymphoma: PD after initial response of PR or SD to prior therapy; Participants must have at least 1 measurable disease site; Must be in need of treatment for relapsed, refractory, or PD as assessed by the investigator according to GELF criteria **Exclusion Criteria:** Any histology other than FL and MZL or clinical evidence of transformed lymphoma by INV assessment; History of radiation therapy to ≥ 25% of the BM for other diseases; History of prior nonhematologic malignancy except for Malignancy treated with curative intent and with no evidence of active disease for more than 2 years before screening, Adequately treated lentigo malignant melanoma without current evidence of disease or adequately controlled nonmelanomatous skin cancer, or adequately treated carcinoma in situ without current evidence of disease; Congestive heart failure; Active systemic infection; Immunocompromised patients; Known CNS lymphoma involvement; Life expectancy < 6 months; History or evidence of rare hereditary problems of galactose intolerance, Lapp lactase deficiency, or glucose-galactose malabsorption; Prior use of lenalidomide in combination with rituximab;	

Non-Hodgkin Lymphoma (Observational)

NDS-DLBCL-003- Connect Lymphoma Disease Registry: A US-Based Prospective Observational Cohort Study. Patient registry in the settings of relapsed/refractory (R/R) diffuse large B-cell lymphoma (DLBCL), R/R follicular lymphoma (FL), and (R/R) primary mediastinal B-cell lymphoma (PMBCL).	
Sponsor: Bristol Myers Squibb/Celgene	Therapy Line: **Relapsed/Refractory**
Principal Investigator: Dr. George Geils	**CRC:** Ashley Morrill ext. 291
Location Clinical Trial Offered: West Ashley, Mt. Pleasant, N. Charleston & Carnes	
Inclusion Criteria: The study will enroll patients over the course of approximately 3 years, and each patient will be followed up for up to 5 years or until death, withdrawal of consent, loss to follow-up, or study termination, whichever occurs first. Enrollment for all 4 cohorts will occur simultaneously, with approximate targets of 1,000 first R/R DLBCL, 500 second R/R DLBCL, 500 first R/R FL, and 100 first R/R PMBCL patients. As this is a real-world observational study, the actual number enrolled in each cohort may differ from what was planned. For first R/R DLBCL cohort, patient must have confirmed R/R disease and must have initiated 2L systemic treatment ≤ 60 days prior to enrollment; HSCT following consolidation therapy will be considered as the same line of therapy*For second R/R DLBCL cohort, patient must have confirmed R/R disease during or after 2L systemic treatment and must have initiated 3L systemic treatment ≤ 60 days prior to enrollment; HSCT following consolidation therapy will be considered as the same line of therapy. **Exclusion Criteria:** Patient whose prior start and end date of DLBCL, FL, or PMBCL treatment, and prior treatment received, including chemotherapy, radiation, surgery (not including excisional biopsies), and other anticancer therapy, are unknown Patient who has any other active malignancy (non-DLBCL, non-PMBCL, ornon-FL) for which the patient is receiving treatment at the time of enrollment, or any other former malignancy that was diagnosed within 6 months prior to Registry enrollment (with the exception of non-melanoma skin cancer) Currently enrolled in any interventional clinical trial where the patient is being treated with an investigational product that cannot be identified	

Chronic Lymphocytic Leukemia (CLL)

U2-VEN-207: Ultra-V- Phase 2/3 Randomized Study to Assess the Efficacy and Safety of Ublituximab in Combination with Umbralisib and Venetoclax (U2-V) Compared to Ublituximab and Umbralisib (U2) in Subjects with Chronic Lymphocytic Leukemia (CLL)

Sponsor: TG Therapeutics, Inc.	Therapy Line: **Relapsed/Refractory** Drug Classification: Ublituximab, Umbralisib, Venetoclax *Sponsor will be providing the Ublituximab, Umbralisib* **You MUST obtain a Prior Authorization for the Venetoclax prior to Cycle 4 as it is NOT provided by the Sponsor.***
Principal Investigator: Dr. George Geils	**CRC:** Ashley Morrill ext. 291

Location Clinical Trial Offered: West Ashley & N. Charleston

Inclusion Criteria: B-cell CLL that warrants treatment consistent with iwCLL 2018 criteria for initiation of therapy with diagnosis established according to iwCLL 2018 criteria and documented within medical records. At least one of the following criteria should be met: a. Evidence of progressive marrow failure as manifested by the onset or worsening of anemia and/or thrombocytopenia; or Massive (i.e., lower edge of spleen ≥ 6 cm below the left costal margin), progressive, or symptomatic splenomegaly; or Massive (i.e., ≥ 10 cm in the longest diameter) or progressive or symptomatic lymphadenopathy; or Progressive lymphocytosis in the absence of infection, with an increase in blood absolute lymphocyte count (ALC) >50% over a 2-month period or lymphocyte doubling time of <6 months; or Constitutional symptoms, defined as any one or more of the following disease-related symptoms or signs occurring in the absence of evidence of infection: i. Unintentional weight loss of ≥10% within the previous 6 months; or Significant fatigue (≥ Grade 2); or Fevers >100.5°F or 38.0°C for ≥2 weeks; or iv. Night sweats for >1 month. Adequate organ system function, independent of growth factor or transfusion support, defined as follows: a. Absolute neutrophil count (ANC) ≥ 750/mm3 (µL) / platelet count ≥ 40,000/mm3 (µL); Total bilirubin ≤1.5 times the upper limit of normal (ULN). Subjects with Gilbert's syndrome with bilirubin > 1.5 × ULN allowed per discussion with the Medical Monitor; Alanine aminotransferase (ALT) and aspartate aminotransferase (AST) ≤2.5 x ULN if no liver involvement, or ≤5 x the ULN if known liver involvement; Calculated creatinine clearance >30 mL/min (as calculated by the Cockcroft-Gault formula). ECOG performance status ≤ 2. Male or female ≥ 18 years of age. Ability to swallow and retain oral medication. Female subjects who are not of child-bearing potential, and female subjects of child-bearing potential who have a negative serum pregnancy test within 3 days prior to Cycle 1, Day 1.

Exclusion Criteria: Subjects receiving cancer therapy (i.e., chemotherapy, radiation therapy, immunotherapy, biologic therapy, hormonal therapy, surgery and/or tumor embolization) or any investigational drug within 21 days of Cycle 1, Day 1 (within 7 days of Cycle 1, Day 1 for prior BTK inhibitor). Corticosteroid use within 1 week prior to first dose of study drug are excluded, with the exception of steroid use for adrenal replacement, inhaled steroid for asthma, topical steroid use or other locally administered corticosteroids. Patients requiring systemic steroids for leukemia control or white blood cell (WBC)-count lowering are excluded. Autologous hematologic stem cell transplant within 6 months of study entry. Prior allogeneic hematologic stem cell transplant. Evidence of chronic active hepatitis B (HBV) infection as evidenced by a detectable hepatitis B surface antigen (HBsAg) [not including subjects with prior hepatitis B vaccination]; or chronic hepatitis C infection (HCV), cytomegalovirus (CMV), or known history of human immunodeficiency virus (HIV). Subjects with positive hepatitis B core antibody (HBc Ab) or hepatitis C virus antibody (HCV AB) or positive CMV by IgM or IgG are eligible only if PCR is negative for HBV DNA, HCV RNA or CMV. Known histological transformation from CLL to an aggressive lymphoma (e.g., Richter's Transformation, prolymphocytic leukemia, or DLBCL). History of CNS involvement with CLL.
Prior exposure to any PI3K inhibitor (e.g. idelalisib, duvelisib, Umbralisib [TGR-1202], etc.) or Venetoclax (ABT-199, GDC-0199). Known barriers to obtain access to commercially available Venetoclax. Evidence of ongoing systemic bacterial, fungal or viral infection, except localized fungal infections of skin or nails. Live virus vaccines within 4 weeks prior to or during study therapy.

HEAD and NECK CANCER:

MNPR-301-001: A Phase 2b/3, multicenter, randomized, double-blind, placebo-controlled study comparing the efficacy and safety of clonidine mucoadhesive buccal tablet to placebo to prevent chemoradiotherapy-induced severe oral mucositis in patients with oropharyngeal cancer.	
Sponsor: Monopar Therapeutics	Therapy Line: **First line supportive care** Drug Classification: I**midazoline derivative and adrenergic alpha 2 receptor agonist**
Principal Investigator: Charles Holladay, MD	**CRC:** Ashley Morrill ext. 291
Location Clinical Trial Offered: West Ashley & N. Charleston	
Basic Enrollment Criteria: Patients treated with surgical resection of their primary tumor for localized or locally advanced disease T ≥ T0 and/or N ≥ N1 without distant metastasis and initiating adjuvant concurrent CRT within 8 weeks post-operatively. Unknown primary with node-positive disease confirmed to be Squamous Cell Carcinoma would be allowed; Patients who will be treated with definitive concurrent chemoradiation for locally advanced disease; Patients eligible to receive continuous course of external fractionated irradiation based on a daily dosing of 1.8 to 2.2 Gy/day 5 days/week in combination with cisplatin monotherapy either every 3 weeks or weekly cisplatin; Alternative treatment regimens are allowed only if cisplatin is contraindicated; Radiation plan must include delivery of a cumulative dose of 60-72 Gy. The oropharynx should receive at least 50 Gy; HPV status documented by immunohistochemical detection of p16 expression in the tumor; Patients with Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 but a performance status of 2 is allowed only if due to a patient's malignancy. **Exclusion Criteria:** Patients with no tumor or lesion in the oropharynx; Prior induction chemotherapy for treatment of current malignancy; Evidence of a concomitant other malignancy and/or any prior malignancy without complete remission in the last 2 years, except adequately treated basal or squamous cell carcinoma of the skin or in situ cervical cancer; Patients with OM at baseline, any other oral ulceration or active oral infection; Patients with systolic blood pressure (BP) < 100 mmHg and/or diastolic BP < 50 mmHg; Patients currently being treated with sultopride, clonidine hydrochloride (eg, Catapres®), pentoxifylline or pilocarpine; Patients who are unable to tolerate oral diet and/or are feeding tube dependent at baseline;	

HEPATOCELLULAR CARCINOMA:

MK1308A-004: A Phase 2, Multicenter, Clinical Study to Evaluate the Safety and Efficacy of MK-1308A (Coformulated MK-1308/MK-3475) in Combination with Lenvatinib (E7080/MK-7902) in First-line Therapy of Participants with Advanced Hepatocellular Carcinoma	
Sponsor: Merck **Randomization 1:1**	**Therapy Line: 1st Line Therapy** **Drug Classification:** Triplet Regimen in 1st Line HCC Combination blockade of CTLA-4 and PD-1 offers complementary mechanisms of action that may lead to synergistic antitumor activity **** MK-1308A-004 and Lenvatinib are providing by the Sponsor. ****
Principal Investigator: Brian Lingerfelt, MD	**CRC:** Ashley Morrill ext. 291
Location Clinical Trial Offered: West Ashley, Mount Pleasant	
Inclusion Criteria: HCC diagnosis confirmed by radiology (AASLD criteria) or pathology. At least 1 measurable HCC lesion per RECIST 1.1. Radiographic inclusion criteria are confirmed by BICR BCLC Stage C/B: Not amenable to locoregional therapy/curative treatment. Previous locoregional therapy (Ablation, RT, TACE, resection), except for transplant, is permitted. Child-Pugh class A and ECOG PS 0 or 1 If HTN+: well controlled (≤150/90 mm Hg). Controlled hepatitis B Antiviral therapy must be given for at least 4 weeks and viral load must be <500 IU/mL prior to first dose of study drug No need for prophylaxis: HBc-Ab(+), HBs-Ag(-), HBs-Ab(-) or (+), HBV viral load <100 IU/mL. Hepatitis C Past or ongoing HCV infection. Complete anti-HCV treatment at least 1 month prior to study intervention. **Exclusion Criteria:** Variceal bleeding within the last 6 months. Bleeding or thrombotic disorders or use of factor X inhibitors or anticoagulants requiring INR monitoring. Clinically apparent ascites on physical examination. Hepatic encephalopathy in the last 6 months unresponsive to therapy. Vascular invasion: inferior vena cava or cardiac involvement confirmed by BICR. Vp4 is allowed. Any history of HCC CNS metastases. Prior systemic HCC treatment (chemo, anti-VEGF/VEGFR) or cancer immunotherapy. Dual active HBV + HCV. Preexisting grade ≥3 fistula (gastrointestinal or non-gastrointestinal) Immunodeficiency or immunosuppressive therapy. Prolongation of QTcF interval to >480 ms. Received a live or live-attenuated vaccine within 30 days before the first dose. No specific recommendations for COVID-19 vaccine.	

LUNG- Non-Small Cell Lung Cancer:

<table>
<tr><td colspan="2">USO #19118 CARMEN-LC03 Randomized, Open Label Phase 3 study of SAR408701 versus Docetaxel in Previously Treated metastatic non-squamous Non-Small Cell Lung Cancer patients with CEACAM5 positive tumors</td></tr>
<tr><td>Sponsor: Sanofi-Aventis

Randomization 1:1

Treatment A: SAR408701 100mg/m2 Q2W
Treatment B: Docetaxel 75mg/m2 Q3W

Prescreening informed consent may be signed while patient is on current treatment</td><td>Therapy Line: Disease progression during or following treatment with platinum-containing chemotherapy and anti PD-L1/PD-1 antibody for metastatic NSCLC

Drug Classification: SAR408701 is an antibody-drug conjugate.</td></tr>
<tr><td>Principal Investigator: Dr. Brian Lingerfelt</td><td>CRC: Ashley Morrill ext. 291</td></tr>
<tr><td colspan="2">Location Clinical Trial Offered: West Ashley Only</td></tr>
<tr><td colspan="2">Inclusion Criteria: ECOG 0-1; Histologically or cytologically proven diagnosis of non-squamous NSCLC metastatic disease at study entry; meeting all 3 of the following criteria: 1) Having progressive disease during or after platinum-based chemotherapy (at least 2 cycles), and 2) Having progressive disease during or after one immune checkpoint inhibitor (anti-PD1/PD-L1); this could be given as monotherapy or in combination with platinum-based chemotherapy, and 3) Participant with EGFR sensitizing mutation or BRAF mutation or ALK/ROS alterations must be able to demonstrate progression of the disease on approved treatments for these conditions, in addition to platinum-based chemotherapy and immune checkpoint inhibitor. At least one measurable lesion by RECIST 1.1. Irradiated lesion can be considered measurable only if progression has been demonstrated on irradiated lesion. Participants with CEACAM5 expression of ≥2+ in intensity in archival tumor sample (or if not available fresh biopsy sample) involving at least 50 % of the tumor cell population as demonstrated prospectively by a centrally assessed ICH assay. At least 7 × 4 µm slides from FFPE tumor tissue are required. If less material is available, patient could still be eligible after discussion with the Sponsor who will assess and confirm that there is sufficient relevant material for key evaluations.

Exclusion Criteria: Concurrent treatment with any other anticancer therapy. Prior treatment with docetaxel. Prior therapy targeting CEACAM5. Prior maytansinoid treatment (DM1 or DM4 antibody drug conjugate). Washout period before first administration of study intervention of less than 3 weeks or less than 5 times the half-life, whichever is shorted, for prior antitumor therapy. Untreated brain metastases and history of leptomeningeal disease. Patients with previously treated brain metastases may participate provided they are stable (ie, without evidence of progression) by imaging performed at least 4 weeks after CNS-directed treatment and at least 2 weeks prior to the first administration of study intervention, and any neurologic symptoms have returned to baseline; and there is no evidence of new or enlarging brain metastases; and the patient does not require any systemic corticosteroids for management of brain metastases within 2 weeks prior to the first dose of study intervention. History within the last 3 years of an invasive malignancy other than the one treated in this study, with the exception of resected/ablated basal or squamous-cell carcinoma of the skin or carcinoma in situ of the cervix, or other local tumors considered cured by local treatment.</td></tr>
</table>

LUNG- Non-Small Cell Lung Cancer:

<table>
<tr><td colspan="2">USO #19211 AEGEAN: A Phase III, Double-blind, Placebo-controlled, Multi-center International Study of Neoadjuvant/Adjuvant Durvalumab for the Treatment of Patients with Resectable Stages II and III Non-small Cell Lung Cancer</td></tr>
<tr><td>Sponsor: AstraZeneca

1:1 Randomization

Durvalumab/Placebo + Investigators choice of:
Carboplatin/Paclitaxel; Cisplatin/Gemcitabine; Pemetrexed/Cisplatin or Pemetrexed/Carboplatin</td><td>Therapy Line: Neoadjuvant Setting for resectable patients Stage IIA to select Stage IIIB

Drug Classification: Humanized igG1 anti-PD-1 monoclonal antibody

Tissue must be sent for PD-L1 status & results received prior to randomization</td></tr>
<tr><td>Principal Investigator: George Geils, MD</td><td>CRC: Ashley Morrill ext. 291</td></tr>
<tr><td colspan="2">Location Clinical Trial Offered: West Ashley Only</td></tr>
<tr><td colspan="2">Basic Enrollment Criteria: Histologically or cytologically documented NSCLC with Resectable (Stage IIA to select [ie, N2] Stage IIIB) disease. ECOG ≤1 at enrollment. Confirmation of PD-L1 status prior to randomization by central laboratory. Documented EGFR and ALK status. At least 1 lesion, no previously irradiated, that qualifies as RECIST 1.1 Target Lesion at baseline. No Prior exposure to immune-mediated therapy including, but not limited to, other anti-CTLA-4, anti-PD-1, anti-PD-L1, and anti-PD-L2 antibodies, excluding therapeutic anticancer vaccines. Adequate organ and marrow function.

Exclusion Criteria: History of allogeneic organ transplantation. Active or prior documented autoimmune or inflammatory disorders (including inflammatory bowel disease, diverticulitis, systemic lupus erythematosus, Sarcoidosis syndrome, or Wegener syndrome). History of another primary malignancy. History of active primary immunodeficiency. Active infection including tuberculosis hepatitis B, or human immunodeficiency virus. Deemed unresectable NSCLC by multidisciplinary evaluation. Patients who have pre-operative radiotherapy treatment as part of their care plan. Patients who have brain metastases or spinal cord compression. Stage IIIB N3 and Stages IIIC, IVA, and IVB NSCLC. Mixed small cell and NSCLC histology. Patients who are candidates to undergo only segmentectomies or wedge resections</td></tr>
</table>

LUNG- Non-Small Cell Lung Cancer:

<table>
<tr><td colspan="2">BMS CA209-73L: 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)</td></tr>
<tr><td>Sponsor: Bristol-Myers

Randomization 1:1:1

Arm A: Nivolumab, Platinum Doublet Chemotherapy and Radiotherapy then Maintenance of Nivolumab and Ipilimumab

Arm B: Nivolumab, Platinum Doublet Chemotherapy and Radiotherapy then Maintenance of Nivolumab

Arm C: Platinum Doublet Chemotherapy and Radiotherapy then Maintenance of Durvalumab</td><td>Therapy Line: Untreated Locally Advanced (Stage 3A, 3B or 3C) amendable to CCRT
Drug Classification: Humanized IgG4 anti-PD-1 monoclonal antibody</td></tr>
<tr><td>Principal Investigator: Gene Saylors, MD</td><td>CRC: Ashley Morrill ext. 291</td></tr>
<tr><td colspan="2">Location Clinical Trial Offered: West Ashley, Mount Pleasant & North Charleston</td></tr>
<tr><td colspan="2">Basic Enrollment Criteria: ECOG performance status ≤1. Locally advanced stage IIIA, IIIB, or IIIC (T1-2 N2-3 M0, T3 N1-3 M0, or T4 N0-3 M0) histologically confirmed NSCLC, according to 8th TNM classification, that is amenable to definitive CCRT. Participants who are not planned for potential curative surgical resection are eligible. i) Overt cT4 disease, including encasement of the large vessels defined by > 50 % of the circumference OR ii) Nodal status N2 or N3 must be proven (by biopsy in at least one N2 or N3 node, via EBUS, mediastinoscopy or thoracoscopy) OR iii) Nodal status N1 must be proven (by biopsy in at least one N1 node, via EBUS, mediastinoscopy or thoracoscopy) for T3 disease.

Exclusion Criteria: Prior malignancy active within the previous 3 years except for locally curable cancers that have been apparently cured, such as basal or squamous cell skin cancer, superficial bladder cancer, or carcinoma in situ of the prostate, cervix, or breast. Prior treatment with an anti-PD-1, anti-PD-L1, anti-PD-L2, or anti-CTLA-4 antibody, or any other antibody or drug specifically targeting T-cell co-stimulation or checkpoint pathways. Prior thoracic radiotherapy. However, other prior radiotherapy is allowed and must be completed at least 30 days prior to study treatment with residual toxicities resolved prior to study enrollment. b) Use of an investigational agent or an investigational device within 28 days before
administration of first dose of study drug c) Participants who have received a live / attenuated vaccine within 30 days before first treatment d) Treatment with botanical preparations (e.g., herbal supplements or traditional Chinese medicines) intended for general health support or to treat the disease under study within 2 weeks prior to randomization/treatment.</td></tr>
</table>

LUNG- Non-Small Cell Lung Cancer:

<table>
<tr><td colspan="2">USO#19151 MRTX891-0001: A Phase ½ Multiple Expansion Cohort Trial of MRTX849 in Patients with Advanced Solid Tumors with KRAS G12C Mutation (STAR TRIAL)</td></tr>
<tr><td>Sponsor: Mirati Therapeutics, Inc.

Phase 1B single agent cohorts:
• All tumor types with limited brain mets- 8 slots available
• NSCLC with KRAS G12C mutation and prior therapy targeting the KRAS G12C mutation- 12 slots available

Phase 2 Cohorts:
Cohort D: Other tumors excluding CRC and NSCLC- reopened
Cohort E: NSCLC tx naïve with KRAS G12C & STK11 co-mutations
Cohort F: CRC with KRAS G12C mutation</td><td>Therapy Line: Unresectable or metastatic disease; dependent on available and prior therapy (see inclusion criteria)

Drug Classification: KRAS G12C inhibitor</td></tr>
<tr><td>Principal Investigator: Dr. David Ellison</td><td>CRC: Ashley Morrill ext. 291</td></tr>
<tr><td colspan="2">Location Clinical Trial Offered: West Ashley Only</td></tr>
<tr><td colspan="2">Basic Enrollment Criteria: Histologically confirmed diagnosis of a solid tumor malignancy with KRAS G12C mutation; Unresectable or metastatic disease; no available treatment with curative intent; no available standard of care treatment or patient is ineligible or declines treatment (except in Phase 2 NSCLC cohorts, patients must have previously received treatment with at least a platinum-containing chemotherapy regimen and checkpoint inhibitor therapy); Measurable disease per RECIST 1.1 Standard treatment is not available or patients.

Exclusion Criteria: Active brain metastases(dependent on cohort); known/suspected presence of another malignancy that could be mistaken for the malignancy under study; prior treatment with a therapy targeting KRAS G12C mutation; Significant hemoptysis/hemorrhage <4 weeks; major surgery <4 weeks; History of intestinal disease/major gastric surgery likely to alter absorption of study treatment; significant cardiac disease; History of stroke or transient ischemic attach <6 months; HIV/HBV/HCV; Uncontrolled infection</td></tr>
</table>

Lung- Non-Small Cell Lung Cancer:

RMC-4630-03- A Phase 2, Open-Label, Mulitcenter Study of the Combination of RMC-4630 and Sotorasib for Non-Small Cell Lung Cancer Subjects with KRAS(G12C) Mutation After Failure of Prior Standard Therapies. Evaluate the antitumor effects of RMC-4630 and Sotorasib as assessed by objective response rate per RECIST v1.1 in locally advanced or metastatic NSCLC subjects with KRASG12C mutation with and without co-existing genetic aberrations in specific genes such as STK11/LKB1, KEAP1, and PIK3CA after failure of prior standard therapy.

Sponsor: Revolution Medicines. Inc ***The Sponsor does NOT provide the Sotorasib. But, they do provide a patient assistance trial card. The prescribing physician will write a prescription (that we will provide to you), forward it to Optum Specialty Pharmacy. This covers the entire cost of the Sotorasib. ***	**Therapy Line**: No more than 3 prior lines **Drug Classification: RMC-4630:** SHP2 is a non-receptor protein tyrosine phosphatase and scaffold protein that functions downstream of multiple RTKs, integrating cell surface growth factor signals to promote RAS Activation **Sotorasib**: KRASG12C inhibitors
Principal Investigator: Dr. David Ellison	**CRC:** Ashley Morrill ext. 291

Location Clinical Trial Offered: West Ashley, Mt. Pleasant & N.Charleston

Basic Enrollment Criteria: Subject must have pathologically documented, locally advanced or metastatic *KRASG12C* NSCLC (not amenable to curative surgery) that has progressed on prior standard therapies **(no more than 3 prior lines of therapies are allowed**), as follows: Subject with actionable oncogenic driver mutations (eg, epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase [ALK], and ROS1) must have received standard-of-care anticancer treatments, including approved drugs for oncogenic drivers in their tumor type. Subject's tumor must harbor a *KRASG12C* mutation assessed by a CLIA-/CAP-certified laboratory. Subject must have measurable disease per RECIST v1.1, criteria. Subject must have a life expectancy of at least 3 months. The subject's ECOG PS of 0 to 1 with no deterioration in PS 2 weeks prior to C1D1.Rescreening is required if PS is >1 for any reason prior to C1D1. Subject must have the ability to typically ingest and retain PO medications. Subject must have adequate hematological and biological function, as follows: Bone marrow function. Absolute neutrophil count (ANC) ≥1.5 × 109/L without use of hematopoietic growth factors Hemoglobin ≥9 g/dL; subject must not have received a red blood cell(RBC) transfusion within 28 days of Screening Platelets ≥100 × 109/L; subject must not have received a platelet transfusion within 14 days of Screening Subject must have hepatic function as follows: AST and ALT ≤2.5 × upper limit of normal (ULN) Bilirubin ≤1.5 × ULN (<2.0 × ULN for subject with documented Gilbert's syndrome or <3.0 × ULN for subject for whom the indirect bilirubin level suggests an extrahepatic source of elevation)

Exclusion Criteria: Subject has primary central nervous system (CNS) tumor(s) Subject has known or suspected leptomeningeal or brain metastases or spinal cord compression. However, a subject who was previously treated for these conditions who have had stable CNS disease (no evidence of clinical and radiographic disease progression and asymptomatic in the absence of corticosteroids or anti-convulsant Protocol RMC-4630-03 V2.0 22 Jul 2021 Revolution Medicines, Inc. CONFIDENTIAL 36therapy) are eligible to participate in the study, as long as stable disease is documented by a brain magnetic resonance imaging (MRI) performed within 28-days of C1D1.
Subject who has any of the following cardiac abnormalities: Medically uncontrolled hypertension (≥160 mmHg systolic blood pressure or ≥100 mm Hg diastolic blood pressure) Congestive heart failure Class ≥2, as defined by the New York Heart Association Acute coronary syndrome (including unstable angina, coronary artery stenting, or angioplasty, bypass grafting within prior 6 months); myocardial infarction within months of informed consent d History or evidence of current, uncontrolled, clinically significant, unstable arrhythmias Subject with medically controlled atrial fibrillation >1 month prior to Study Day 1 is eligible. Subject who has a pacemaker in place to control atrial arrhythmias is a candidate for the study.

Small Cell Lung Cancer: (Observational)

JZP712-402: Phase IV Observational Study to Collect Safety and Outcome Data in Real-world setting in Adult Patients with Extensive Stage Small Cell Lung Cancer(SCLC) Receiving Zepzelca	
Sponsor: Jazz Pharmaceuticals ***OBSERVATIONAL***	*Patients who will be receiving Zepzelca treatment or patients that already started Zepzelca and have received up to 2 cycles.
Principal Investigator: Dr. Brian Lingerfelt	**CRC:** Ashley Morrill ext. 291
Location Clinical Trial Offered: West Ashley, Mount Pleasant, Carnes & North Charleston	
Inclusion Criteria: A patient must meet all of the following criteria to be eligible for participation in the study: Patient has initiated or will be receiving Zepzelca treatment in line with the Zepzelca US prescribing information. Decision to initiate treatment with Zepzelca was made as per investigator's routine treatment practice prior to enrollment in the study. Patient, or a legally acceptable representative, signed the informed consent before any study-related activities are undertaken. **Patient has initiated or will be receiving Zepzelca treatment in line with the Zepzelca US prescribing information. This can include patients that already started Zepzelca and have received up to 2 cycles.** **Exclusion Criteria** A patient who meets any of the following criteria is not eligible for participation in the study: Patients who discontinued a prior Zepzelca treatment due to adverse events. Patient who received more than 2 cycles of Zepzelca treatment in their current treatment schedule. Patient received treatment with any investigational agent within 30 days prior to first Zepzelca infusion or plans to use another investigational agent while receiving Zepzelca. Baseline visit date should be considered as the date when the patient´s first visit is done after consenting to participate in the study. Baseline is NOT the date when the patient started on Zepzelca. Zepzelca Treatment Completion Form should be completed ONLY when Zepzelca treatment has been discontinued.	

MULTIPLE MYELOMA (Observational):

IONA: A prospective, non-interventional, multinational, observational study with Isatuximab in patients with relapsed and/or refractory multiple myeloma (RRMM)	
Sponsor: SANOFI ***OBSERVATIONAL***	Therapy Line: **Relapsed/ Refractory**
Principal Investigator: George Geils, Jr., MD	**CRC:** Ashley Morrill ext. 291
Location Clinical Trial Offered: West Ashley, Mount Pleasant, Carnes & North Charleston	
Inclusion Criteria: Patients who are considered as RRMM according to the IMWG criteria; **Patients who initiated Isatuximab treatment up to a maximum of three months prior to study enrollment as well as patients who are Isatuximab-naïve at enrollment are eligible.** Able to understand and complete study related questionnaires **Exclusion Criteria:** Patients who are receiving Isatuximab for an indication other than RRMM; Patients who have received any other investigational drug or prohibited therapy for this study within 28 days or five half-lives from randomization.	

MDS:

ASTX727-03: A Randomized, Open-Label, Phase 1-2 Study of ASTX727 Low Dose (ASTX727 LD) Extended Schedule in Subjects with Lower Risk (IPSS Low or Intermediate-1) Myelodysplastic Syndromes (MDS)	
Sponsor: Astex Pharmaceuticals **Arm A: ASTX727 Standard Dose 35mg Decitabine + 100mg Cedazuridine x 3 days** **Amr B: ASTX727 Low Dose 10mg Decitabine + 100mg Cedazuridine x 5 days**	Therapy Line: **1st Line Chemotherapy** Drug Classification: **DNA methyltransferase (DNMT) inhibition** **PHASE 2 of protocol**
Principal Investigator: George Geils, Jr., MD	**CRC:** Ashley Morrill ext. 291
Location Clinical Trial Offered: West Ashley, Mount Pleasant & North Charleston	
Basic Enrollment Criteria: ECOG 0-2. Subjects with IPSS low-risk or Int-1 MDS**; Subjects must have had at least 1 of the following disease-related criteria during the 8 weeks before randomization:** a) RBC transfusion dependence of 2 or more units of RBCs or Hb of <8.5 g/dL in at least 2 blood counts prior to randomization, b) ANC of <0.5 × 109/L in at least 2 blood counts prior to randomization, c) Platelet counts of <50 × 109/L in at least 2 blood counts prior to randomization. Adequate organ function. **Exclusion Criteria: Treatment with any investigational drug or therapy within 2 weeks before study treatment, or 5 half-lives, whichever is longer before the first dose of study treatment, or ongoing clinically significant AEs from previous treatment.** Diagnosis of CMML. Prior malignancy, except for adequately treated basal cell or squamous cell skin cancer, in situ cervical cancer, prostate cancer or breast cancer under control with hormone therapy, or other cancer from which the subject has been disease free for at least 1 year. **Treatments for MDS, including erythropoietin's, colony-stimulating factors (CSFs), thrombopoietin's, chemotherapy, and immunosuppression including calcineurin inhibitors, glucocorticoids, etc., must be concluded 1 month prior to study treatment.**	

MDS:

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)	
Sponsor: FibroGen **IP is provided by the Sponsor in 20mg, 50mg, 100mg, 150mg doses.**	Drug Classification: **HIF prolyl-hydroxylase inhibitor**
Principal Investigator: David Ellison, MD	**CRC:** Ashley Morrill ext. 291
Location Clinical Trial Offered: West Ashley, Mount Pleasant & North Charleston	
Basic Enrollment Criteria: Diagnosis of primary MDS classified by the IPSS-Ras very low, low, or intermediate risk with <5% bone marrow blasts; RBC transfusion requirement of either 2 to 4 pRBC during the 8-weeks prior to registration /randomization, or 1 pRBC during the 8-weeks prior to registration/randomization; no restriction on prior use of recombinant erythropoietins or analogues; Hb ≤10.0 g/dL during Screening; ECOG performance status of 0 - 2 during screening; Body weight ≥45 kg **Exclusion Criteria:** Diagnosis of secondary MDS associated with prior chemotherapy, extensive radiation therapy (>25% of bone marrow reserve), and or/other significant chemical or radiation exposure; Previous diagnosis of IPSS-R high risk or very high risk MDS; Planned myeloablative or craniospinal radiation during the study; Prior bone marrow or stem cell transplantation; Significant myelofibrosis; MDS associated with 5q(del) cytogenetic abnormality; Screen serum erythropoietin level: >400 mIU/mL; Azacitidine, decitabine, thalidomide, lenalidomide, granulocyte colony-stimulating factor (G-CSF), or luspatercept, or any investigational drugs within 8-weeks prior to Day 1; Clinically significant anemia, as determined by the investigator, due to non-MDS etiologies; Thromboembolic event (such as deep vein thrombosis (DVT)), pulmonary embolism, myocardial infarction, stroke, or transient ischemic attack (TIA), within previous 6 months of randomization; Active infection(s) requiring systemic antibiotic therapy; History of leukemia or other active malignancy except localized and non-metastatic squamous or basal cell carcinoma of the skin, or cervical intraepithelial neoplasm; patients with a history of cured malignancy with no evidence of recurrence for at least 3 years are eligible; Previous recipient of roxadustat or another hypoxia-inducible factor prolyl hydroxylase inhibitor	

PROSTATE CANCER:

<table>
<tr><td colspan="2">USO #19191 BMS CA209-7DX: A Phase 3 Randomized, Double-Blind Study of Nivolumab or Placebo in Combination with Docetaxel, in Men with Metastatic Castration-resistant Prostate Cancer (Check-Mate 7DX: CHECKpoint pathway and nivoluMAB clinical Trial Evaluation 7DX)</td></tr>
<tr><td>Sponsor: BMS

1:1 Randomization

Arm A: Nivolumab + Prednisone + Docetaxel
Arm B: Placebo + Prednisone+ Docetaxel

Docetaxel + Prednisone not provided by sponsor</td><td>Therapy Line: 1st Line Metastatic and have received at least 1 but no more than 2 second-generation antiandrogen therapies
Drug Classification: Humanized IgG4 anti-PD-1 monoclonal antibody

Combination phase (10 cycles maximum):
Docetaxel 75mg/m2 Q3W + Prednisone 5mg PO BID + Nivolumab/Placebo 360mg Q3W

Monotherapy Phase: Nivolumab/Placebo 480mg Q4W</td></tr>
<tr><td>Principal Investigator: David Ellison, MD</td><td>CRC: Ashley Morrill ext. 291</td></tr>
<tr><td colspan="2">Location Clinical Trial Offered: West Ashley Only</td></tr>
<tr><td colspan="2">Inclusion Criteria: Chemotherapy naïve for mCRPC and have received at least 1 but no more than 2 second-generation novel antiandrogen therapies (NATs) in the recurrent non metastatic setting and/or the metastatic setting (no more than 1 prior novel androgen therapy is allowed in the mCRPC setting), or have become intolerant of the drug. Patients must have progressed during or after NATs or have documented intolerance to the drug (ie, unacceptable toxicity in spite of comprehensive supportive therapy). Histologic confirmation of adenocarcinoma of the prostate without small cell features. Diagnosis must be stated in a pathology report and confirmed by investigator. Evidence of stage IV disease as defined by AJCC criteria on previous bone, CT, and/or MRI scan. ECOG 0-1. Ongoing ADT with a GnRH analogue or bilateral orchiectomy confirmed by testosterone level ≤ 1.73 nmol/L (50ng/dL) at the screening visit. Castrate levels of testosterone must be maintained by surgical or medical means throughout the conduct of the study. For patients who have not had an orchiectomy, LHRH/GnRH analogues must have been initiated at least 4 weeks prior to first dose of study treatment. Documented prostate cancer progression per PCWG3 criteria within 6 months prior to screening. Exclusion Criteria: Prior treatment with docetaxel or another chemotherapy agent for metastatic castration-resistant prostate cancer; Prior docetaxel allowed if greater than 12 months from last dose. More than 10mg daily prednisone equivalent or other immunosupportive medications within 14 days of start of study treatment. Prior malignancy active within the previous 3 years except for locally curable cancers that have been apparently cured, such as basal or squamous cell skin cancer, superficial bladder cancer, or carcinoma in situ of the breast. Active brain mets (unless treated and there is no evidence of progression for at least 4 weeks after treatment is complete and within 28 days prior to first dose of study drug) Previously irradiated brain lesions are not considered measurable disease.</td></tr>
</table>

PROSTATE CANCER: Cohorts within Solid Tumor Exelixis Study

XL184-021 EXELIXIS: A Phase Ib Dose-Escalation Study of Cabozantinib (XL184) Administered Alone or in Combination with Atezolizumab to Subjects with Locally Advanced or Metastatic Solid Tumors

Combination Therapy Cabozantinib 20, 40, or 60mg plus Atezolizumab 1200mg
Exploratory Single-Agent Cabozantinib 60mg
Exploratory Single-Agent Atezolizumab 1200mg

Sponsor: Exelixis **Cabozantinib** will be given at 20, 40, or 60 mg orally administered every day. **Atezolizumab** (1200 mg infusion) will be administered once every 3 weeks on day 1 of each cycle ***Sponsor approval needed prior to consenting patient***	Therapy Line: **Locally Advanced/Metastatic** Drug Classification: **Cabozantinib:** Thyroxine Kinase Inhibitor (TKI) **Atezolizumab:** Anti-PD-L1 monoclonal antibody *** Dose expansion phase** **Patients will continue to receive treatment as long as long as they continue to experience clinical benefit or until there is unacceptable toxicity.**
Principal Investigator: Gene Saylors, MD	**CRC:** Ashley Morrill ext. 291

Location Clinical Trial Offered: West Ashley, North Charleston, Mt Pleasant

Multiple Cohorts: Exploratory Single-Agent Cabozantinib Cohort 21 and Combination-Therapy Expansion Cohort 23: Subjects with metastatic CRPC who have histologically or cytologically confirmed adenocarcinoma of the prostate without small cell component (Note: Neuroendocrine differentiation and other histologic components are permitted if adenocarcinoma is the primary histology) with the following requirements:

•Prior treatment with one, and only one, NHT (eg, abiraterone, apalutamide, darolutamide, or enzalutamide) for castration-sensitive locally advanced (T3 or T4) or metastatic castration-sensitive prostate cancer (mCSPC), M0 CRPC, or mCRPC. **Note: Subjects may have previously received Taxane-based chemotherapy for mCSPC but no other approved or experimental nonhormonal systemic therapies for metastatic prostate cancer**. • Bilateral orchiectomy or ongoing androgen deprivation therapy with a GnRH agonist/antagonist (surgical or medical castration), with serum testosterone ≤ 50 ng/dL (≤ 1.73 nmol/L) at screening. • Progressive disease at study entry as defined by at least one of the following two criteria: a. PSA progression defined by a minimum of 2 rising PSA values from 3 or 4 consecutive assessments with an interval of at least 7 days between assessments. The most recent qualifying PSA value must be drawn within 28 days of planned enrollment. (Note: If qualifying solely by PSA progression, the screening central lab PSA value must be at least 2 ng/mL [2 µg/L] but need not serve as last PSA value for determination of PSA progression; up to one PSA decrease is permitted as long as it is not the most recent value), OR b. Soft tissue disease progression in the opinion of the Investigator. Note: Bone disease progression alone does not qualify. • High risk metastatic disease per Investigator read as defined by at least one of the following: a. Measurable visceral disease (eg, adrenal, kidney, liver, lung, pancreas, spleen), OR b. Measurable extrapelvic adenopathy (ie, adenopathy above the aortic bifurcation)
.

SOLID TUMORS:

<table>
<tr><td colspan="2">CytomX (PROCLAIM-CX-2029): A Phase 1-2, First-in-Human Study of CX-2029 in Adults with Metastatic or Locally Advanced Unresectable Solid Tumors or Diffuse Large B-cell Lymphomas</td></tr>
<tr><td>Part C: Histologically or cytologically confirmed metastatic or locally advanced unresectable HNSCC, DLBCL, NSCLC (squamous cell histology only), or esophageal (EAC, ESCC, or GE junction) cancer</td><td>Therapy Line: Metastatic, Locally Advanced, or Unresectable. Patients must have exhausted available life prolonging therapies

Drug Classification: Humanized anti-CD71 Probody-drug conjugate (PDC)</td></tr>
<tr><td>Principal Investigator: Dr. James Orcutt</td><td>CRC: Ashley Morrill ext. 291</td></tr>
<tr><td colspan="2">Location: West Ashley, Mt. Pleasant, N. Charleston</td></tr>
<tr><td colspan="2">Basic Inclusion Criteria: ECOG 0 to 1, Agree to provide tumor tissue; archival, new, or recent acquisition confirmed to be available prior to initiation of study drug for performance of correlative tissue and cellular studies from a tumor site not previously irradiated. Subjects with advanced or metastatic stage IV NSCLC with known EGFR or ALK genomic alterations are eligible if they have progressed on treatment or did not tolerate appropriate targeted therapy. Subjects with known NSCLC with known ROS1 rearrangement must have received prior treatment with crizotinib. Subjects with known B-RAF mutations must have received prior treatment with a B-RAF inhibitor. Subjects with HNSCC and esophageal (EAC, ESCC, or GE junction) cancer must have received a platinum-containing regimen (unless intolerant or not suitable) and a PD-1 inhibitor if approved for subject's indication in their locality. Relapsed or refractory DLBCL after 2 lines of systemic therapy. At least 1 line should contain anti-CD20 based immunochemotherapy, and subjects should not be candidates for autologous hematopoietic stem cell transplantation. Subjects with EAC, ESCC, or GE junction cancer should have received at least 1 line of systemic chemotherapy or chemoradiation, unless intolerant or not suitable. Subjects with known HER2 overexpressing tumors should have received treatment with HER2-targeted therapy. Documented progression or relapse after at least 1 prior systemic therapy. Moreover, subjects must have exhausted available life prolonging therapies

Basic Exclusion Criteria: Serious concurrent illness. History of another malignancy within 2 years. Current anticoagulation with Warfarin. Transfusion dependent anemia. Inability to discontinue treatment with a strong CYP3A4 inhibitor or inducer prior to start of treatment. Neuropathy >Grade 1. History of severe allergy or anaphylactic reaction to previous monoclonal antibodies or known hypersensitivity to auristatins. Clinically significant iron metabolism disorders. Use of iron chelators. Major surgery within 3 months prior to study enrollment. Live vaccine within 28 days prior to planned dose. Participation in any clinical study involving medications, radiation, or surgery. Women who are pregnant or breast-feeding.</td></tr>
</table>

SOLID TUMORS:

<table>
<tr><td colspan="2">USO#19151 MRTX891-0001: A Phase ½ Multiple Expansion Cohort Trial of MRTX849 in Patients with Advanced Solid Tumors with KRAS G12C Mutation (STAR TRIAL)</td></tr>
<tr><td>Sponsor: Mirati Therapeutics, Inc.

Phase 1B single agent cohorts:
• All tumor types with limited brain mets- 8 slots available
• NSCLC with KRAS G12C mutation and prior therapy targeting the KRAS G12C mutation- 12 slots available

Phase 2 Cohorts:
Cohort D: Other tumors excluding CRC and NSCLC- reopened
Cohort E: NSCLC tx naïve with KRAS G12C & STK11 co-mutations
Cohort F: CRC with KRAS G12C mutation</td><td>Therapy Line: Unresectable or metastatic disease; dependent on available and prior therapy (see inclusion criteria)

Drug Classification: KRAS G12C inhibitor</td></tr>
<tr><td>Principal Investigator: Dr. David Ellison</td><td>CRC: Ashley Morrill ext. 291</td></tr>
<tr><td colspan="2">Location Clinical Trial Offered: West Ashley Only</td></tr>
<tr><td colspan="2">Basic Enrollment Criteria: Histologically confirmed diagnosis of a solid tumor malignancy with KRAS G12C mutation; Unresectable or metastatic disease; no available treatment with curative intent; no available standard of care treatment or patient is ineligible or declines treatment (except in Phase 2 NSCLC cohorts, patients must have previously received treatment with at least a platinum-containing chemotherapy regimen and checkpoint inhibitor therapy); Measurable disease per RECIST 1.1 Standard treatment is not available or patients.

Exclusion Criteria: Active brain metastases(dependent on cohort); known/suspected presence of another malignancy that could be mistaken for the malignancy under study; prior treatment with a therapy targeting KRAS G12C mutation; Significant hemoptysis/hemorrhage <4 weeks; major surgery <4 weeks; History of intestinal disease/major gastric surgery likely to alter absorption of study treatment; significant cardiac disease; History of stroke or transient ischemic attach <6 months; HIV/HBV/HCV; Uncontrolled infection</td></tr>
</table>