Erik Letko, MD

Location: Rock Creek

Area of expertise: Ophthalmology

ACTIVELY ENROLLING

Humanitarian Use Device - Keratoconus patients where a corneal transplant is the only remaining option to improve vision

Title: Correction of Myopia and Astigmatism Associated with Keratoconus Using Intacs Corneal Implants (INTACS)



Principal Investigator Portfolio

Daniel Mogyoros, MD Location: Skyline

Area of expertise: Infectious Diseases

ACTIVELY ENROLLING

Expanded Access Program - Non-Tuberculosis Mycobacterial Infections

Title: Multiple Patient Program for Lamprene (clofazimine) for the treatment of Non-Tuberculous Mycobacterial (NTM) Infections (CLAM320B2002M)



Mpox Brincidofovir eIND

Title: Emergency Use of Brincidofovir (TEMBEXA) for a Single Adult with Positive Results of Human Monkeypox Viral Testing

Principal Investigator Portfolio

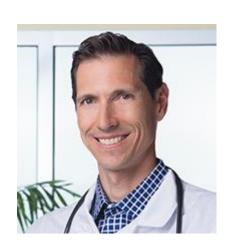
Christopher Shepela, MD Location: Lone Tree

Area of expertise: Gastroenterology



Crohn's Disease

Title: A Phase 4 Study Evaluating Real-World Use of CDPATH™, a Crohn's Disease Risk Prediction Tool



Carla Saveli, MD Location: Skyline

Area of expertise: Infectious Disease

ACTIVELY ENROLLING

TPOXX

Title: Expanded Access IND Protocol: Use of Tecovirimat (TPOXX) for Treatment of Human Non-Variola Orthopoxvirus Infections in Adults and Children



Principal Investigator Portfolio

Toya Ellis, MD

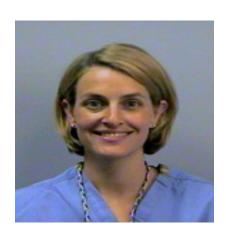
Location: East Denver

Area of expertise: Obstetrics and Gynecology

ACTIVELY ENROLLING

Genomic Markers in Menstrual Blood

Title: Case-Control Study II of Genomic Markers in Menstrual Blood for Diagnosis of Uterine Disorders (NextGenJane)



Principal Investigator Portfolio

Brittany Bastow, MD Location: East Denver

Area of expertise: Obstetrics and Gynecology

ACTIVELY ENROLLING

Endometroisis - HerResolve

Title: HerResolve Clinical Performance Study



Debra Ritzwoller, PhD Location: Waterpark III

Area of Expertise: Oncology (CCDR)

ACTIVELY ENROLLING

Metastatic Breast Cancer

Title: (EAQ221CD) Improving Medication Adherence in Metastatic Breast Cancer using a CONnected Customized

Treatment Platform (CONCURxP)



CONNECT Intervention – Lung Cancer Caregivers

Title: (WF2301CD) Multi-site Community Oncology Planning for the CONNECT Intervention Targeting Lung Cancer Caregivers.

CLOSED TO ENROLLMENT

Cancer-Related Financial Hardship (Financial Navigation Intervention)

Title: (S1912CD) A Randomized-Trial Addressing Cancer-Related Financial Hardship through Delivery of a Proactive Financial Navigation Intervention (CREDIT)

Principal Investigator Portfolio

Alex Menter, MD Location: Lone Tree

Area of expertise: Oncology

ACTIVELY ENROLLING

1) Cancer Disparities in Trials

Title: Use of a Clinical Trial Screening Tool to Address Cancer Health Disparities in the NCI Community Oncology Research Program (DCP-001)

2) Pain Management for Cancer Survivors

Title: Internet-delivered Management of Pain Among Cancer Treatment Survivors (WF-1901)

3) Cancer Related Fatigue (Breast Cancer)

Title: Randomized Placebo Controlled Trial of Bupropion For Cancer Related Fatigue (URCC-18007)

4) Resected Non-Small Cell Lung Cancer (NSCLC)

Title: (A081801) Integration of Immunotherapy Into Adjuvant Therapy for Resected NSCLC: ALCHEMIST Chemo-IO (ACCIO)

5) Metastatic EGFR-Mutant Non-Small Cell Lung Cancer (NSCLC)

Title: (EA5182) Randomized Phase III Study of Combination Osimertinib (AZD9291) and Bevacizumab Versus Osimertinib (AZD9291) Alone as First-Line Treatment for Patients with Metastatic EGFR-Mutant Non-Small Cell Lung Cancer (NSCLC)

6) Colon Adjuvant Chemotherapy

Title: (NRG-GI008) Colon Adjuvant Chemotherapy based on Evaluation of Residual Disease (CIRCULATE – US)

7) Squamous Cell Carcinoma of Head and Neck

Title: (NRG-HN009) Randomized Phase II/III Trial of Radiation with High-Dose Cisplatin (100 mg/m2) Every Tree Weeks versus Radiation with Low-Dose Weekly Cisplatin (40 mg/m2) for Patients with Locoregionally Advanced Squamous Cell Carcinoma of the Head and Neck (SCCHN)

8) Immune Checkpoint Inhibitor: Anti-PD-1/Anti-PD-L1 Immunotherapy

Title: (URCC-21038) Disparities in Results of Immune Checkpoint Inhibitor Treatment with anti-PD-1/anti-PD-L1 Immunothereapy in a Community Oncology Setting (DiRECT)

9) Lung MAP Screening – Non Small Cell Lung Cancer

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

10) Anti-PD-1 Therapy – Advanced Melanoma

Title: (EA6192) A Phase II Study of Biomarker Driven Early Discontinuation of Anti-PD-1 Therapy in Patients with Advanced Melanoma (PET-Stop)

11) Behavioral Therapy – Randomized Control Trial

Title: (URCC-19185) Multicenter Randomized Controlled Trial comparing Brief Behavioral Therapy for Cancer Related Insomnia (BBT-CI) and Healthy Eating Education Learning (HEAL).

12) FORTE – Colonoscopy for 1-2 Non-Advanced Adenomatous Polyps

Title: (NRG-CC005) FORTE – Five or Ten Year Colonoscopy for 1-2 Non-Advanced Adenomatous Polyps

13) Multiple Myeloma

Title: Phase III Study of Daratumumab/rHuPH20 (NSC-810307) + Lenalidomide or Lenalidomide as Post-Autologous Stem Cell Transplant Maintenance Therapy in Patients with Multiple Myeloma (MM) Using Minimal Residual Disease to Direct Therapy Duration (DRAMMATIC Study) (S1803)

14) Triple-Negative Breast Cancer (TNBC)

Title: (A012103) OptimICE-pCR: De-Escalation of Therapy in Early-Stage TNBC Patients Who Achieve pCR After Neoadjuvant Chemotherapy with Checkpoint Inhibitor Therapy

15) Optimizing Endocrine Therapy (Breast Cancer)

Title: Optimizing Endocrine Therapy Through Motivational Interviewing and Text Interventions (A191901)

16) Stage III and IV Melanoma

Title: Randomized Phase II/III Study of Nivolumab plus Ipilimumab plus Sargramostim versus Nivolumab plus Ipilimumab in Patients with Unresectable Stage III or Stage IV Melanoma (EA6141)

17) Immune Checkpoint Inhibitor Toxicity

Title: Immune Checkpoint Inhibitor Toxicity (I-CHECHIT): A Prospective Observational Study (S2013)

18) Newly Diagnosed Multiple Myeloma

Title: A Phase III Randomized Trial for Newly Diagnosed Multiple Myeloma (NDMM) Patients Considered Frail or in a Subset of "Intermediate Fit" Comparing Upfront Three-Drug Induction Regimens Followed by Double or Single-Agent Maintenance (S2209)

19) Complementary Options for Symptom Management in Cancer (COSMIC)

Title: Complementary Options for Symptom Management in Cancer (COSMIC): Assessing Benefits and Harms of Cannabis and Cannabinoid Use Among a Cohort of Cancer Patients Treated in Community Oncology Clinics (WF2304-A172401)

CLOSED TO ENROLLMENT

1) Breast Cancer

Title: Randomized Phase III Trial Evaluating the Role of Weight Loss in Adjuvant Treatment of Overweight and Obese Women With Early Breast Cancer (A011401 (BWEL))

2) Stage II and III Bladder Urothelial Cancer

Title: Phase III Randomized Adjuvant Study of MK-3475 (Pembrolizumab) in Muscle Invasive and Locally Advanced Urothelial Carcinoma (AMBASSADOR) Versus Observation (A031501)

3) High-Risk Anal Cancer

Title: A Randomized Phase II Study of Nivolumab after Combined Modality Therapy (CMT) in High Risk Anal Cancer (EA2165)

4) Stage IB-IIIA Non-Small Cell Lung Cancer

Title: Adjuvant Nivolumab in Resected Lung Cancers (ANVIL) - A Randomized Phase III Study of Nivolumab After Surgical Resection and Adjuvant Chemotherapy in Non-Small Cell Lung (Daughter study of ALCHEMIST) (EA5142)

5) Chronic Lymphocytic Leukemia (CLL)

Title: A Randomized Phase III Study of the Addition of Venetoclax to Ibrutinib and Obinutuzumab Versus Ibrutinib and Obinutuzumab in Untreated Younger Patients With Chronic Lymphocytic Leukemia (CLL) (EA9161)

6) Untreated Chronic Lymphocytic Leukemia

Title: A Randomized Phase III Study of Bendamustine Plus Rituximab Versus Ibrutinib Plus Rituximab Versus Ibrutinib Alone in Untreated Older Patients (≥ 65 Years of Age) with Chronic Lymphocytic Leukemia (CLL) (A041202)

7) Plasma Cell Myeloma/Multiple Myeloma

Title: Randomized Phase III Trial of Bortezomib, Lenalidomide, and Dexamethasone (VRd) Versus Carfilzomib, Lenalidomide, and Dexamethasone (CRd) Followed by Limited or Indefinite Duration Lenalidomide Maintenance in Patients With Newly Diagnosed Symptomatic Multiple Myeloma (E1A11)

8) Mantle Cell Lymphoma

Title: Intergroup Randomized Phase II Four Arm Study in Patients With Previously Untreated Mantle Cell Lymphoma Of Therapy With: Arm A = Rituximab + Bendamustine Followed By Rituximab Consolidation (RB \rightarrow R); Arm B = Rituximab + Bendamustine + Bortezomib Followed By Rituximab Consolidation (RBV \rightarrow R), Arm C = Rituximab + Bendamustine Followed By Lenalidomide + Rituximab Consolidation (RB \rightarrow LR) or Arm D = Rituximab + Bendamustine + Bortezomib Followed By Lenalidomide + Rituximab Consolidation (RBV \rightarrow LR) (E1411)

9) Melanoma

Title: A Phase III Randomized Study of Adjuvant Ipilimumab Anti-CTLA4 Therapy Versus High-Dose Interferon alfa-2b for Resected High-Risk Melanoma (E1609)

10) Chronic Lymphocytic Leukemia or small lymphocytic lymphoma

Title: A Randomized Phase III Study of Ibrutinib (PCI-32765)-Based Therapy vs Standard Fludarabine, Cyclophosphamide, and Rituximab (FCR) Chemoimmunotherapy in Untreated Younger Patients With Chronic Lymphocytic Leukemia (CLL) (E1912)

11) Breast Cancer

Title: A Double-Blind Phase III Trial of Doxorubicin and Cyclophosphamide Followed by Paclitaxel With Bevacizumab or Placebo in Patients With Lymph Node Positive and High Risk Lymph Node Negative Breast Cancer (E5103)

12) ALK Rearrangements/Translocation

Title: Crizotinib in Patients with Tumors (other Than Adenocarcinoma of Lung or ALCL) with ALK Rearrangements (MATCH Substudy F) (EAY131)

13) ROS1 Translocation or Inversion

Title: Phase II Study of Crizotinib in Patients with ROS1 Translocations (Other Than Patients with Non-Small Cell Lung Cancer) (MATCH Substudy G)

14) BRAF V600E or V600K Mutations

Title: Phase II Study of Dabrafenib and Trametinib in Patients with Tumors with BRAF V600E or V600K Mutations (Excluding Melanoma, Thyroid Cancer, Colorectal Adenocarcinoma, and Non-Small Cell Lung Cancer) (MATCH Substudy H)

15) PIK3CA Mutation

Title: GDC-0032 (taselisib) in Patients with Tumors (other than breast cancer) with PIK3CA Mutation but without KRAS Mutation or PTEN Loss (MATCH Substudy I)

16) HER2 Amplification

Title: Ado-trastuzumab Emtansine in Patients with Tumors with HER2 Amplification (Except Breast and Gastric/Gastro-Esophageal Junction (GEJ) Adenocarcinomas) (MATCH Substudy Q)

17) BRAF Fusion or BRAF Non-V600 Mutation

Title: Phase II Study of Trametinib in Patients with BRAF Fusions, or with Non-V600E, Non-V600K BRAF Mutations (MATCH Substudy R)

18) NF2 Inactivating Mutation

Title: VS-6063 (defactinib) in Patients with Tumors with NF2 Loss (MATCH Substudy U)

19) AKT Mutation

Title: AZD5363 in Patients with Tumors with AKT Mutations (MATCH Substudy Y)

20) Women with Recurrent Platinum-Sensitive Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

Title: A Phase III Study Comparing Single-Agent Olaparib or the Combination of Cediranib and Olaparib to Standard Platinum-Based Chemotherapy in Women with Recurrent Platinum-Sensitive Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (GY004)

21) High-risk, Hormone Receptor Positive, HER2 Negative Breast Cancer

Title: Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients With High-Risk, Hormone Receptor-Positive and HER2/Neu Negative Breast Cancer (S1207)

22) High Risk Resected Melanoma

Title: A Phase III Randomized Trial Comparing Physician/Patient Choice of Either High Dose Interferon or Ipilimumab to MK-3475 (Pembrolizumab) in Patients with High Risk Resected Melanoma (S1404)

23) Triple-Negative Breast Cancer

Title: A Randomized, Phase III Trial to Evaluate the Efficacy and Safety of MK-3475 (Pembrolizumab) as Adjuvant Therapy for Triple Receptor-Negative Breast Cancer With ≥ 1 CM Residual Invasive Cancer or Positive Lymph Nodes (ypN+) After Neoadjuvant Chemotherapy (S1418)

24) EGFR T790M Mutation or Rare Activating Mutations of EGFR

Title: AZD9291 in Patients with Tumors Having EGFR T790M Mutations (Except Non-Small Cell Lung Cancer) or Rare Activating Mutations of EGFR (MATCH Substudy E)

25) Tumors with cKIT Exon 9, 11, 13, or 14 Mutation

Title: Phase II Study of Sunitinib in Patients with Tumors with cKIT Mutations (Excluding GIST, Renal Cell Carcinoma or Pancreatic Neuorendocrine Tumor) (MATCH Substudy V)

26) Advanced Refractory Cancers/Lymphomas/Multiple Myeloma

Title: Molecular Analysis for Therapy Choice (MATCH)

Arms: After screening, patients assigned to 1 of 30 subprotocols

27) Metastatic Untreated Colorectal Cancer

Title: Randomized Double-Blind Phase III Trials of Vitamin D3 Supplementation in Patients with previously Untreated Metastatic Colorectal Cancer (SOLARIS) (A021703)

28) Stage III Colon Cancer & DNA Repair Disorder

Title: Randomized Trial of Standard Chemotherapy Alone or Combined With Atezolizumab as Adjuvant Therapy for Patients With Stage III Colon Cancer and Deficient DNA Mismatch Repair (A021502)

29) Chronic Lymphocytic Leukemia (CLL)

Title: A Randomized Phase III Study of Ibrutinib Plus Obinutuzumab Versus Ibrutinib Plus Venetoclax and Obinutuzumab in Untreated Older Patients (>/= 70 Years of Age) with Chronic Lymphocytic Leukemia (CLL) (A041702)

30) Triple-Negative Breast Cancer

Title: A Randomized Phase III Trial of Adjuvant Therapy Comparing Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel With or Without Carboplatin for Node-Positive or High-Risk Node-Negative Triple-Negative Invasive Breast Cancer (NRG-BR003)

31) Stage III-IV High-Risk Melanoma

Title: A Phase II Randomized Study of Adjuvant vs. Neoadjuvant MK-3475 (Pembrolizumab) for Clinically Detectable Stage III-IV High-Risk Melanoma (S1801)

32) Rare Tumors

Title: DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors (S1609)

33) Non-Small Cell Lung Cancer (NSCLC)

Title: INSIGNA A Randomized, Phase III Study of Firstline Immunotherapy Alone or in Combination with Chemotherapy in Induction/Maintenance or Postprogression in Advanced Nonsquamous Non-Small Cell Lung Cancer (NSCLC) with Immunobiomarker SIGNature-Driven Analysis (EA5163)

34) Stage IB-IIIA Non-Small Cell Lung Cancer + ALK gene mutation

Title: A Randomized Phase III Trial for Surgically Resected Early Stage Non-small Cell Lung Cancer: Crizotinib Versus Observation for Patients With Tumors Harboring the Anaplastic Lymphoma Kinase (ALK) Fusion Protein (*Daughter study of ALCHEMIST*) (E4512)

35) Metastatic Untreated Renal Cell Cancer

Title: PD-Inhibitor (Nivolumab) and Ipilimumab Followed by Nivolumab Vs. VEGF TKI Cabozantinib with Nivolumab: A Phase III Trial in Metastatic Untreated REnal Cell CancEr [PDIGREE] (A031704)

36) Peripheral Neuropathy

Title: Duloxetine to Prevent Oxaliplatin-Induced Chemotherapy-Induced Peripheral Neuropathy: A Randomized, Double-Blind, Placebo-Controlled Phase II to Phase III Study (A221805)

37) Non-Small Cell Lung Cancer (NSCLC)

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

38) PRAGMATICA – Immunotherapy for Stage IV or Recurrent Non-Small Cell Lung Cancer

Title: (S2302) Pragmatica - Lung: A Prospective Randomized Study of Ramucirumab (LY3009806; NSC 749128) Plus Pembrolizumab (MK-3475; NSC 776864) Versus Standard of Care for Participants Previously Treated with Immunotherapy for Stage IV or Recurrent Non-Small Cell Lung Cancer.

39) Stage IB-IIIA Non-Small Cell Lung Cancer

Title: Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST) (A151216)

Fady Iskander, MD Location: Rock Creek

Area of expertise: Cardiology

ACTIVELY ENROLLING

Actue Coronarary Syndrome (ACS)

Title: A phase III, double blind, randomized placebo-controlled study to evaluate the effects of dalcetrapib on cardiovascular (CV) risk in a genetically defined population with recent Acute Coronarary Syndrome (ACS): The DAL-302 (dal-GenE-2) trial



Principal Investigator Portfolio

Jill Gersh, MD

Location: Skyline/Lone Tree

Area of Expertise: Infectious Disease

ACTIVELY ENROLLING

Mpox JYNNEOS Vaccine EUA

Title: Expanded Access IND Protocol: Use of Vaccinia Immune Globulin Intravenous (VIGIV, CNJ-016) for Treatment of Human Orthopoxvirus

