

### **Principal Investigator Portfolio**

Erik Letko, MD  
Location: Rock Creek  
Area of expertise: Ophthalmology

#### **ACTIVELY ENROLLING**

#### **Humanitarian Use Device**

##### **1) 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**

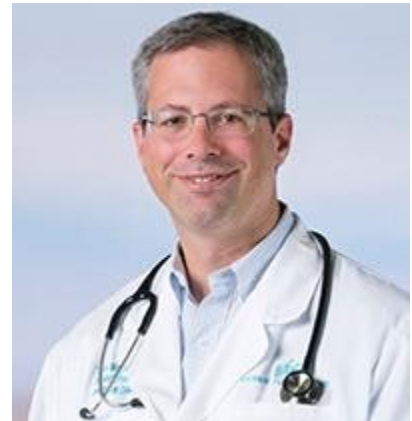
##### **1) Non-Tuberculosis Mycobacterial Infections**

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

#### **Single Patient Use**

##### **2) Mycobacterial Diseases**

Title: (Clofazimine SPU D.Mogyoros HKR) Single Patient Use Of Clofazimine For The Treatment Of Mycobacterial Disease



**Principal Investigator Portfolio**

Miguel Mogyoros, MD  
Location: Skyline  
Area of expertise: Infectious Diseases



**ACTIVELY ENROLLING**

**Expanded Access Program**

**1) Stamaril Yellow Fever Vaccine**

Title: Expanded Access IND Program to Provide Stamaril Vaccine to Persons in the United States for Vaccination Against Yellow Fever

**CLOSED TO ENROLLMENT**

**1) HIV-1 Infection**

Title: A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of GS-9883/Emtricitabine/Tenofovir Alafenamide Versus Dolutegravir + Emtricitabine/Tenofovir Alafenamide in HIV-1 Infected, Antiretroviral Treatment-Naïve Adults

**2) HIV**

Title: A Phase III Multicenter, Double-Blind, Randomized, Active Comparator-Controlled Clinical Trial to Evaluate the Safety and Efficacy of MK-1439A Once-Daily Versus ATRIPLA™ Once-Daily in Treatment-Naïve HIV-1 Infected Subjects

**Principal Investigator Portfolio**

Peter Schultze, MD  
Location: Aurora Centrepont  
Area of expertise: OB/GYN



**CLOSED TO ENROLLMENT**

**1) Contraception**

Title: A Multi-Center, Multi-National Clinical Study to Evaluate the Safety and Effectiveness of the Essure (Model ESS505) Device to Prevent Pregnancy in Women Who are Seeking Permanent Contraception

**Principal Investigator Portfolio**

Chris Shepela, MD

Location: Lone Tree

Area of expertise: Gastroenterology

**ACTIVELY ENROLLING**

**1) Crohn's Disease**

Title: A Phase 2 Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of BMS-986165 in Subjects with Moderate-to-Severe Crohn's Disease

**2) Crohn's Disease**

Title: An Open-Label, Phase 4 Study to Evaluate the Efficacy and Safety of Triple Combination Therapy with Vedolizumab IV, Adalimumab SC, and Oral Methotrexate in Early Treatment of Subjects with Crohn's Disease Stratified at Higher Risk for Developing Complications



**Principal Investigator Portfolio**

Matthew Eadens, MD

Location: Franklin

Area of expertise: Oncology

**CLOSED TO ENROLLMENT**

**Urothelial Cancer**

Title: A Phase III Randomized, Controlled Clinical Trial of Pembrolizumab With or Without Platinum-Based Combination Chemotherapy Versus Chemotherapy in Subjects With Advanced or Metastatic Urothelial Carcinoma (MK-3475-361)



### **Principal Investigator Portfolio**

Jennifer Eisenstein, MD  
Location: Rock Creek  
Area of expertise: Oncology



#### **CLOSED TO ENROLLMENT**

##### **1) Non-Small Cell Lung Cancer**

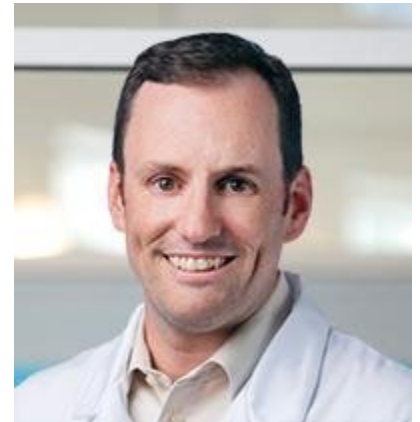
Title: A Randomized Phase 2 Trial of AM0010 in Combination With Pembrolizumab vs. Pembrolizumab Alone as First-Line (1L) Therapy in Patients With Stage IV / Metastatic Wild Type (WT) Non-Small Cell Lung Cancer and Tumors With High Expression of PD-L1 (> 50%) (ARMO 201, Cypress 1)

##### **2) Non-Small Cell Lung Cancer**

Title: A Randomized Phase 2 Trial of AM0010 in Combination With Nivolumab vs. Nivolumab Alone as Second-Line Therapy in Subjects With Stage IV / Metastatic Wild Type Non-Small Cell Lung Cancer and Low Tumor Expression of PD-L1 (ARMO 202, Cypress 2)

### **Principal Investigator Portfolio**

Joshua Klopper, MD  
Location: Skyline  
Area of expertise: Endocrinology



#### **ACTIVELY ENROLLING**

##### **Differentiated Thyroid Cancer (DTC)**

Title: Clinical Performance Evaluation of a New Thyroglobulin Assay in Subjects with Differentiated Thyroid Cancer; TG II assay  
Observational Device Study

## **Principal Investigator Portfolio**

Scott Kono, DO

Location: Lone Tree

Area of expertise: Oncology

### **ACTIVELY ENROLLING**

#### **1) Colorectal cancer**

Title: Phase 2 Study Comparing Efficacy and Safety of ABT-165 Plus FOLFIRI vs Bevacizumab Plus FOLFIRI in Metastatic Colorectal Cancer Previously Treated With Fluoropyrimidine/Oxaliplatin and Bevacizumab (M14-064)

### **CLOSED TO ENROLLMENT**

#### **1) Non-Small Cell Lung Cancer**

Title: A Phase III, Open-Label, Randomized Study of Atezolizumab (MPDL3280A, Anti-PD-L1 Antibody) in Combination With Carboplatin+Paclitaxel With or Without Bevacizumab Compared With Carboplatin + Paclitaxel + Bevacizumab in Chemotherapy-Naïve Patients With Stage IV Non-Squamous Non-Small Cell Lung Cancer

#### **2) Stage IV Pancreatic Ductal Adenocarcinoma**

Title: A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study of PEGylated Recombinant Human Hyaluronidase (PEGPH20) in Combination With Nab-Paclitaxel Plus Gemcitabine Compared With Placebo Plus Nab-Paclitaxel and Gemcitabine in Participants With Hyaluronan-High Stage IV Previously Untreated Pancreatic Ductal Adenocarcinoma (Halozyme (HALO))

#### **3) Triple Negative Breast Cancer**

Title: A Phase III, Multicenter, Randomized, Placebo-Controlled Study of Atezolizumab (Anti-PD-L1 Antibody) in Combination With Nab-Paclitaxel Compared With Placebo With Nab-Paclitaxel for Patients With Previously Untreated Metastatic Triple-Negative Breast Cancer (WO29522)



## Principal Investigator Portfolio

Alex Menter, MD  
Location: Lone Tree  
Area of expertise: Oncology



### ACTIVELY ENROLLING

#### **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) Node Positive HER2 Negative Breast Cancer**

Title: A Randomized Phase III Double Blinded Placebo Controlled Trial of Aspirin as Adjuvant Therapy for HER2 Negative Breast Cancer: The ABC Trial (A011502)

#### **3) 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

#### **4) 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

#### **5) Chronic Lymphocytic Leukemia (CLL)**

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

#### **6) Stage IB-III A Non-Small Cell Lung Cancer**

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

#### **7) Non-Small Cell Lung Cancer**

Title: Randomized Study of Erlotinib vs Observation in Patients With Completely Resected Epidermal Growth Factor Receptor (EGFR) Mutant Non-small Cell Lung Cancer (NSCLC) (Daughter study of ALCHEMIST)

#### **8) Stage IB-III A 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*)

#### **9) Stage IB-III A 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)

## **10) Chronic Lymphocytic Leukemia**

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)

## **11) 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

## **12) Cancer Disparities in Trials**

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

## **13) Stage I, II, or III Colorectal Cancer**

Title: Longitudinal Assessment of Financial Burden in Patients With Colon or Rectal Cancer Treated With Curative Intent

## **14) Advanced Refractory Cancers/Lymphomas/Multiple mMyeloma**

Title: Molecular Analysis for Therapy Choice (MATCH)  
Arms: After screening, patients assigned to 1 of 30 subprotocols

### *MATCH SUBSTUDIES*

## **15) Solid Tumors; EGFR Activating Mutation**

Title: Phase II Trial of Afatinib in Patients with Solid Tumors (Other Than Small Cell and Non-Small Cell Lung Cancer) or Lymphomas, That Have Activating Mutations of EGFR and Have Progressed After Standard Treatment (MATCH Substudy)

## **16) 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)

## **17) 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 Neuroendocrine Tumor) (MATCH Substudy)

## **18) Stage I, II, or III Breast or Gynecological Cancer**

Title: Phase II Double Blind Dose Finding Trial of Bupropion Versus Placebo for Sexual Desire in Women With Breast or Gynecologic Cancer

### **19) Recurrent Platinum-Resistant or -Refractory Ovarian, Fallopian Tube or Primary Peritoneal Cancer**

Title: A Randomized Phase II/III study of the combination of Cediranib and Olaparib compared to Cediranib or Olaparib alone, or Standard of care chemotherapy in women with recurrent platinum-resistant or -refractory ovarian, fallopian tube, or primary peritoneal cancer (COCOS)

### **20) Recurrent Platinum-Resistant Ovarian, Fallopian Tube, or Primary Peritoneal Cancer**

Title: A Randomized, Phase II/III Study of Pegylated Liposomal Doxorubicin and CTEP-Supplied Atezolizumab Versus Pegylated Liposomal Doxorubicin/Bevacizumab and CTEP-Supplied Atezolizumab Versus Pegylated Liposomal Doxorubicin/Bevacizumab in Platinum Resistant Ovarian Cancer

### **21) 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  $\geq 1$  CM Residual Invasive Cancer or Positive Lymph Nodes (ypN+) After Neoadjuvant Chemotherapy

### **22) Metastatic HER2 Positive Breast Cancer**

Title: Prospective Evaluation of Carvedilol in Prevention of Cardiac Toxicity in Patients with Metastatic HER-2+ Breast Cancer, Phase III

### **23) Rare Tumors**

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

### **24) 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

### **25) Cancer Treatment based on Molecular Alterations**

Title: Profiling Biospecimens From Cancer Patients to Screen for Molecular Alterations Related to Treatment Selection

### **26) Breast Cancer Survivors with Cognitive Impairment after Chemotherapy Exposure**

Title: A Phase 3 Randomized Placebo Controlled Clinical Trial of Donepezil in Chemotherapy Exposed Breast Cancer Survivors With Cognitive Impairment



## CLOSED TO ENROLLMENT

### **1) Castration-Resistant Metastatic Prostate Cancer**

Title: Phase III Trial of Enzalutamide Versus Enzalutamide, Abiraterone and Prednisone for Castration Resistant Metastatic Prostate Cancer

### **2) 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)

### **3) Glioblastoma Multiforme**

Title: A Phase II/III Randomized Trial Of Veliparib Or Placebo In Combination With Adjuvant Temozolomide In Newly Diagnosed Glioblastoma With MGMT Promoter Hypermethylation

### **4) Breast Cancer**

Title: A Randomized, Multicenter, Open-Label Phase III Study to Evaluate the Efficacy and Safety of Trastuzumab Emtansine Versus Trastuzumab as Adjuvant Therapy for Patients With HER2-Positive Primary Breast Cancer Who Have Residual Tumor Present Pathologically in the Breast or Axillary Lymph Nodes Following Preoperative Therapy

### **5) High risk HER2 Negative Breast Cancer + Germline BRCA 1/2 Mutation**

Title: A Randomised, Double-blind, Parallel Group, Placebo-controlled Multi-centre Phase III Study to Assess the Efficacy and Safety of Olaparib Versus Placebo as Adjuvant Treatment in Patients With gBRCA1/2 Mutations and High Risk HER2 Negative Primary Breast Cancer Who Have Completed Definitive Local Treatment and Neoadjuvant or Adjuvant Chemotherapy

### **6) Advanced Transitional Cell Urinary Tract Cancer**

Title: A Randomized Double-Blinded Phase III Study Comparing Gemcitabine, Cisplatin, and Bevacizumab to Gemcitabine, Cisplatin, and Placebo in Patients With Advanced Transitional Cell Carcinoma

### **7) Metastatic Colon Cancer**

Title: A Phase III Trial of 6 Versus 12 Treatments of Adjuvant FOLFOX Plus Celecoxib or Placebo for Patients With Resected Stage III Colon Cancer

### **8) 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

## **9) 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 → R); Arm B = Rituximab + Bendamustine + Bortezomib Followed By Rituximab Consolidation (RBV → R), Arm C = Rituximab + Bendamustine Followed By Lenalidomide + Rituximab Consolidation (RB → LR) or Arm D = Rituximab + Bendamustine + Bortezomib Followed By Lenalidomide + Rituximab Consolidation (RBV → LR)

## **10) Diffuse Large B Cell Lymphoma**

Title: Randomized Phase II Open Label Study of Lenalidomide RCHOP (R2CHOP) vs RCHOP (Rituximab, Cyclophosphamide, Doxorubicin, Vincristine and Prednisone) in Patients with Newly Diagnosed Diffuse Large B Cell Lymphoma

## **11) Melanoma**

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

## **12) 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)

## **13) 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

## **14) 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

## **15) Tumor Testing for Genetic Mutations**

Title: COMET - Communication and Education in Tumor Profiling: A Randomized Study of Pre-disclosure Genetic Education v. Usual Care in Tumor Profiling for Advanced Cancer

## **16) ALK Rearrangements/Translocation**

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

## **17) 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)

### **18) 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)

### **19) 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)

### **20) HER2 Amplification**

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

### **21) 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)

### **22) NF2 Inactivating Mutation**

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

### **23) Akt Mutation**

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

### **24) Stage III or IV Ovarian Cancer**

Title: Veliparib With Carboplatin and Paclitaxel and as Continuation Maintenance Therapy in Subjects With Newly Diagnosed Stage III or IV, High-grade Serous, Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

### **25) Small Cell Lung Cancer**

Title: A Randomized, Double-Blind, Placebo-Controlled Phase 3 Study of Rovalpituzumab Tesirine as Maintenance Therapy Following First-Line Platinum-Based Chemotherapy in Subjects With Extensive Stage Small Cell Lung Cancer

### **26) Breast Cancer**

Title: A Phase III Randomized Trial of Metformin Versus Placebo on Recurrence and Survival in Early Stage Breast Cancer

### **27) Multiple Myeloma**

Title: A Prospective, Longitudinal, Observational Study in Newly Diagnosed Multiple Myeloma (MM) Patients to Assess the Relationship between Patient Outcomes, Treatment Regimens and Molecular Profiles

## **28) 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

## **29) Multiple Myeloma**

Title: A Randomized Phase III Trial of CC-5013 (Lenalidomide, NSC-703813) and Low Dose Dexamethasone (LLD) Versus Bortezomib (PS-341, NSC-681239), Lenalidomide and Low Dose Dexamethasone (BLLD) for Induction, in Patients with Previously Untreated Multiple Myeloma Without an Intent for Immediate Autologous Stem Cell Transplant

## **30) Newly Diagnosed Cancer**

Title: A Sero-Epidemiologic Survey and Cost-Effectiveness Study of Screening for Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) Among Newly Diagnosed Cancer Patients

## **31) 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

## **32) Stage III or IV Unresectable BRAF Mutant Melanoma**

Title: A Randomized Phase II Trial of Intermittent Versus Continuous Dosing of Dabrafenib (NSC-763760) and Trametinib (NSC-763093) in BRAF V600E/K Mutant Melanoma

## **33) Advanced Squamous Cell Lung Cancer**

Title: A Biomarker-Driven Master Protocol for Previously Treated Squamous Cell Lung Cancer (Lung-MAP)

## **34) Stage IV Squamous Cell Lung Cancer**

Title: A Phase III Randomized Study of Nivolumab Plus Ipilimumab Versus Nivolumab for Previously Treated Patients with Stage IV Squamous Cell Lung Cancer and No Matching Biomarker (Lung-Map Sub-Study)

## **35) High-risk 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

## **36) Metastatic pancreatic cancer**

Title: Randomized Phase II Study of 2nd Line FOLFIRI Versus Modified FOLFIRI with PARP Inhibitor ABT-888 (Veliparib) (NSC-737664) in Metastatic Pancreatic Cancer

## **37) Recurrent Bladder Urothelial Cancer**

Title: Phase II Trial of Atezolizumab in BCG-Unresponsive Non-Muscle Invasive Bladder Cancer