

# CLINICAL *Trials*



Karmanos offers clinical trials for many different forms of cancer. Below are the most current clinical trials open to new participants as of this publication's issue date. If you have any questions regarding these clinical trials, please contact 313-576-9790.

**MARCH 2020**

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Bone Marrow Transplant	Gynecologic	Immunotherapy	Phase 1
Breast	Head & Neck	Melanoma/Skin	Sarcoma
Gastrointestinal	Hematology	Neuro-Oncology	Thoracic
Genitourinary			

## Bone Marrow Clinical Trials

For more information on Bone Marrow Clinical Trials, contact the Karmanos Clinical Trials Office at 313-576-9790. To refer a patient for this clinical trial contact the Karmanos Patient Concierge at 800-527-6266, email [newpt@karmanos.org](mailto:newpt@karmanos.org) or fill out this [online referral form](#).

### **BONE MARROW TRANSPLANT**

#### **STUDY 2018-145**

##### **Phase III**

Tisagenlecleucel versus Standard of Care in Adult Patients with Relapsed or Refractory Aggressive B-cell Non-Hodgkin Lymphoma: A Randomized, Open Label, Phase III Trial (BELINDA)

#### **STUDY 2019-024**

##### **Phase I/II**

An Open-Label, Phase 1/2 Study of JCAR017 in Subjects with Relapsed or Refractory Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma (017004)

#### **STUDY 2018-084**

##### **Phase I/II**

A Phase 1/2, Open-Label, Multicenter, Single-Arm Study to Assess the Safety, Tolerability, and Efficacy of BIVV003 for Autologous Hematopoietic Stem Cell Transplantation in Patients With Severe Sickle Cell Disease

**STUDY BMTCTN1506**

**Phase III**

A Multi-center, Randomized, Double-blind, Placebo-controlled Phase III Trial of the FLT3 Inhibitor Gilteritinib Administered as Maintenance Therapy Following Allogeneic Transplant for Patients with FLT3/ITD AML.

**STUDY 2017-081**

**Phase III**

Phase 3 Randomized Trial of Carfilzomib, Lenalidomide, Dexamethasone versus Lenalidomide Alone after Stem-Cell Transplant for Multiple Myeloma

**STUDY NEW 2019-096**

**NA**

Managed Access Program (MAP) to Provide Access to CTL019, for Acute Lymphoblastic Leukemia (ALL) or Large B-Cell Lymphoma Patients with Out of Specification Leukapheresis Product and/or Manufactured Tisagenlecleucel Out of Specification for Commercial Release

**STUDY NEW 2018-121**

**Phase I/II**

An Open-Label Phase 1/2 Study of JCARH125, BCMA-targeted Chimeric Antigen Receptor (CAR) T Cells, in Subjects with Relapsed and/or Refractory Multiple Myeloma

**STUDY 2014-103**

**Phase I/II**

A Phase 1-2 Multi-Center Study Evaluating the Safety and Efficacy of KTE-C19 in Subjects with Refractory Aggressive Non-Hodgkin Lymphoma (NHL)

**STUDY 2016-209**

**Phase II**

A Phase II Trial of CD24Fc for Prevention of Acute Graft-versus-Host Disease Following Myeloablative Allogeneic Hematopoietic Stem Cell Transplant

**STUDY A051301**

**Phase III**

A Randomized Double-Blind Phase III Study of Ibrutinib During and Following Autologous Stem Cell Transplantation Versus Placebo in Patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma of the Activated B-Cell Subtype

**STUDY BMTCTN1703**

**Phase III**

A Randomized, Multicenter, Phase III Trial of Tacrolimus/Methotrexate versus Post-Transplant Cyclophosphamide/Tacrolimus/Mycophenolate Mofetil in Non-Myeloablative/Reduced Intensity Conditioning Allogeneic Peripheral Blood Stem Cell Transplantation

**STUDY 2019-005**

**Phase III**

A Global Randomized Multicenter Phase 3 Trial to Compare the Efficacy and Safety of JCAR017 to Standard of Care in Adult Subjects with High-Risk, Transplant-Eligible Relapsed or Refractory Aggressive B-Cell Non-Hodgkin Lymphomas (TRANSFORM)

**STUDY 2011-086**

**NA**

A Multicenter Access and Distribution Protocol for Unlicensed Cryopreserved Cord Blood Units (CBUs) for Transplantation in Pediatric and Adult Patients with Hematologic Malignancies and Other Indications.

**STUDY 2019-100**

**Phase III**

A Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Vedolizumab in the Prophylaxis of Intestinal Acute Graft-Versus-Host Disease in Subjects Undergoing Allogeneic Hematopoietic Stem Cell Transplantation

## Breast Clinical Trials

For more information on Breast Clinical Trials, contact the Karmanos Clinical Trials Office at 313-576-9790. To refer a patient for this clinical trial contact the Karmanos Patient Concierge at 800-527-6266, email [newpt@karmanos.org](mailto:newpt@karmanos.org) or fill out this [online referral form](#).

### ADJUVANT

#### STUDY NRG-BR003

##### Phase III

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

#### STUDY A011502

##### Phase III

A Randomized Phase III Double Blinded Placebo Controlled Trial of Aspirin as Adjuvant Therapy for Node Positive HER2 Negative Breast Cancer: The ABC Trial

#### STUDY 2017-129

##### NA

Improving Treatment Cost Discussions between Cancer Patients and their Oncologists: Feasibility and Utilization of an Application-based Question Prompt List.

### ADJUVANT HORMONAL

#### STUDY 2017-129

##### NA

Improving Treatment Cost Discussions between Cancer Patients and their Oncologists: Feasibility and Utilization of an Application-based Question Prompt List.

#### STUDY 2019-127

##### Phase II

A Multinational, Multicenter, Phase 2 Study of Tese taxel plus a Reduced Dose of Capecitabine in Patients with HER2 Negative, Hormone Receptor Positive, Locally Advanced or Metastatic Breast Cancer Who Have Not Previously Received a Taxane

### ADJUVANT RADIATION

#### STUDY 2017-129

##### NA

Improving Treatment Cost Discussions between Cancer Patients and their Oncologists: Feasibility and Utilization of an Application-based Question Prompt List.

### NEOADJUVANT

#### STUDY RTOG1304

##### Phase III

NSABP B-51 RTOG1304: A Randomized Phase III Clinical Trial Evaluating Post Mastectomy Chest Wall and Regional Nodal XRT and Post-Lumpectomy Regional Nodal XRT in Patients with Positive Axillary Nodes Before Neoadjuvant Chemotherapy Who Convert to Pathologically Negative Axillary Nodes After Neoadjuvant Chemotherapy.

#### STUDY S1418

##### Phase III

A Randomized, Phase III Trial to Evaluate the Efficacy and Safety of MK-3475 as Adjuvant Therapy for Triple Receptor-Negative Breast Cancer with > 1 cm Residual Invasive Cancer or Positive Lymph Nodes (>pN1mic) After Neoadjuvant Chemotherapy.

#### STUDY EA1131

##### Phase III

A Randomized Phase III Post-Operative Trial of Platinum Based Chemotherapy vs. Capecitabine in Patients with Residual Triple-Negative Breast Cancer following Neo-adjuvant Chemotherapy

**STUDY 2017-129**

**NA**

Improving Treatment Cost Discussions between Cancer Patients and their Oncologists: Feasibility and Utilization of an Application-based Question Prompt List.

**ADVANCED (STAGE IV) CHEMOTHERAPY**

**STUDY 2017-129**

**NA**

Improving Treatment Cost Discussions between Cancer Patients and their Oncologists: Feasibility and Utilization of an Application-based Question Prompt List.

**STUDY 2018-009**

**Phase II**

A Phase II Open-Label, Randomized Study of PARP inhibition (olaparib) Either Alone or in Combination with Anti-PD-L1 Therapy (atezolizumab; MPDL3280A) in Homologous DNA Repair (HDR) Deficient, Locally Advanced or Metastatic Non-HER2-positive Breast Cancer

**STUDY 2017-064**

**Phase I/II**

A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of INCAGN01876 in Combination With Immune Therapies in Subjects With Advanced or Metastatic Malignancies

**STUDY NEW 2019-079**

**Phase I/II**

A Phase 1/2, open-label, dose-escalation study of GBR 1302 in subjects with Phase I/II HER2-positive metastatic breast cancer

**STUDY 2019-114**

**Phase IV**

A Multicenter, Open-Label, Randomized, Controlled Phase 4 Study of Abemaciclib, a CDK4 and 6 Inhibitor, in Combination with Fulvestrant Compared to Chemotherapy in Women with HR Positive, HER2 Negative Advanced Breast Cancer with Visceral Metastases

**STUDY 2019-043**

**Phase III**

Elacestrant Monotherapy VS. Standard of care for the Treatment of Patients with ER+/HER2- Advanced Breast Cancer Following CDK4/6 Inhibitor Therapy: A Phase 3 Randomized, Open-Label, Active-Controlled, Multicenter Trial (EMERALD)

**STUDY NRG-BR004**

**Phase III**

A Randomized, Double-Blind, Phase III Trial of Paclitaxel/Trastuzumab/Pertuzumab with Atezolizumab or Placebo in First-Line HER2-Positive Metastatic Breast Cancer

**STUDY 2018-054**

**Phase I**

A Phase 1a/1b Study of FPA150, and Anti-B7-H4 Antibody, in Patients With Advanced Solid Tumors

**HORMONAL**

**STUDY 2017-129**

**NA**

Improving Treatment Cost Discussions between Cancer Patients and their Oncologists: Feasibility and Utilization of an Application-based Question Prompt List.

**STUDY A171601**

**Phase II**

A Phase II Trial Assessing the Tolerability of Palbociclib in Combination With Letrozole or Fulvestrant in Patients Aged 70 and Older With Estrogen Receptor-Positive, HER2-Negative Metastatic Breast Cancer

## **OTHERS**

### **STUDY 2016-055**

#### **Phase I**

A Phase 1/1b, Open-Label, Multicenter, Repeat-Dose, Dose-Selection Study of CPI-444 as Single Agent and in Combination with Atezolizumab in Patients with Selected Incurable Cancers

### **STUDY S1501**

#### **Phase III**

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

### **STUDY 2017-073**

#### **Phase II**

The Effect of Statins on Markers of Breast Cancer Proliferation and Apoptosis in Women with Early Stage Breast Cancer

### **STUDY A011401**

#### **Phase III**

Randomized Phase III Trial Evaluating the Role of Weight Loss in Adjuvant Treatment of Overweight and Obese Women With Early Breast Cancer

### **STUDY NEW 2019-079**

#### **Phase I/II**

A Phase 1/2, open-label, dose-escalation study of GBR 1302 in subjects with Phase I/II HER2-positive metastatic breast cancer

### **STUDY 2016-116**

#### **Phase II**

A Phase 2 Study of Cediranib in Combination with Olaparib in Advanced Solid Tumors

### **STUDY A221702**

#### **NA**

ARM: Axillary Reverse Mapping- A Prospective Trial to Study Rates of Lymphedema and Regional Recurrence after Sentinel Lymph Node Biopsy and Sentinel Lymph Node Biopsy Followed by Axillary Lymph Node Dissection With and Without Axillary Reverse Mapping

### **STUDY 2013-118**

#### **Phase I**

A Phase 1, Open-label, Dose-Escalation Study to Evaluate the Safety and Tolerability of SGN-LIV1A in Patients with LIV-1-positive Metastatic Breast Cancer.

### **STUDY 2017-029**

#### **Phase I**

An Open-Label, Phase I Trial To Determine The Maximum-Tolerated Dose And Investigate Safety, Pharmacokinetics, And Efficacy Of BI 754091 In Patients With Advanced Solid Tumours

### **STUDY 2018-141**

#### **Phase I/II**

A Phase 1b/2a Two-Part Open-Label Multicenter Study to Evaluate the Safety and Efficacy of LY2880070 as Monotherapy and in Combination with Gemcitabine in Patients with Advanced or Metastatic Cancer

### **STUDY 2018-062**

#### **NA**

Reducing Metabolic Syndrome and Unmet needs Among Rural Breast Cancer Survivors During the Survivorship Transition

### **STUDY 2016-037**

#### **Phase I**

A Phase I Study of ALKS 4230 Administered Intravenously as Monotherapy and in Combination with Pembrolizumab in Subjects with Advanced Solid Tumors

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## Gastrointestinal Clinical Trials

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### ESOPHAGUS

#### Metastatic

#### STUDY 2017-064

##### Phase I/II

A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of INCAGN01876 in Combination With Immune Therapies in Subjects With Advanced or Metastatic Malignancies

#### STUDY 2019-008

##### Phase III

A Randomized, Placebo-Controlled, Double-Blind Phase 3 Study to Evaluate the Efficacy and Safety of Tislelizumab (BGB-A317) in Combination with Chemotherapy as First-Line Treatment in Patients with Unresectable, Locally Advanced Recurrent or Metastatic Esophageal Squamous Cell Carcinoma

#### STUDY 2019-101

##### Phase I

A Phase 1a/b Dose-Escalation Study Followed by Expansion Cohorts of NGM120, a GFRAL Antagonist Monoclonal Antibody Blocking GDF15 Signaling, in Subjects With Advanced Solid Tumors and Pancreatic Cancer Using Combination Therapy

### GASTRIC AND GASTROESOPHAGEAL JUNCTION

#### Metastatic

#### STUDY 2017-150

##### Phase I/II

A Phase 1/2 Study of Olaparib in Combination with Ramucirumab in Metastatic Gastric and Gastroesophageal Junction Adenocarcinoma

#### STUDY 2017-064

##### Phase I/II

A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of INCAGN01876 in Combination With Immune Therapies in Subjects With Advanced or Metastatic Malignancies

#### STUDY 2018-088

##### Phase III

A Phase 3, Global, Multi-Center, Double-Blind, Randomized, Efficacy Study of Zolbetuximab (IMAB362) Plus mFOLFOX6 Compared with Placebo Plus mFOLFOX6 as First-line Treatment of Subjects with Claudin (CLDN)18.2-Positive, HER2 Negative, Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma

#### STUDY 2017-029

##### Phase I

An Open-Label, Phase I Trial To Determine The Maximum-Tolerated Dose And Investigate Safety, Pharmacokinetics, And Efficacy Of BI 754091 In Patients With Advanced Solid Tumours

#### STUDY 2016-003

##### Phase I/II

A Phase 1b/2 Study of Ibrutinib Combination Therapy in Selected Advanced Gastrointestinal And Genitourinary Tumors

#### STUDY NEW 2019-105

##### Phase III

A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Clinical Study Comparing the Efficacy and Safety of Tislelizumab (BGB-

A317) plus Platinum and Flucropymidine Versus Placebo plus Platinum and Flucropymidine as First-Line Treatment in Patients with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

**STUDY 2016-037**

**Phase I**

A Phase 1/2 Study of ALKS 4230 Administered Intravenously as Monotherapy and in Combination with Pembrolizumab in Subjects with Advanced Solid Tumors- ATRISTRY-1

**STUDY 2017-087**

**Phase I**

An Open-Label, Phase I Trial to Determin The Maximum-Tolerated Dose And Investigate Safety, Pharmacokinetics, And Efficacy Of BI 754091 In Patients With Advanced Solid Tumors

**STUDY 2019-101**

**Phase I**

A Phase 1a/b Dose-Escalation Study Followed by Expansion Cohorts of NGM120, a GFRAL Antagonist Monoclonal Antibody Blocking GDF15 Signaling, in Subjects With Advanced Solid Tumors and Pancreatic Cancer Using Combination Therapy

**PANCREAS**

**Adenocarcinoma**

**Locally Advanced Unresectable**

**STUDY 2018-048**

**Phase III**

PANOVA-3: Pivotal, Randomized, Open-Label Study of Tumor Treating Fields (TTFields, 150kHz) Concomitant with Gemcitabine and nab-Pacliatxel for Font-Line Treatment of Locally-Advanced Pancreatic Adenocarcinoma

**STUDY 2018-076**

**Phase I/II**

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

**Metastatic**

**STUDY 2017-069**

**Phase I/II**

A Phase 1/2a Study of BMS-986205 Administered in Combination with Nivolumab (anti-PD-1 Monoclonal Antibody) and in Combination with Both Nicolumab and Ipilimumab (anti-CTLA-4 Monoclonal Antibody) in Advanced Malignant Tumors

**STUDY 2019-002**

**Phase III**

A Phase III Multicenter Open-Label Randomized Trial to Evaluate Efficacy and Safety of FOLFIRINOX (FFX) versus Combination of CPI-613 with modified FOLFIRINOX (mFFX) in Patients with Metastatic Adenocarcinoma of the Pancreas

**STUDY 2016-116**

**Phase II**

A Phase 2 Study of Cediranib in Combination with Olaparib in Advanced Solid Tumors

**STUDY 2018-166**

**Phase I/II**

A Phase 1/2 Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Preliminary Efficacy of GP-2250 in Combination with Gemcitabine in Subjects with Advanced Unresectable or Metastatic Pancreatic Adenocarcinoma Who Have Progressed on Prior Treatment with FOLFIRINOX Chemotherapy

**STUDY 2018-076**

**Phase I/II**

A Phase 1-2, First-in-Human Study of CX-2029 in Adults with Metastatic or Locally Advance Unresectable Solid Tumors or Diffuse Large B-cell Lymphomas

**STUDY NEW 2018-046****Phase II/III**

A Randomized Phase 2/3 Multi-Center Study of SM-88 in Subjects with Pancreatic Cancer Whose Disease Has Progressed or Recurred

**STUDY 2018-090****Phase III**

A Randomized Controlled, Open label, Adaptive Phase-3 Trial to Evaluate Safety and Efficacy of EndoTAG-1 Plus Gemcitabine versus Gemcitabine alone in Patients with Measurable Locally Advanced and/or Metastatic Adenocarcinoma of the Pancreas Failed on FOLFIRINOX Treatment

**STUDY 2019-088****Phase I/II**

A Phase 1b/2, Open-Label, Multicenter Dose Escalation and Dose-Expansion Study of the Combination of RMC-4630 and Cobimetinib in Adults Participants With Relapsed/Refractory Solid Tumors With Specific Genomic Aberrations

**STUDY 2019-101****Phase I**

A Phase 1a/b Dose-Escalation Study Followed by Expansion Cohorts of NGM120, a GFRAL Antagonist Monoclonal Antibody Blocking GDF15 Signaling, in Subjects With Advanced Solid Tumors and Pancreatic Cancer Using Combination Therapy

**HCC****Adjuvant****STUDY 2019-048****Phase III**

A Phase III, Randomized, Double-blind, Placebo-controlled, Multicenter Study of Transarterial Chemoembolization (TACE) in Combination with either Durvalumab Monotherapy or Durvalumab plus Bevacizumab Therapy in Patients with Locoregional Hepatocellular Carcinoma

**STUDY RTOG1112****Phase III**

Randomized Phase III Study of Sorafenib Versus Stereotactic Body Radiation Phase III Therapy Followed By Sorafenib in Hepatocellular Carcinoma

**Metastatic****STUDY 2017-064****Phase I/II**

A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of INCAGN01876 in Combination With Immune Therapies in Subjects With Advanced or Metastatic Malignancies

**BILIARY/GALL BLADDER****Metastatic****STUDY 2019-009****Phase III**

A Phase 3, Open-Label, Randomized, Active-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of INCB054828 Versus Gemcitabine Plus Cisplatin Chemotherapy in First-Line Treatment of Participants With Unresectable or Metastatic Cholangiocarcinoma With FGFR2 Rearrangement

**STUDY S1815****Phase III**

A Phase III Randomized Trial of Gemcitabine, Cisplatin, and NAB-Paclitaxel versus Gemcitabine and Cisplatin in Newly Diagnosed, Advanced Biliary Tract Cancers

**STUDY 2014-081****Phase II**

A Phase II Multicenter, Single Arm Study of Oral BGJ398 in Adult Patients with Advanced or Metastatic Cholangiocarcinoma with FGFR2 Gene Fusions or other FGFR Genetic Alterations who Failed or Are Intolerant to Platinum-Based Chemotherapy



**STUDY 2019-003****Phase III**

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

**COLON****Adjuvant****STUDY A021502****Phase III**

Randomized Trial of Standard Chemotherapy Alone or Combined with Atezolizumab as Adjuvant Therapy of Patients with Stage III Colon Cancer with Deficient DNA Mismatch Repair

**Metastatic (Includes Rectal)****2nd Line****STUDY 2016-055****Phase I**

A Phase 1/1b, Open-Label, Multicenter, Repeat-Dose, Dose-Selection Study of CPI-444 as Single Agent and in Combination with Atezolizumab in Patients with Selected Incurable Cancers

**STUDY NEW A021703****Phase III**

Randomized Double-Blind Phase III Trial of Vitamin D3 Supplementation in Patients with Previously Untreated Metastatic Colorectal Cancer (SOLARIS)

**STUDY NEW NRG-GI005****Phase II/III**

Phase II/III Study of Circulating Tumor DNA as a Predictive Biomarker in Adjuvant Chemotherapy in Patients with Stage IIA Colon Cancer (COBRA)

**STUDY 2019-010****Phase III**

A Randomized, Multicenter, Parallel-Group, Phase III Study to Compare the Efficacy of Arfollitoxorin versus Leucovorin in Combination with 5-fluorouracil, Oxaliplatin, and Bevacizumab in Patients with Advanced Colorectal Cancer

**STUDY 2018-021****Phase II**

A Phase 2, Multicenter, Open-Label Study of DS-8201A in Subjects with HER2- Expressing Advanced Colorectal Cancer

**STUDY 2016-003****Phase I/II**

A Phase 1b/2 Study of Ibrutinib Combination Therapy in Selected Advanced Gastrointestinal And Genitourinary Tumors

**STUDY 2016-037****Phase I**

A Phase 1 Study of ALKS 4230 Administered Intravenously as Monotherapy and in Combination with Pembrolizumab in Subjects with Advanced Solid Tumors

**STUDY 2017-129****NA**

Improving Treatment Cost Discussions between Cancer Patients and their Oncologists: Feasibility and Utilization of an Application-based Question Prompt List

**STUDY 2019-088****Phase I/II**

A Phase 1b/2, Open-Label, Multicenter Dose Escalation and Dose-Expansion Study of the Combination of RMC-4630 and Cobimetinib in Adults Participants With Relapsed/Refractory Solid Tumors With Specific Genomic Aberrations

**STUDY S1613****Phase II**

A Randomized Phase II Study of Trastuzumab and Pertuzumab (TP) Compared to Cetuximab and Irinotecan (CETIRI) in Advanced/Metastatic Colorectal Cancer (MCRC) with HER-2 Amplification

**STUDY 2019-101****Phase I**

A Phase 1a/b Dose-Escalation Study Followed by Expansion Cohorts of NGM120, a GFRAL Antagonist Monoclonal Antibody Blocking GDF15 Signaling, in Subjects With Advanced Solid Tumors and Pancreatic Cancer Using Combination Therapy

**RECTUM****STUDY 2017-129****NA**

Improving Treatment Cost Discussions between Cancer Patients and their Oncologists: Feasibility and Utilization of an Application-based Question Prompt List

**STUDY EA2165****Phase II**

A Randomized Phase II Study of Nivolumab After Combined Modality Therapy (CMT) in High Risk Anal Cancer

**ANAL****Localized****STUDY NEW EA2182****Phase II**

A Randomized Phase II Study of De-Intensified ChemoRadiation for Early-Stage Anal Squamous Cell Carcinoma (DECREASE)

**Metastatic****STUDY EA2165****Phase II**

A Randomized Phase II Study of Nivolumab After Combined Modality Therapy (CMT) in High Risk Anal Cancer

**STUDY 2018-122****Phase II**

A Multi-Institutional Phase 2 Study of Nivolumab or Nivolumab in Combination with Ipilimumab in Refractory Metastatic Squamous Cell Carcinoma of the Anal Canal

**NEUROENDOCRINE TUMORS AND CARCINOID****STUDY A021602****Phase III**

Randomized, Double-Blind Phase III Study of Cabozantinib versus Placebo in Patients with Advanced Neuroendocrine Tumors After Progression on Everolimus (CABINET)

**STUDY 2017-144****NA**

Monitoring Telotristat Ethyl Inhibition of Tryptophan hydroxylase (TPH) in Neuroendocrine Tumors Using alpha-[11C]methyl-L-tryptophan (AMT)-PET

**IMAGING STUDIES****Metastatic****STUDY 2018-171****Phase II**

A Phase II, Open Label, Multi-Dose Study of 89ZR-DF-IAB22M2C (CD8 PET Tracer) for Positron Emission Tomography (PET/CT) in Patients with Metastatic Solid Tumors

**STUDY 2006-127**

**NA**

Use of [F-18] FLT for Imaging with Positron Emission Tomography (PET)

**OTHER**

**STUDY 2017-064**

**Phase I/II**

A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of INCAGN01876 in Combination With Immune Therapies in Subjects With Advanced or Metastatic Malignancies

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## Genitourinary Clinical Trials

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**RENAL**

**STUDY 2016-003**

**Phase I/II**

A Phase 1b/2 Study of Ibrutinib Combination Therapy in Selected Advanced Gastrointestinal And Genitourinary Tumors

**STUDY 2016-037**

**Phase I**

A Phase 1 Study of ALKS 4230 in Subjects with Advanced Solid Tumors

**STUDY EA8143**

**Phase III**

A Phase 3 RandOmized Study Comparing PERioperative Nivolumab vs. Observation in Patients with Renal Cell Carcinoma Undergoing Nephrectomy (PROSPER RCC)

**STUDY 2019-084**

**Phase III**

A Randomized, Double-Blind, Controlled Phase 3 Study of Cabozantinib in Combination with Nivolumab and Ipilimumab versus Nivolumab and Ipilimumab in Subjects with Previously Untreated Advanced or Metastatic Renal Cell Carcinoma of Intermediate or Poor Risk

**STUDY 2017-082**

**Phase I/II**

A Phase I/II Trial of Pazopanib Alternating with Bevacizumab in Treatment-Naïve Metastatic Clear Cell Renal Cell Carcinoma Patients

**STUDY 2017-069**

**Phase I/II**

A Phase 1/2a Study of BMS-986205 Administered in Combination with Nivolumab anti-PD-1 Monoclonal Antibody) and in Combination with Both Nivolumab and Ipilimumab (anti-CTLA-4 Monoclonal Antibody) in Advanced Malignant Tumors

**STUDY 2017-111**

**Phase I**

A Phase 1b Dose-Escalation Study of Cabozantinib (XL184) Administered in Combination with Atezolizumab to Subjects with Locally Advanced or Metastatic Solid Tumors

**STUDY 2016-211****Phase II**

A Phase 2, Fast Real-time Assessment of Combination Therapies in Immuno-ONcology Study in Participants with Advanced Renal Cell Carcinoma (FRACTION-RCC)

**STUDY 2017-029****Phase I**

An Open-Label, Phase I Trial To Determine The Maximum-Tolerated Dose And Investigate Safety, Pharmacokinetics, And Efficacy Of BI 754091 In Patients With Advanced Solid Tumours

**STUDY 2017-064****Phase I/II**

A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of INCAGN01876 in Combination With Immune Therapies in Subjects With Advanced or Metastatic Malignancies

**STUDY 2016-055****Phase I**

A Phase 1/1b, Open-Label, Multicenter, Repeat-Dose, Dose-Selection Study of CPI-444 as Single Agent and in Combination with Atezolizumab in Patients with Selected Incurable Cancers

**STUDY 2018-098****Phase I/II**

A Phase 1/2a Study to Evaluate the Safety, Tolerability, Immunogenicity, and Anti-Tumor Activity of GEN-009 Adjuvanted Vaccine in Adult Patients with Selected Solid Tumors

**PROSTATE****STUDY 2013-108****NA**

Immune Evaluation Study of Sipuleucel-T in African American and Non African American Men with Castrate Resistant Prostate Cancer

**STUDY 2019-035****Phase II**

A Phase II Study of Olaparib and Durvalumab in Men with Castration Sensitive Biochemically Recurrent Non-Metastatic Prostate Cancer Harboring Mutations in DNA Damage Repair

**STUDY 2018-170****NA**

Genetic Counseling Processes and Outcomes Among Males with Prostate Cancer (ProGen)

**STUDY 2019-123****Phase 1**

A Phase 1, Open-Label Study in Two Parts, Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Clinical Activity of CCW702 in Patients with Metastatic, Castration Resistant Prostate Adenocarcinoma

**STUDY 2019-027****Phase II**

IMPACT: Immunotherapy in Patients with Metastatic Cancers and CDK12 Mutations

**STUDY 2019-045****Phase II**

A Multicentre Phase IIb Trial to Evaluate the Efficacy and Tolerability of ModraDoc006/r in Subjects with Metastatic Castration Resistant Prostate Cancer (mCRPC), Suitable for Treatment with a Taxane

**STUDY 2019-047****Phase I/II**

A Phase 1/2 Study of Combination Olaparib and Radium-223 in Men with Metastatic Castration-Resistant Prostate Cancer with Bone Metastases (COMRADE)

**STUDY 2018-163**

**Phase I**

A Phase 1 Study of FOR46 Administered Every 21 Days in Patients with Metastatic Castration-Resistant Prostate Cancer (mCRPC)

**STUDY NRG-GU002****Phase II/III**

Phase II-III Trial of Adjuvant Radiotherapy and Androgen Deprivation Following Radical Prostatectomy With or Without Adjuvant Docetaxel

**STUDY 2018-124****Phase I/II**

Phase 1/2a Dose-Escalation and Expansion Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of CORT125281 with Enzalutamide in Patients with Metastatic Castration-Resistant Prostate Cancer

**STUDY S1802****Phase III**

Phase III Randomized Trial of Standard Systemic Therapy (SST) versus Standard Systemic Therapy Plus Definitive Treatment (Surgery or Radiation) of the Primary Tumor in Metastatic Prostate Cancer.

**STUDY 2018-173****Phase III**

The MAP TRIAL: Phase III Study of Muscadine Plus (MPX) in Men with Prostate Cancer: A Randomized Double-Blind, Placebo-Controlled Study of the Effects of MPX Capsules on Rising Prostate-Specific Antigen Levels in Alanine/Alanine SOD2 Genotype Men Following Initial Therapy for Prostate Cancer

**STUDY 2017-126****Phase II**

Phase II Study of Olaparib in Men with High-Risk Biochemically-Recurrent Prostate Cancer Following Radical Prostatectomy, with Integrated Biomarker Analysis

**STUDY EA8153****Phase II**

Cabazitaxel with Abiraterone versus Abiraterone alone Randomized Trial for Extensive Disease following Docetaxel: Phase II the CHAARTED2 Trial

**STUDY NRG-GU005****Phase III**

Phase III IGRT and SBRT vs IGRT and Hypofractionated IMRT for Localized Intermediate Risk Prostate Cancer

**STUDY 2015-135****Phase II**

Phase II Trial of Immune Checkpoint Inhibitor with Anti-CD3 x Anti-HER2 Bispecific Antibody Armed Activated T Cells in Metastatic Castrate Resistant Prostate Cancer.

**STUDY 2015-167****Phase II**

A Randomized Phase 2 Trial of Ascorbic Acid in Combination with Docetaxel in Men with Metastatic Prostate Cancer

**STUDY 2015-029****Phase II**

Phase II Randomized Placebo-Controlled Double-Blind Study of Salvage Radiation Therapy (SRT) Plus Placebo Versus SRT Plus Enzalutamide in Men with High-Risk PSA-Recurrent Prostate Cancer after Radical Prostatectomy

**STUDY 2017-156****Phase II**

A Phase II Open-Label, a Multisite Study of Apalutamide, Abiraterone and Prednisone in African American and Caucasian Men with Metastatic Castrate Resistant Prostate Cancer

**STUDY 2017-129**

NA

Improving Treatment Cost Discussions between Cancer Patients and their Oncologists: Feasibility and Utilization of an Application-based Question Prompt List

**STUDY NEW 2019-031**

**Phase II**

Phase II Multi-center Trial of ESK981 in combination with Nivolumab in Patients with Metastatic Castrate Resistant Prostate Cancer

**BLADDER**

**STUDY 2016-055**

**Phase I**

A Phase 1/1b, Open-Label, Multicenter, Repeat-Dose, Dose-Selection Study of CPI-444 as Single Agent and in Combination with Atezolizumab in Patients with Selected Incurable Cancers

**STUDY 2017-070**

**Phase II**

QUILT-3.032: A Multicenter Clinical Trial of Intravesical Bacillus Calmette-Guerin(BCG) in Combination with ALT-803 in Patients with BCG Unresponsive High Grade Non-Muscle Invasive Bladder Cancer

**STUDY 2017-064**

**Phase I/II**

A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of INCAGN01876 in Combination With Immune Therapies in Subjects With Advanced or Metastatic Malignancies

**STUDY 2019-019**

**Phase II**

A Phase II Open Label, Study of IMMU-132 in Metastatic Urothelial Cancer After Failure of Platinum-Based Regimen or Anti-PD-1/ PD-L1 Based Immunotherapy

**STUDY 2016-195**

**Phase II**

Phase II Trial of Concurrent Nivolumab in Urothelial Bladder Cancer with Radiation Therapy in Localized/Locally Advanced Disease for Chemotherapy Ineligible Patients [NUTRA]

**STUDY 2018-110**

**Phase II**

A Phase 2 Study of Sitravatinib in Combination with Nivolumab in Patients with Advanced or Metastatic Urothelial Carcinoma

**STUDY 2016-003**

**Phase I/II**

A Phase 1b/2 Study of Ibrutinib Combination Therapy in Selected Advanced Gastrointestinal And Genitourinary Tumors

**STUDY 2019-081**

**Phase II**

A Phase 2, Multicenter, Randomized, Double-Blind, Active-Control Study to Evaluate the Efficacy and Safety of Nivolumab Administered in Combination with IPI-549 Compared to Nivolumab Monotherapy in the Treatment of Patients with Immune Therapy-Naïve, Advanced Urothelial Carcinoma

**STUDY 2015-101**

**Phase I/II**

A Study of Intravesical Bacillus Calmette-Guerin (BCG) in Combination with ALT-803 in patients with BCG-naïve Non-Muscle Invasive Bladder Cancer

**STUDY 2017-069**

**Phase I/II**

A Phase 1/2a Study of BMS-986205 Administered in Combination with Nivolumab anti-PD-1 Monoclonal Antibody) and in Combination with Both Nivolumab and Ipilimumab (anti-CTLA-4 Monoclonal Antibody) in Advanced Malignant Tumors

**STUDY 2017-029**

**Phase I**

An Open-Label, Phase I Trial To Determine The Maximum-Tolerated Dose And Investigate Safety, Pharmacokinetics, And Efficacy Of BI 754091 In Patients With Advanced Solid Tumours

**STUDY 2018-165**

**Phase III**

A Phase III, Randomized, Open-Label, Multi-Center, Global Study to Determine the Efficacy and Safety of Durvalumab in Combination with Gemcitabine+Cisplatin for Neoadjuvant Treatment Followed by Durvalumab Alone for Adjuvant Treatment in Patients with Muscle-Invasive Bladder Cancer (NIAGARA)

**STUDY 2018-044**

**Phase II**

Phase 2 Trial of Olaparib in Patients with Metastatic Urothelial Cancer Harboring DNA Damage Response Gene Alterations

**STUDY 2016-037**

**Phase I**

A Phase 1 Study of ALKS 4230 Administered Intravenously as Monotherapy and in Combination with Pembrolizumab in Subjects with Advanced Solid Tumors

**STUDY 2018-023**

**Phase I/II**

An International, Multicenter, Phase 1b/2 Study of Rogaratinib (BAY 1163877) in Combination with Atezolizumab as First-line Treatment in Cisplatin-Ineligible Patients with FGFR-positive locally advanced or metastatic urothelial carcinoma

**STUDY 2018-098**

**Phase I**

A Phase 1/2a Study to Evaluate the Safety, Tolerability, Immunogenicity, and Anti-Tumor Activity of GEN-009 Adjuvanted Vaccine in Adult Patients with Selected Solid Tumors

**STUDY S1806**

**Phase III**

Phase III Randomized Trial of Concurrent Chemoradiotherapy With or Without Atezolizumab in Localized Muscle Invasive Bladder Cancer

**STUDY 2019-101**

**Phase I**

A Phase 1a/b Dose-Escalation Study Followed by Expansion Cohorts of NGM120, a GFRAL Antagonist Monoclonal Antibody Blocking GDF15 Signaling, in Subjects With Advanced Solid Tumors and Pancreatic Cancer Using Combination Therapy

**OTHER**

**STUDY 2018-171**

**Phase II**

A Phase II, Open Label, Multi-Dose Study of 89ZR-DF-IAB22M2C (CD8 PE Tracer) for Positron Emission Tomography (PET/CT) in Patients with Metastatic Solid Tumors

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## Gynecologic Clinical Trials

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**CERVIX**

**STUDY 2017-010**

**Phase II**

A Phase 2, Multicenter Study to Evaluate the Efficacy and Safety Using Autologous Tumor Infiltrating Lymphocytes (LN-145) in Patients with Recurrent, Metastatic or Persistent Cervical Carcinoma

**STUDY 2017-064**

**Phase I/II**

A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of INCAGN01876 in Combination With Immune Therapies in Subjects With Advanced or Metastatic Malignancies

**STUDY 2019-094**

**Phase I**

Phase I Dose-Escalation Bioavailability Study of Oral Triapine in Combination with Concurrent Chemoradiation for Locally Advanced Cervical Cancer (LACC) and Vaginal Cancer

**STUDY 2017-069**

**Phase I/II**

A Phase 1/2a Study of BMS-986205 Administered in Combination with Nivolumab (anti-PD-1 Monoclonal Antibody) and in Combination with Both Nivolumab and Ipilimumab (anti-CTLA-4 Monoclonal Antibody) in Advanced Malignant Tumors

**OVARY**

**STUDY GOG-3018**

**Phase III**

The OVAL Study: A Randomized, Controlled, Double-Arm, Double-Blind, Multi-Center Study of Ofranergene Obadenovec (VB-111) Combined with Paclitaxel vs. Paclitaxel Combined with Placebo for the Treatment of Recurrent Platinum-Resistant Ovarian Cancer

**STUDY 2018-126**

**Phase II**

Phase II Study of ONC201 Plus Weekly Paclitaxel in Patients with Platinum-Resistant Refractory or Recurrent Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

**STUDY 2018-159**

**Phase II**

Open Label Phase 2 Study of Tisotumab Vedotin for Patients with Platinum-Resistant Ovarian Cancer with a Safety Run-in of a Dose-Dense Regimen

**STUDY NRG-GY005**

**Phase II/III**

Randomized Phase II/III Study of the Combination of Cediranib and Olaparib Compared to Cediranib Alone or Olaparib Alone or Standard of Care Chemotherapy in Women with Recurrent Platinum-Resistant or -Refractory Ovarian, Fallopian Tube or Primary Peritoneal Cancer

**STUDY 2018-141**

**Phase I/II**

A Phase 1b/2a Two-Part Open-Label Multicenter Study to Evaluate the Safety and Efficacy of LY2880070 as Monotherapy and in Combination with Gemcitabine in Patients with Advanced or Metastatic Cancer

**STUDY 2017-064**

**Phase I/II**

A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of INCAGN01876 in Combination With Immune Therapies in Subjects With Advanced or Metastatic Malignancies

**STUDY 2016-037**

**Phase I**

A Phase 1 Study of ALKS 4230 in Subjects with Advanced Solid Tumors

**STUDY 2018-054**

**Phase I**

A Phase 1a/1b Study of FPA 150, an Anti-B7-H4 Antibody, in Patients With Solid Advanced Tumors

**STUDY 2017-029**



**Phase I**

An Open-Label, Phase I Trial To Determine The Maximum-Tolerated Dose And Investigate Safety, Pharmacokinetics, And Efficacy of BI 754091 In Patients With Advanced Solid Tumors

**STUDY 2019-046****Phase I/II**

Phase 1 Dose Escalation and Expansion Cohort of Carboplatin and Gemcitabine with or without M6620 (VX-970) in First or Second Recurrence Platinum-Sensitive Epithelial Ovarian, Peritoneal, and Fallopian Tube Cancer

**STUDY NRG-GY019****Phase III**

A Randomized, Phase III, Two-Arm Trial of Paclitaxel/Carboplatin/Maintenance Letrozole Versus Letrozole Monotherapy in Patients with Stage II-IV, Primary Low-grade Serous Carcinoma of the Ovary or Peritoneum

**STUDY 2019-101****Phase I**

A Phase 1a/b Dose-Escalation Study Followed by Expansion Cohorts of NGM120, a GFRAL Antagonist Monoclonal Antibody Blocking GDF15 Signaling, in Subjects With Advanced Solid Tumors and Pancreatic Cancer Using Combination Therapy

**UTERUS****STUDY 2017-064****Phase I/II**

A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of INCAGN01876 in Combination With Immune Therapies in Subjects With Advanced or Metastatic Malignancies

**STUDY 2018-141****Phase I/II**

A Phase 1b/2a Two-Part Open-Label Multicenter Study to Evaluate the Safety and Efficacy of LY2880070 as Monotherapy and in Combination with Gemcitabine in Patients with Advanced or Metastatic Cancer

**OTHER****STUDY 2018-054****Phase I**

A Phase 1a/1b Study of FPA 150, an Anti-B7-H4 Antibody, in Patients With Advanced Solid Tumors

**STUDY 2019-046****Phase I/II**

Phase I Dose Escalation and Expansion Cohort of Carboplatin and Gemcitabine with or without M6620 (VX-970) in First or Second Recurrence Platinum-Sensitive Epithelial Ovarian, Peritoneal, and Fallopian Tube Cancer

**STUDY NRG-GY019****Phase III**

A Randomized, Phase III, Two-Arm Trial of Paclitaxel/Carboplatin/Maintenance Letrozole Versus Letrozole Monotherapy in Patients with Stage II-IV, Primary Low-grade Serous Carcinoma of the Ovary or Peritoneum

**STUDY 2019-094****Phase I**

Phase I Dose-Escalation Bioavailability Study of Oral Triapine in Combination with Concurrent Chemoradiation for Locally Advanced Cervical Cancer (LACC) and Vaginal Cancer

**STUDY 2018-126****Phase II**

Phase II Study of ONC201 Plus Weekly Paclitaxel in Patients with Platinum-Resistant Refractory or Recurrent Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

**STUDY GOG-3031****Phase III**

A Phase 3, Randomized, Double-Blind, Multicenter Study of Dostarlimab (TSR-042) plus Carboplatin-paclitaxel versus Placebo plus Carboplatin-paclitaxel in Patients with Recurrent or Primary Advanced Endometrial Cancer (RUBY)

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## Head & Neck Clinical Trials

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### **STAGES I/II/III**

#### **STUDY EA3132**

##### **Phase II**

Phase II Randomized Trial of Radiotherapy with or without Cisplatin for Surgically Resected Squamous Cell Carcinoma of the Head and Neck (SCCHN) with TP53 Sequencing

#### **STUDY 2018-117**

##### **Phase II**

The AIM-HN and SEQ-HN Study: A 2 Cohort, Non-comparative, Pivotal Study Evaluating the Efficacy of Tipifarnib in Patients with Head and Neck Squamous Cell Carcinoma (HNSCC) with HRAS Mutations (AIM-HN) and the Impact of HRAS Mutations on Response to First Line Systemic Therapies for HNSCC (SEQ-HN).

#### **STUDY 2017-157**

##### **Phase III**

A Phase III, Randomized, Open-label Study to Evaluate Pembrolizumab as Neoadjuvant Therapy and in Combination With Standard of Care as Adjuvant Therapy for Stage III-IVA Resectable Locoregionally Advanced Head and Neck Squamous Cell Carcinoma (LA HNSCC)

#### **STUDY EA3163**

##### **Phase II**

Phase II Randomized Trial of Neo-Adjuvant Chemotherapy Followed by Surgery and Post-Operative Radiation versus Surgery and Post-Operative Radiation for Organ Preservation of T3 and T4a Nasal and Paranasal Sinus Squamous Cell Carcinoma (NPNSCC)

#### **STUDY RTOG-1008**

##### **Phase II/III**

A Randomized Phase II/Phase III Study of Adjuvant Concurrent Radiation and Chemotherapy Versus Radiation Alone in Resected High-Risk Malignant Salivary Gland Tumors

#### **STUDY NRG-HN001**

##### **Phase II/III**

Randomized Phase II and Phase III Studies of Individualized Treatment for Nasopharyngeal Carcinoma Based on Biomarker Epstein Barr Virus (EBV) Deoxyribonucleic Acid (DNA)

#### **STUDY 2019-083**

##### **Phase II**

A Phase 2 Open Label Study of Sacituzumab Govitecan (IMMU-132) in Subjects with Metastatic Solid Tumors

#### **STUDY EA3161**

##### **Phase II/III**

Phase II/III Randomized Study of Maintenance Nivolumab versus Observation in Patients with Locally Advanced, Intermediate Risk HPV Positive OPCA

#### **STUDY 2019-069**

##### **Phase III**

A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of Cabozantinib (XL184) in Subjects with Radioiodine-Refractory Differentiated Thyroid Cancer Who Have Progressed after Prior VEGFR-Targeted Therapy

**ANY STAGE****STUDY 2016-212****Phase II**

A Phase 2 Study to Evaluate the Safety, Tolerability and Efficacy of Cell Transfer Therapy Using Autologous Tumor Infiltrating Lymphocytes (LN-145) followed by IL-2 in Patients with Recurrent and/or Metastatic Squamous Cell Carcinoma of the Head and Neck

**STUDY 2017-107****Phase III**

A Pivotal, Double-Blind, Randomized, Placebo-Controlled, Multinational Study of SGX942(Dusquetide) for the Treatment of Oral Mucositis in Patients Being Treated with Concomitant Chemoradiation for the Treatment of Squamous Cell Carcinoma of the Head and Neck

**STUDY NEW 2020-006****Phase III**

A Phase 3, Randomized, Placebo-Controlled, Double-Blind, Clinical Study of Pembrolizumab (MK-3475) with or without Lenvatinib (E7080/MK-7902) to Evaluate the Safety and Efficacy of Pembrolizumab and Lenvatinib as 1L Intervention in a PD-L1 Selected Population of Participants with Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma (R/M HNSCC) (LEAP-010)

**STUDY 2018-076****Phase I/II**

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

**STUDY 2017-069****Phase I/II**

A Phase 1/2a Study of BMS-986205 Administered in Combination with Nivolumab anti-PD-1 Monoclonal Antibody) and in Combination with Both Nivolumab and Ipilimumab (anti-CTLA-4 Monoclonal Antibody) in Advanced Malignant Tumors

**STUDY NEW 2016-017****Phase I/II**

A Phase 1B/2 Open-Label Study to Evaluate Safety, Clinical Activity, Pharmacokinetics and Pharmacodynamics of Avelumab\* (MSB0010718C) in Combination with Other Cancer Immunotherapies in Patients with Advanced Malignancies

**STUDY 2018-098****Phase I/II**

A Phase 1/2a Study to Evaluate the Safety, Tolerability, Immunogenicity, and Anti-Tumor Activity of GEN-009 Adjuvanted Vaccine in Adult Patients with Selected Solid Tumors

**STUDY 2019-099****Phase II**

A Phase 2 Efficacy and Safety Trial of ADU-S100 and Pembrolizumab in Adults with Head and Neck Cancer

**OTHER****STUDY 2017-064****Phase I/II**

A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of INCAGN01876 in Combination With Immune Therapies in Subjects With Advanced or Metastatic Malignancies

**STUDY 2016-055****Phase I**

A Phase 1/1b, Open-Label, Multicenter, Repeat-Dose, Dose-Selection Study of CPI-444 as Single Agent and in Combination with Atezolizumab in Patients with Selected Incurable Cancers

**STUDY 2018-171****Phase II**

A Phase II, Open Label, Multi-Dose Study of 89ZR-DF-IAB22M2C (CD8 PET Tracer) for Positron Emission Tomography (PET/CT) in Patients with Metastatic Solid Tumors

**STUDY 2016-037**

**Phase 1**

A Phase 1 Study of ALKS 4230 Administered Intravenously as Monotherapy and in Combination with Pembrolizumab in Subjects with Advanced Solid Tumors

**STUDY 2017-087****Phase I**

A Phase 1, Open-Label, Dose-Escalation Study of SEA-CD40 in Adult Patients with Advanced Malignancies

**STUDY 2019-101****Phase I**

A Phase 1a/b Dose-Escalation Study Followed by Expansion Cohorts of NGM120, a GFRAL Antagonist Monoclonal Antibody Blocking GDF15 Signaling, in Subjects With Advanced Solid Tumors and Pancreatic Cancer Using Combination Therapy

**STUDY NRG-HN005****Phase II/III**

A Randomized Phase II/III Trial of De-Intensified Radiation Therapy for Patients with Early-Stage, P16-Positive, Non-Smoking Associated Oropharyngeal Cancer

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## Hematology Clinical Trials

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**MULTIPLE MYELOMA****STUDY 2012-122****Phase I/II**

Multicenter, Open-label, Single-arm, Phase 1b/2 Study of the Safety and Efficacy of Combination Treatment with Pomalidomide, Dexamethasone, and Carfilzomib (PdC) in Subjects with Relapsed and Relapsed/Refractory Multiple Myeloma

**STUDY 2019-071****Phase I/II**

A Phase 1/2, Multicenter, Open-label, Study to Determine the Recommended Dose and Regimen, and Evaluate the Safety and Preliminary Efficacy of CC- 92480 in Combination with Standard Treatments in Subjects with Relapsed or Refractory (RRMM) and Newly Diagnosed Multiple Myeloma (NDMM)

**STUDY 2018-112****Phase I**

A Phase 1 Study of FOR46 Administered Every 21 Days in Patients with Relapsed or Refractory Multiple Myeloma (RRMM)

**STUDY 2017-136****Pilot**

An Open-label, Pilot Study of Dabrafenib and/or Trametinib in Patients with Relapsed and/or Refractory Multiple Myeloma

**STUDY 2018-014****Phase I**

A Phase 1, Open-label Study to Evaluate the Safety, Pharmacokinetics, Immunogenicity, and Preliminary Efficacy of MEDI2228 in Subjects with Relapsed/Refractory Multiple Myeloma

**STUDY 2012-122****Phase I/II**

Multicenter, Open-label, Single-arm, Phase 1b/2 Study of the Safety and Efficacy of Combination Treatment with Pomalidomide, Dexamethasone, and Carfilzomib (PdC) in Subjects with Relapsed and Relapsed/Refractory Multiple Myeloma

**STUDY 2014-090****Phase I**

A Phase I Study of the Combination of a Selective Inhibitor of Nuclear Export (SINE), Selinexor with Carfilzomib and Dexamethasone in Patients with Relapsed or Relapsed/Refractory Multiple Myeloma.

**STUDY 2016-086****Phase I**

A Phase 1b/2a Multicenter, Open-label, Dose-escalation Study to Determine the Maximum Tolerated Dose, Assess the Safety and Tolerability, Pharmacokinetics and Preliminary Efficacy of CC-220 Monotherapy and in Combination with Dexamethasone in Subjects with Relapsed and Refractory Multiple Myeloma

**STUDY 2018-176****Phase I/II**

MyDRUG: Myeloma-Developing Regimens Using Genomics (Genomics Guided Multi-arm Trial of Targeted Agents Alone or in Combination with a Backbone Regimen)

**STUDY 2019-054****Phase II**

A Phase 2 Study of Daratumumab Subcutaneous (Dara-SC) Administration in Combination with Carfilzomib and Dexamethasone (DKd) Compared with Carfilzomib and Dexamethasone (Kd) in Participants with Multiple Myeloma who have been Previously Treated with Daratumumab Intravenous (Dara-IV) to Evaluate Daratumumab Retreatment

**STUDY S1803****Phase III**

Phase III Study of Daraumumab/rGuPH20 (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 (DRAMATIC Study)

**STUDY 2019-014****Phase II**

Open-Label, Single-arm, Phase 2 Study of Initial Treatment with Elotuzumab, Carfilzomib (Kyprolis), Lenalidomide (Revlimid) and Low dose Dexamethasone (E-KRd) in Newly Diagnosed, Multiple Myeloma Requiring Systemic Chemotherapy

**STUDY 2018-042****Phase III**

A Phase 3, Multicenter, Randomized, Open-Label Study of Venetoclax and Dexamethasone Compared with Pomalidomide and Dexamethasone in Subjects with t(11;14) Positive Relapsed or Refractory Multiple Myeloma

**STUDY 2019-006****Phase I/II**

Phase 1/2 FIH Study of REGN5458 (Anti-CD3 Bispecific Antibody) in Patients with Relapsed or Refractory Multiple Myeloma

**AMYLOIDOSIS or LIGHT CHAIN DEPOSITION DISEASE****STUDY 2016-200****Phase II**

A Randomized Phase 2 Trial of Revlimid/ Dexamethasone/ Elotuzumab +/- Cyclophosphamide followed by Revlimid/ Dexamethasone/Elotuzumab Maintenance as Second-line Therapy for Patients with Relapsed AL Amyloidosis

**STUDY 2016-060****Phase I**

A Phase 1, First-in-Human, Open-Label, Dose Escalation Study of JNJ-63709178, a Humanized CD123x CD3 DuoBody in Subjects with Relapsed or Refractory AML

**LEUKEMIA****Acute Myeloid Leukemia (AML)****STUDY BMTCTN1506****Phase III**

A Multi-center, Randomized, Double-blind, Placebo-controlled Phase III Trial of the FLT3 Inhibitor Gilteritinib Administered as Maintenance Therapy Following Allogeneic Transplant for Patients with FLT3/ITD AML.

**STUDY 2018-027**

**Phase I/II**

A Phase I/II, Open-Label, Multicenter 2-Part Study to Assess the Safety, Tolerability, Pharmacokinetics, and Efficacy of AZD2811 Nanoparticle in Patients with Relapsed Acute Myeloid Leukemia/High-Risk Myelodysplastic Syndrome or Treatment-Naïve Patients Not Eligible for Intensive Induction Therapy

**STUDY 2017-119**

**Phase III**

Phase III Randomized, Double-blind, Placebo-controlled Study Investigating the Efficacy of the Addition of Crenolanib to Salvage Chemotherapy Versus Salvage Chemotherapy Alone in Subjects  $\leq$  75 Years of Age with Relapsed/Refractory FLT3 Mutated Acute Myeloid Leukemia

**STUDY 2019-023**

**Phase I**

A Phase 1, First-in-Human, Dose Escalation Study of JNJ-67571244 (bispecific antibody targeting CD33 and CD3) in Subjects with Relapsed or Refractory Acute Myeloid Leukemia (AML) or Myelodysplastic Syndrome (MDS)

**STUDY 2017-120**

**Phase III**

Phase III Randomized Study of Crenolanib versus Midostaurin Administered Following Induction Chemotherapy and Consolidation Therapy in Newly Diagnosed Subjects with FLT3 Mutated Acute Myeloid Leukemia

**STUDY 2016-035**

**Phase I**

A Phase 1/1b, Multicenter, Open-label, Dose-Escalation Study of FT-2102 as a Single Agent and in Combination with Azacitidine in Patients with Acute Myeloid Leukemia or Myelodysplastic Syndrome with an IDH1 Mutation

**STUDY 2019-111**

**Phase III**

A Phase III Randomized, Double-Blind Trial to Evaluate the Efficacy of Uproleselan Administered with Chemotherapy versus Chemotherapy Alone in Patients with Relapsed/Refractory Acute Myeloid Leukemia

**Chronic Lymphocytic Leukemia (CLL)**

**STUDY 2014-132**

**Phase III**

A Phase 3b, Multicenter, Open-label, PCI-32765 (Ibrutinib) Long-term Extension Study

**STUDY EA9161**

**Phase III**

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)

**STUDY 2019-110**

**Phase II**

ULTRA-V: Phase 2 Study to Assess the Efficacy and Safety of Ublituximab in Combination With Umbralisib and Venetoclax (U2-V) in Subjects With Chronic Lymphocytic Leukemia (CLL)

**STUDY A041702**

**Phase III**

A Randomized Phase III Study of Ibrutinib Plus Obinutuzumab versus Ibrutinib Plus Venetoclax and Obinutuzumab in Untreated Older Patients (greater than or equal to 70 Years of Age) with Chronic Lymphocytic Leukemia (CLL)

**Chronic Myeloid Leukemia (CML)**

**STUDY 2015-128**

**Phase II**

A Randomized, Open-label, Phase 2 Trial of Ponatinib in Patients with Resistant Chronic Phase Chronic Myeloid Leukemia to Characterize the Efficacy and Safety of a Range of Doses

## **LYMPHOMA**

### **Hodgkin's**

#### **STUDY 2017-132**

##### **Phase II**

An Open-label, Uncontrolled, Multicenter Phase II Trial of MK-3475 (Pembrolizumab) in Children and Young Adults with Newly Diagnosed Classical Hodgkin Lymphoma with Inadequate (Slow Early) Response to Frontline Chemotherapy (KEYNOTE 667)

#### **STUDY 2019-074**

##### **Phase II**

A Phase 2, Multicenter, Single-arm Study of Retreatment with Brentuximab Vedotin in Subjects with Relapsed or Refractory Classical Hodgkin Lymphoma (cHL) or CD30-Expressing Peripheral T Cell Lymphoma (PTCL)

#### **STUDY 2016-033**

##### **Phase II**

A Phase II Multicenter Single Arm Study to Evaluate the Efficacy and Safety of Single Agent Bruton's Tyrosine Kinase Inhibitor, Ibrutinib, in Patients with Relapsed Refractory Hodgkin's Lymphoma

#### **STUDY S1826**

##### **Phase III**

A Phase III, Randomized Study of Nivolumab (Opdivo) Plus AVD or Brentuximab Vedotin (Adcetris) Plus AVD in Patients (Age  $\geq$  12 Years) with Newly Diagnosed Advanced Stage Classical Hodgkin Lymphoma

#### **STUDY 2019-102**

##### **Phase II**

A Phase 2 Open-Label Study of Brentuximab Vedotin in Front-Line Therapy of Hodgkin Lymphoma (HL) and CD30-Expressing Peripheral T Cell Lymphoma (PTCL) In Adults Age 60 and Above

### **Non-Hodgkin's**

#### **Aggressive (Mantle Cell, Large B-Cell Lymphoma)**

#### **STUDY 2013-047**

##### **Phase I**

A Phase 1 Multiple Ascending Dose Study of DS-3032B, an Oral MDM2 Inhibitor, in Subjects with Advanced Solid Tumors or Lymphomas

#### **STUDY NEW EA4181**

##### **Phase II**

A Randomized 3-Arm Phase II Study Comparing 1.) Bendamustine, Rituximab and High Dose Cytarabine (BR/CR)2.) Bendamustine, Rituximab, High Dose Cytarabine and Acalabrutinib (BR/CR-A), and 3.) Bendamustine, Rituximab and Acalabrutinib (BR-A) in Patients less than or equal to 70 years old with Untreated Mantle Cell Lymphoma

#### **STUDY 2018-094**

##### **Phase I/II**

An Open-Label, Randomized, Multicenter, Phase Ib/II Trial Evaluating The Safety, Tolerability, Pharmacokinetics, And Efficacy Of Mosunetuzumab (Btct4465a) In Combination With Polatuzumab Vedotin In Patients With B-Cell Non-Hodgkin Lymphoma

#### **STUDY 2015-150**

##### **Phase I/II**

A Phase Ib/II Study Evaluating the Safety and Efficacy of Obinutuzumab in Combination with Polatuzumab Vedotin and Lenalidomide in Patients with Relapsed or Refractory Follicular Lymphoma and Rituximab in Combination with Polatuzumab Vedotin and Lenalidomide in Patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma

#### **STUDY 2014-132**

##### **Phase III**

A Phase 3b, Multicenter, Open-Label, PCI-32765 (Ibrutinib) Long-term Extension Study

## **T cell**

### **STUDY 2016-056**

#### **Phase II**

A Phase II Study of Single Agent Brentuximab Vedotin in Relapsed/Refractory CD30 Low (<10%) Mature T Cell Lymphoma (TCL)

### **STUDY 2018-003**

#### **Phase I**

A Phase 1a/1b Dose Escalation and Expansion Trial of TTI-622 in Patients with Advanced Relapsed or Refractory Lymphoma or Myeloma

### **STUDY 2018-076**

#### **Phase I/II**

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

### **STUDY 2019-074**

#### **Phase II**

A Phase 2, Multicenter, Single-arm Study of Retreatment with Brentuximab Vedotin in Subjects with Relapsed or Refractory Classical Hodgkin Lymphoma (cHL) or CD30-Expressing Peripheral T Cell Lymphoma (PTCL)

### **STUDY 2018-119**

#### **Phase I/II**

Phase I/II Study of Ixazomib and Romidepsin in Relapsed/ Refractory Peripheral T-cell Lymphoma (PTCL)

### **STUDY 2017-069**

#### **Phase I/II**

A Phase 1/2a Study of BMS-986205 Administered in Combination with Nivolumab anti-PD-1 Monoclonal Antibody) and in Combination with Both Nivolumab and Ipilimumab (anti-CTLA-4 Monoclonal Antibody) in Advanced Malignant Tumors

### **STUDY 2016-037**

#### **Phase I**

A Phase 1 Study of ALKS 4230 Administered Intravenously as Monotherapy and in Combination with Pembrolizumab in Subjects with Advanced Solid Tumors

### **STUDY 2019-102**

#### **Phase II**

A Phase 2 Open-Label Study of Brentuximab Vedotin in Front-Line Therapy of Hodgkin Lymphoma (HL) and CD30-Expressing Peripheral T Cell Lymphoma (PTCL) In Adults Age 60 and Above

### **STUDY 2019-115**

#### **Phase III**

A Phase 3 Randomized, Open-Label, Multicenter Study Comparing Zanubrutinib (BGB-3111) plus Rituximab Versus Bendamustine plus Rituximab in Patients with Previously Untreated Mantle Cell Lymphoma Who Are Ineligible for Stem Cell Transplantation

## **MYELODYSPLASTIC SYNDROME (MDS)**

### **STUDY 2016-035**

#### **Phase I**

A Phase 1/1b, Multicenter, Open-label, Dose-Escalation Study of FT-2102 as a Single Agent and in Combination with Azacitidine in Patients with Acute Myeloid Leukemia or Myelodysplastic Syndrome with an IDH1 Mutation

### **STUDY 2019-023**

#### **Phase I**

A Phase 1, First-in-Human, Dose Escalation Study of JNJ-67571244 (bispecific antibody targeting CD33 and CD3) in Subjects with Relapsed or Refractory Acute Myeloid Leukemia (AML) or Myelodysplastic Syndrome (MDS)

### **STUDY NEW 2019-042**

#### **Phase III**



A Phase 3b, open-label, single-arm, rollover study to evaluate long-term safety in subjects who have participated in other luspatercept (ACE-536) clinical trials

**Study 2018-027**

**Phase I/II**

A Phase I/II, Open-Label, Multicenter 2-Part Study to Assess the Safety, Tolerability, Pharmacokinetics, and Efficacy of AZD2811 Nanoparticle in Patients with Relapsed Acute Myeloid Leukemia/High-Risk Myelodysplastic Syndrome or Treatment-Naive Patients Not Eligible for Intensive Induction Therapy

**OTHER**

**STUDY 2013-113**

**Phase II**

A Multicenter Phase 2 Study of the Bruton's Tyrosine Kinase Inhibitor PCI-32765 (Ibrutinib) for Treatment of Relapsed Hairy Cell Leukemia

**STUDY 2019-057**

**Phase II**

A Phase 2 Study of the Hepcidin Mimetic PTG-300 in Patients with Phlebotomy-Requiring Polycythemia Vera

**STUDY 2019-100**

**Phase III**

A Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Vedolizumab in the Prophylaxis of Intestinal Acute Graft-Versus-Host Disease in Subjects Undergoing Allogeneic Hematopoietic Stem Cell Transplantation

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## Immunotherapy Clinical Trials

For more information on Immunotherapy Clinical Trials, contact the Karmanos Clinical Trials Office at 313-576-9790. To refer a patient for these clinical trials, contact the Karmanos Patient Concierge at 800-527-6266, email [newpt@karmanos.org](mailto:newpt@karmanos.org) or fill out this online referral form.

**IMMUNOTHERAPY**

**STUDY 2018-015**

**Phase I/II**

A Phase 1b/2 Study To Evaluate Safety And Anti Tumor Activity Of Avelumab In Combination With The Poly(Adenosine Diphosphate [Adp]-Ribose) Polymerase (Parp) Inhibitor Talazoparib In Patients With Locally Advanced Or Metastatic Solid Tumors

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## Melanoma/Skin Clinical Trials

For more information on Melanoma/Skin Clinical Trials, contact the Karmanos Clinical Trials Office at 313-576-9790. To refer a patient for these clinical trials, contact the Karmanos Patient Concierge at 800-527-6266, email [newpt@karmanos.org](mailto:newpt@karmanos.org) or fill out this [online referral form](#).

**ADVANCED**

**STUDY 2017-029**

**Phase I**

An Open-Label, Phase I Trial To Determine The Maximum-Tolerated Dose And Investigate Safety, Pharmacokinetics, And Efficacy Of BI 754091 In Patients With Advanced Solid Tumors

**STUDY 2017-064**

**Phase I/II**

A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of INCAGN01876 in Combination With Immune Therapies in Subjects With Advanced or Metastatic Malignancies

**STUDY EA6134****Phase III**

A Randomized Phase III trial of Dabrafenib + Trametinib followed by Ipilimumab + Nivolumab at Progression vs. Ipilimumab + Nivolumab followed by Dabrafenib + Trametinib at Progression in Patients With Advanced BRAFV600 Mutant Melanoma

**STUDY 2017-069****Phase I/II**

A Phase 1/2a Study of BMS-986205 Administered in Combination with Nivolumab anti-PD-1 Monoclonal Antibody) and in Combination with Both Nivolumab and Ipilimumab (anti-CTLA-4 Monoclonal Antibody) in Advanced Malignant Tumors

**STUDY 2016-037****Phase I**

A Phase 1 Study of ALKS 4230 in Subjects with Advanced Solid Tumors

**STUDY 2013-047****Phase I**

A Phase 1 Multiple Ascending Dose Study of DS-3032B, an Oral MDM2 Inhibitor, in Subjects with Advanced Solid Tumors or Lymphomas

**STUDY NEW 2016-017****Phase I/II**

A Phase 1B/2 Open-Label Study to Evaluate Safety, Clinical Activity, Pharmacokinetics and Pharmacodynamics of Avelumab\* (MSB0010718C) in Combination with Other Cancer Immunotherapies in Patients with Advanced Malignancies

**STUDY 2018-098****Phase I/II**

A Phase 1/2a Study to Evaluate the Safety, Tolerability, Immunogenicity, and Anti-Tumor Activity of GEN-009 Adjuvanted Vaccine in Adult Patients with Selected Solid Tumors

**STUDY 2017-087****Phase I**

A Phase 1, Open-Label, Dose-Escalation Study of SEA-CD40 in Adult Patients with Advanced Malignancies

**STUDY 2019-101****Phase I**

A Phase 1a/b Dose-Escalation Study Followed by Expansion Cohorts of NGM120, a GFRAL Antagonist Monoclonal Antibody Blocking GDF15 Signaling, in Subjects With Advanced Solid Tumors and Pancreatic Cancer Using Combination Therapy

**OTHER****STUDY 2017-029****Phase I**

An Open-Label, Phase I Trial To Determine The Maximum-Tolerated Dose And Investigate Safety, Pharmacokinetics, And Efficacy Of BI 754091 In Patients With Advanced Solid Tumours

**STUDY 2017-064****Phase I/II**

A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of INCAGN01876 in Combination With Immune Therapies in Subjects With Advanced or Metastatic Malignancies

**STUDY 2016-055****Phase I**

A Phase 1/1b, Open-Label, Multicenter, Repeat-Dose, Dose-Selection Study of CPI-444 as Single Agent and in Combination with Atezolizumab in Patients with Selected Incurable Cancers

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## Neuro-Oncology Clinical Trials

There are currently no open clinical trials. For more information on Karmanos Clinical Trials please contact the Karmanos Clinical Trials Office at 313-576-9790.

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## Phase I Clinical Trials

For more information on Phase 1 Clinical Trials or to refer a patient, please call 313-576-9204 or email [Phase1NewPt@karmanos.org](mailto:Phase1NewPt@karmanos.org). All patients will need to go through an initial new patient screening consultation to determine if they are eligible for one of our Phase 1 studies and to ensure that it is the best treatment option available for them.

### ALL SOLID TUMORS

#### STUDY 2017-111

##### Phase I

A Phase 1b Dose-Escalation Study of Cabozantinib (XL184) Administered in Combination with Atezolizumab to Subjects with Locally Advanced or Metastatic Solid Tumors

#### STUDY 2017-122

##### Phase I

A Phase 1 Trial of MK-4280 as Monotherapy and in Combination with Pembrolizumab in Subjects with Advanced Solid Tumors

#### STUDY 2018-019

##### Phase I

A First-in-Human Phase I Trial to Determine the Safety and the Pharmacokinetic Profile of DSP-0337 in Patients with Advanced Solid Tumors

#### STUDY 2018-076

##### Phase I/II

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

#### STUDY 2018-156

##### Phase 1

A Phase 1 Study of ALKS 4230 Administered Subcutaneously as Monotherapy and in Combination With Pembrolizumab in Subjects With Advanced Solid Tumors

#### STUDY 2016-170

##### Phase I/II

A Phase I/IIa, Open-Label, Dose-escalation Study Investigating the Safety, Tolerability, and Pharmacokinetics of Intravenous Liposomal Vinorelbine Tartrate Injection in Patients with Advanced Malignancy

#### STUDY 2018-104

##### Phase I/II

A Phase I-II, First-in-Human Study of A166 in Patients with Locally Advanced/Metastatic Solid Tumors which are Human Epidermal Growth Factor Receptor 2 (HER2)-Positive who did not Respond or Stopped Responding to Approved Therapies and Patients with HER2 Positive (by ISH or NGS) or Low Expressing (by IHC) Solid Tumors who did not Respond or Stopped Responding to Approved Therapies

#### STUDY 2018-034

##### Phase I

A Phase 1b Study of ASP8374, an Immune Checkpoint Inhibitor, as a Single Agent and in Combination with Pembrolizumab in Subjects with Advanced Solid Tumors

#### STUDY 2017-088

##### Phase I

A Phase 1 Trial of MK-7684 as Monotherapy and in Combination with Pembrolizumab in Subjects with Advanced Solid Tumors

**STUDY 2017-052**

**Phase I/II**

A Phase 1 Dose Escalation and Cohort Expansion Study of TSR-042, an anti-PD-1 Monoclonal Antibody, in Patients with Advanced Solid Tumors

**STUDY 2018-158**

**Phase I/II**

First-in-human, Phase I/II, Multicenter, Open-Label Study of EMB-01 in Patients with Advanced/Metastatic Solid Tumors

**STUDY 2016-037**

**Phase I**

A Phase 1 Study of ALKS 4230 in Subjects with Advanced Solid Tumors

**STUDY 2018-066**

**Phase I**

A Phase 1 Multiple Dose Study to Evaluate the Safety and Tolerability of XmAb®20717 in Subjects with Selected Advanced Solid Tumors (DUET-2)

**STUDY 2018-035**

**Phase I**

A Phase 1, Multi-Center, Open-Label, Single-Arm, Dose-Escalation, Clinical Study to Evaluate the Safety, Tolerability, Pharmacokinetics (PK) and Anti-Tumor Activity of FN-1501 Monotherapy in Patients with Advanced Solid Tumors

**STUDY 2018-054**

**Phase I**

A Phase 1a/1b Study of FPA150, an Anti-B7-H4 Antibody, in Patients With Advanced Solid Tumors

**STUDY 2018-157**

**Phase I**

An Open Label, Dose-Escalation, Phase 1 Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of TAK-981 in Adult Patients With Metastatic Solid Tumors or Lymphomas

**STUDY 2017-086**

**Phase I/II**

A Phase 1-2, Open-Label, Dose-Finding, Proof of Concept, First-in-Human Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of CX-2009 in Adults with Metastatic or Locally Advanced Unresectable Solid Tumors

**STUDY 2018-100**

**Phase I**

A Phase 1, Multicenter, Open-label Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of TAB001 in Subjects with Advanced Malignancies

**STUDY 2019-082**

**Phase I**

A Phase 1, Open-Label, Dose Escalation and Expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-Tumor Activity of PSB205 in Patients with Relapsed/Refractory Solid Tumors

**STUDY 2017-087**

**Phase I**

A Phase 1, Open-Label, Dose-Escalation Study of SEA-CD40 in Adult Patients with Advanced Malignancies

**TUMOR SPECIFIC**

**STUDY 2018-157**

**Phase I**

An Open Label, Dose-Escalation, Phase 1 Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of TAK-981 in Adult Patients With Metastatic Solid Tumors or Lymphomas

**STUDY 2018-076**

**Phase I/II**

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

**STUDY 2019-071****Phase I/II**

A Phase 1/2, Multicenter, Open-label, Study to Determine the Recommended Dose and Regimen, and Evaluate the Safety and Preliminary Efficacy of CC- 92480 in Combination with Standard Treatments in Subjects with Relapsed or Refractory (RRMM) and Newly Diagnosed Multiple Myeloma (NDMM)

**STUDY 2018-141****Phase I/II**

A Phase 1b/2a Two-Part Open-Label Multicenter Study to Evaluate the Safety and Efficacy of LY2880070 as Monotherapy and in Combination with Gemcitabine in Patients with Advanced or Metastatic Cancer

**STUDY 2018-163****Phase I**

A Phase 1 Study of FOR46 Administered Every 21 Days in Patients with Metastatic Castration-Resistant Prostate Cancer (mCRPC)

**STUDY 2019-007****Phase I/II**

A Phase 1b/2 Study of BXCL701, a Small Molecule Inhibitor of Dipeptidyl Peptidases (DPP), Administered in Combination with the Anti-Programmed Cell Death 1 (PD-1) Monoclonal Antibody Pembrolizumab (PEMBRO; Keytruda®) in Patients with Small Cell Neuroendocrine Prostate Cancer (SCNC; NEPC)

**STUDY 2019-026****Phase I**

A Phase 1 Multiple-Dose Study to Evaluate the Safety and Tolerability of XmAb®22841 Monotherapy and in Combination with Pembrolizumab in Subjects with Selected Advanced Solid Tumors (DUET-4)

**STUDY 2018-166****Phase I/II**

A Phase 1/2 Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Preliminary Efficacy of GP-2250 in Combination with Gemcitabine in Subjects with Advanced Unresectable or Metastatic Pancreatic Adenocarcinoma Who Have Progressed on Prior Treatment with FOLFIRINOX Chemotherapy

**STUDY 2013-047****Phase I**

A Phase 1 Multiple Ascending Dose Study of DS-3032B, an Oral MDM2 Inhibitor, in Subjects with Advanced Solid Tumors or Lymphomas

**STUDY 2017-029****Phase I**

An Open-Label, Phase I Trial To Determine The Maximum-Tolerated Dose And Investigate Safety, Pharmacokinetics, And Efficacy Of BI 754091 In Patients With Advanced Solid Tumours

**STUDY 2019-053****Phase I**

A Phase 1, First-in-Human, Open-Label, Dose Escalation Study of JNJ- 61186372, a Human Bispecific EGFR and cMet Antibody, in Subjects with Advanced Non-Small Cell Lung Cancer

**STUDY 2017-069****Phase I/II**

A Phase 1/2a Study of BMS-986205 Administered in Combination with Nivolumab anti-PD-1 Monoclonal Antibody) and in Combination with Both Nivolumab and Ipilimumab (anti-CTLA-4 Monoclonal Antibody) in Advanced Malignant Tumors

**STUDY 2016-055****Phase I**

A Phase 1/1b, Open-Label, Multicenter, Repeat-Dose, Dose-Selection Study of CPI-444 as Single Agent and in Combination with Atezolizumab in Patients with Selected Incurable Cancers

**STUDY 2018-098****Phase I/II**

A Phase 1/2a Study to Evaluate the Safety, Tolerability, Immunogenicity, and Anti-Tumor Activity of GEN-009 Adjuvanted Vaccine in Adult Patients with Selected Solid Tumors

**STUDY 2019-088****Phase I/II**

A Phase 1b/2, Open-Label, Multicenter Dose-Escalation and Dose-Expansion Study of the Combination of RMC-4630 and Cobimetinib in Adult Participants with Relapsed/Refractory Solid Tumors with Specific Genomic Aberrations

**STUDY NEW 2019-079****Phase I/II**

A Phase 1/2, open-label, dose-escalation study of GBR 1302 in subjects with Phase I/II HER2-positive metastatic breast cancer

**STUDY 2019-123****Phase 1**

A Phase 1, Open-Label Study in Two Parts, Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Clinical Activity of CCW702 in Patients with Metastatic, Castration Resistant Prostate Adenocarcinoma

**STUDY 2013-118****Phase I**

A Phase 1, Open-label, Dose-Escalation Study to Evaluate the Safety and Tolerability of SGN-LIV1A in Patients with LIV-1-positive Metastatic Breast Cancer.

**STUDY 2019-047****Phase I/II**

A Phase 1/2 Study of Combination Olaparib and Radium-223 in Men with Metastatic Castration-Resistant Prostate Cancer with Bone Metastases (COMRADE)

**STUDY 2019-070****Phase I**

Phase 1 Study of KN026 in HER2 Expressing Breast Cancer, Gastric/Gastroesophageal Junction Cancer and other Locally Advanced/Metastatic Solid Tumors

**STUDY 2019-101****Phase I**

A Phase 1a/b Dose-Escalation Study Followed by Expansion Cohorts of NGM120, a GFRAL Antagonist Monoclonal Antibody Blocking GDF15 Signaling, in Subjects With Advanced Solid Tumors and Pancreatic Cancer Using Combination Therapy

**GENOMIC TESTING SPECIFIC****STUDY 2018-054****Phase I**

A Phase 1a/1b Study of FPA150, an Anti-B7-H4 Antibody, in Patients With Advanced Solid Tumors

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**Sarcoma Clinical Trials**

There are currently no open clinical trials. For more information on Karmanos Clinical Trials please contact the Karmanos Clinical Trials Office at 313-576-9790.

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## Thoracic Clinical Trials

For more information on Thoracic Clinical Trials, contact the Karmanos Clinical Trials Office at 313-576-9790. To refer a patient for these clinical trials, contact the Karmanos Patient Concierge at 800-527-6266, email [newpt@karmanos.org](mailto:newpt@karmanos.org) or fill out this [online referral form](#).

### ADJUVANT

#### STUDY 2018-142

##### Phase III

A Phase III, Double-blinded, Multicenter, Randomized Study Evaluating the Efficacy and Safety of Neoadjuvant Treatment with Atezolizumab or Placebo in Combination with Platinum-**Based** Chemotherapy in Patients with Resectable Stage II, IIIA, or SELECT IIIB Non-Small Cell Lung Cancer

### MAINTENANCE

#### STUDY NRG-LU002

##### Phase II/III

Maintenance Systemic Therapy Versus Consolidative Stereotactic Body Radiation Therapy (SBRT) Plus Maintenance Systemic Therapy for Limited Metastatic Non-Small Cell Lung Cancer (NSCLC): A Randomized Trial

#### STUDY NRG-LU004

##### Phase I

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

### STAGE I/II

#### STUDY 2019-018

##### Phase I/II

A Phase 1/2, Open-Label, Multi-Center, First-in-Human Study of the Safety, Tolerability, Pharmacokinetics, and Anti-Tumor Activity of TPX-0005 in Patients with Advanced Solid Tumors Harboring ALK, ROS1, or NTRK1-3 Rearrangements (TRIDENT-1)

#### STUDY 2019-053

##### Phase I

A Phase 1, First-in-Human, Open-Label, Dose Escalation Study of JNJ- 61186372, a Human Bispecific EGFR and cMet Antibody, in Subjects with Advanced Non-Small Cell Lung Cancer

#### STUDY 2018-098

##### Phase I/II

A Phase 1/2a Study to Evaluate the Safety, Tolerability, Immunogenicity, and Anti-Tumor Activity of GEN-009 Adjuvanted in Adult Patients with Selected Solid Tumors

### STAGE III A/B

#### STUDY 2017-152

##### Phase II

Phase II Study of Consolidation Immunotherapy with Nivolumab and Ipilimumab or Nivolumab alone following Concurrent Chemoradiotherapy for Unresectable Stage IIIA/IIIB Non-small Cell Lung Cancer (NSCLC)

#### STUDY 2018-120

##### Phase I/II

An Open Label, Single Arm, Phase 1b/2 Study to Evaluate the Safety and Efficacy of Grapiprant (ARY-007) in Combination with Pembrolizumab in Patients with Advanced or Metastatic Post-PD-1/L1 Non-Small Cell Lung Cancer (NSCLC) Adenocarcinoma

#### STUDY 2019-020

##### Phase III

A Phase III, Randomized, Placebo-controlled, Double-blind, Multi-center, International Study of Durvalumab Following Stereotactic Body Radiation Therapy (SBRT) for the Treatment of Patients with Unresected Stage I/II, Lymph-node Negative Non-small Cell Lung Cancer (PACIFIC-4/RTOG-3515)

**STUDY 2019-034****Phase III**

A Phase 3 Study of Pembrolizumab in Combination with Carboplatin/Taxane (Paclitaxel or Nab-paclitaxel) Followed by Pembrolizumab with or without Maintenance Olaparib in the First-Line Treatment of Metastatic Squamous Non-Small Cell Lung Cancer (NSCLC)

**STUDY 2019-036****Phase III**

A Phase 3 Study of Pembrolizumab in Combination with Pemetrexed/Platinum Carboplatin or Cisplatin) Followed by Pembrolizumab and Maintenance Olaparib vs Maintenance Pemetrexed in the First-Line Treatment of Participants with Metastatic Nonsquamous Non-Small-Cell Lung Cancer

**STUDY 2018-065****Phase II**

A Phase 2, Multicenter Study of Autologous Tumor Infiltrating Lymphocytes (LN 144 or N-145) in Patients with Solid Tumors

**STUDY 2018-111****Phase III**

A Phase III, Randomized, Double-blind, Placebo-controlled, Multi-center, International Study of Durvalumab or Durvalumab and Tremelimumab as Consolidation Treatment for Patients with Stage I-III Limited Disease Small-Cell Lung Cancer Who Have Not Progressed Following Concurrent Chemoradiation Therapy (ADRIATIC)

**STUDY 2018-060****Phase II**

A Phase 2, Multicenter, Open-Label, 2-Cohort Study of Trastuzumab Deruxtecan (DS-8201a), an anti-HER2 Antibody Drug Conjugate (ADC), for HER2-Over-Expressing or -Mutated, Unresectable and/or Metastatic Non-Small Cell Lung Cancer (NSCLC)

**STUDY 2018-098****Phase I/II**

A Phase 1/2a Study to Evaluate the Safety, Tolerability, Immunogenicity, and Anti-Tumor Activity of GEN-009 Adjuvanted Vaccine in Adult Patients with Selected Solid Tumors

**STAGE IV****EGFR****STUDY 2017-145****Phase II**

A Phase 2 Study of Pozitotinib in Patients with Non-Small Cell Lung Cancer, Locally Advanced or Metastatic, with EGFR or HER2 Exon 20 Insertion Mutation (POZITIVE20-1)

**Other Genetic Marker****STUDY 2017-145****Phase II**

A Phase 2 Study of Pozitotinib in Patients with Non-Small Cell Lung Cancer, Locally Advanced or Metastatic, with EGFR or HER2 Exon 20 Insertion Mutation (POZITIVE20-1)

**STUDY 2015-174****Pilot**

Study of the Effects of Dexamethasone on Non-Small Cell Lung Cancer Using [F-18] FLT for Imaging with Positron Emission Pilot Tomography (PET)

**STUDY NEW 2016-017****Phase I/II**

A Phase 1B/2 Open-Label Study to Evaluate Safety, Clinical Activity, Pharmacokinetics and Pharmacodynamics of Avelumab\* (MSB0010718C) in Combination with Other Cancer Immunotherapies in Patients with Advanced Malignancies

**STUDY 2018-065****Phase II**

A Phase 2, Multicenter Study of Autologous Tumor Infiltrating Lymphocytes (LN 144 or N-145) in Patients with Solid Tumors



**STUDY 2018-120****Phase I/II**

An Open Label, Single Arm, Phase 1b/2 Study to Evaluate the Safety and Efficacy of Grapiprant (ARY-007) in Combination with Pembrolizumab in Patients with Advanced or Metastatic Post-PD-1/L1 Non-Small Cell Lung Cancer (NSCLC) Adenocarcinoma

**STUDY 2017-111****Phase I**

A Phase 1b Dose-Escalation Study of Cabozantinib (XL184) Administered in Combination with Atezolizumab to Subjects with Locally Advanced or Metastatic Solid Tumors

**STUDY 2016-055****Phase I**

A Phase 1/1b, Open-Label, Multicenter, Repeat-Dose, Dose-Selection Study of CPI-444 as Single Agent and in Combination with Atezolizumab in Patients with Selected Incurable Cancers

**STUDY 2014-002****Phase II**

A Study to Assess the Ability to Initiate Therapy in Advanced Non-Small Cell Lung Cancer (NSCLC) Patients Based on Genomic Analyses of Tumor Specimens

**STUDY 2016-037****Phase I**

A Phase 1 Study of ALKS 4230 Administered Intravenously as Monotherapy and in Combination with Pembrolizumab in Subjects with Advanced Solid Tumors

**STUDY 2018-060****Phase II**

A Phase 2, Multicenter, Open-Label, 2-Cohort Study of Trastuzumab Deruxtecan (DS-8201a), an anti-HER2 Antibody Drug Conjugate (ADC), for HER2-Over-Expressing or -Mutated, Unresectable and/or Metastatic Non-Small Cell Lung Cancer (NSCLC)

**STUDY 2017-129****NA**

Improving Treatment Cost Discussions between Cancer Patients and their Oncologists: Feasibility and Utilization of an Application-based Question Prompt List

**STUDY 2018-053****Phase III**

METIS: Pivotal, Open-Label, Randomized Study of Radiosurgery with or without Tumor Treating Fields (TTFields) for 1-10 Brain Metastases from Non-Small Cell Lung Cancer (NSCLC)

**STUDY 2018-098****Phase I/II**

A Phase 1/2a Study to Evaluate the Safety, Tolerability, Immunogenicity, and Anti-Tumor Activity of GEN-009 Adjuvanted Vaccine in Adult Patients with Selected Solid Tumors

**STUDY 2019-101****Phase I**

A Phase 1a/b Dose-Escalation Study Followed by Expansion Cohorts of NGM120, a GFRAL Antagonist Monoclonal Antibody Blocking GDF15 Signaling, in Subjects With Advanced Solid Tumors and Pancreatic Cancer Using Combination Therapy

**STUDY 2019-121****Phase I/II**

A Phase I/II Study of MCLA-128, a Full Length IgG1 Bispecific Antibody Targeting HER2 and HER3, in Patients with Solid Tumors

**RECURRENT****ALK****STUDY 2017-106****Phase II**

Phase II Multi-Center Study of Pembrolizumab in Combination with Platinumbased Doublet Chemotherapy in Patients with EGFR

Mutation and ALK Positive NSCLC (Non-Small Cell Lung Cancer) with Progressive Disease Following Prior Tyrosine Kinase Inhibitors (TKIs)

## **EGFR**

### **STUDY 2017-106**

#### **Phase II**

Phase II Multi-Center Study of Pembrolizumab in Combination with Platinumbased Doublet Chemotherapy in Patients with EGFR Mutation and ALK Positive NSCLC (Non-Small Cell Lung Cancer) with Progressive Disease Following Prior Tyrosine Kinase Inhibitors (TKIs)

### **STUDY 2018-065**

#### **Phase II**

A Phase 2, Multicenter Study of Autologous Tumor Infiltrating Lymphocytes (LN 144 or N-145) in Patients with Solid Tumors

## **SCLC LIMITED**

### **STUDY NRG-LU005**

#### **Phase I/II**

Limited Stage Small Cell Lung Cancer (LS-SCLC): A Phase II/III Randomized Study of Chemoradiation Versus Chemoradiation Plus Atezolizumab

## **SCLC EXTENSIVE**

### **STUDY 2017-064**

#### **Phase I/II**

A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of INCAGN01876 in Combination With Immune Therapies in Subjects With Advanced or Metastatic Malignancies

## **MESOTHELIOMA**

### **STUDY 2018-105**

#### **Phase II**

Study of Nivolumab and Ramucirumab for Patients with Previously-Treated Mesothelioma

### **STUDY 2017-064**

#### **Phase I/II**

A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of INCAGN01876 in Combination With Immune Therapies in Subjects With Advanced or Metastatic Malignancies

## **OTHER**

### **STUDY 2017-064**

#### **Phase I/II**

A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of INCAGN01876 in Combination With Immune Therapies in Subjects With Advanced or Metastatic Malignancies

### **STUDY 2018-081**

#### **Phase I**

A Phase I Open Label, Multicenter Study to Assess the Safety, Tolerability, Pharmacokinetics, and Anti-Tumor Activity of ZN-e4 (KP-673) in Patients with Advanced Non-Small Cell Lung Cancer with Activating Epidermal Growth Factor Receptor (EGFR) Mutations

### **STUDY 2018-171**

#### **Phase II**

A Phase II, Open Label, Multi-Dose Study of 89ZR-DF-IAB22M2C (CD8 PET Tracer) for Positron Emission Tomography (PET/CT) in Patients with Metastatic Solid Tumors

### **STUDY 2018-076**

#### **Phase I/II**

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

**STUDY 2016-116****Phase II**

A Phase 2 Study of Cediranib in Combination with Olaparib in Advanced Solid Tumors

**STUDY 2017-069****Phase I/II**

A Phase 1/2a Study of BMS-986205 Administered in Combination with Nivolumab (anti-PD-1 Monoclonal Antibody) and in Combination with Both Nivolumab and Ipilimumab (anti-CTLA-4 Monoclonal Antibody) in Advanced Malignant Tumors

**STUDY 2017-029****Phase I**

An Open-Label, Phase I Trial To Determine The Maximum-Tolerated Dose And Investigate Safety, Pharmacokinetics, And Efficacy Of BI 754091 In Patients With Advanced Solid Tumours

**STUDY 2017-087****Phase I**

A Phase 1, Open-Label, Dose-Escalation Study of SEA-CD40 in Adult Patients with Advanced Malignancies

**STUDY 2019-088****Phase I/II**

A Phase 1b/2, Open-Label, Multicenter Dose-Escalation and Dose-Expansion Study of the Combination of RMC-4630 and Cobimetinib in Adult Participants With Relapsed/Refractory Solid Tumors With Specific Genomic Aberrations

**STUDY 2019-032****Phase I**

A Randomized Phase 3 Study of Sitravatinib in Combination with Nivolumab Versus Docetaxel in Patients with Advanced Non-Squamous Non-Small Cell Lung Cancer with Disease Progression On or After Platinum-Based Chemotherapy and Checkpoint Inhibitor Therapy

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