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.

To view the current issue online, please click here.

Get access to our clinical trials on your iPhone®, iPad® or Android™ mobile devices with the FREE KCI Trials App.

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</table>

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 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 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 2016-049**  
**Phase I/II**  
A Phase 1, Non-Randomized, Open-Label/Phase 2, Randomized, Blinded Study of ProTmune (ex vivo Programmed Mobilized Peripheral Blood Cells) Versus Non- Programmed Mobilized Peripheral Blood Cells for Allogeneic Hematopoietic Cell Transplantation in Adult Subjects with Hematologic Malignancies

**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 NEW 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 NEW 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 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.

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 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

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 2019-043
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 A17160
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 2016-116
Phase II
A Phase 2 Study of Cediranib in Combination with Olaparib in Advanced Solid 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 2018-141
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 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

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

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 2019-088
Phase III
A Randomized, Placebo-Controlled, Double-Blind Phase 3 Study to Evaluate the Efficacy and Safety of Tislelizumab (BGB-A317) in Combination with Cemotherapyas First-Line Treatment in Patients with Unresectable, Locally Advanced Recurrent or Metastatic Esophageal Squamous Cell Carcinoma
GASTRIC AND GASTROESOPHAGEAL JUNCTION

**Metastatic**

**STUDY 2016-210**
Phase I/II
An Open-Label, Dose-Finding And Proof Of Concept Study Of The PD-L1 Probody Therapeutic, CX-072, As Monotherapy And In Combination With Yervoy (Ipilimumab) Or With Zelboraf (Vemurafenib) In Subjects With Advanced Or Recurrent Solid Tumors Or Lymphomas

**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 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

**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

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-Paclitaxel for Front-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**
<table>
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<th>Phase I/II</th>
<th>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</th>
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| STUDY RTOG1112 | Phase III | Randomized Phase III Study of Sorafenib Versus Stereotactic Body Radiation Phase III Therapy Followed By Sorafenib in Hepatocellular Carcinoma |

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<th>STUDY 2017-064</th>
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</table>
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 BGI398 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

**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)**  

**1st Line**  
**STUDY NRG-GI004**  
**Phase III**  
Colorectal Cancer Metastatic dMMR Immuno-Therapy (COMMIT) Study: A Randomized Phase III Study of mFOLFOX6/Bevacizumab Combination Chemotherapy with or without Atezolizumab or Atezolizumab Monotherapy in the First-Line Treatment of Patients with Deficient DNA Mismatch Repair (dMMR) Metastatic Colorectal Cancer

**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 2016-157**  
**Phase I**  
Phase I Clinical Trial of VX-970 in Combination with the Topoisomerase I Inhibitor Irinotecan in Patients with Advanced Solid Tumors

**STUDY 2019-010**  
**Phase III**  
A Randomized, Multicenter, Parallel-Group, Phase III Study to Compare the Efficacy of Arfolitixorin 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 Pembrolizmab in Subjects with Advanced Solid Tumors

STUDY 2017-129
NA
Improving Treatment Cost Discussions between Cancer Patients and their Oncologists: Feasability and Utilization of an Application-based Question Prompt List

STUDY NEW 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

RECTUM
STUDY 2017-129
NA
Improving Treatment Cost Discussions between Cancer Patients and their Oncologists: Feasability 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
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

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
**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 S1500**  
Phase II  
A Randomized, Phase II Efficacy Assessment of Multiple MET Kinase Inhibitors (Cabozantinib [NSC #761968], Crizotinib [NSC #749005], Savolitinib [NSC #785348], and Sunitinib [NSC #736511]) in Metastatic Papillary Renal Carcinoma (PAPMET)

**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
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<td>A Phase 2, Fast Real-time Assessment of Combination Therapies in Immuno-ONcology Study in Participants with Advanced Renal Cell Carcinoma (FRACTION-RCC)</td>
</tr>
<tr>
<td>STUDY 2017-029</td>
<td>Phase I</td>
<td>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</td>
</tr>
<tr>
<td>STUDY 2016-157</td>
<td>Phase I</td>
<td>Phase I Clinical Trial of VX-970 in Combination with the Topoisomerase I Inhibitor Irinotecan in Patients with Advanced Solid Tumors</td>
</tr>
<tr>
<td>STUDY 2017-064</td>
<td>Phase I/II</td>
<td>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</td>
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<tr>
<td>STUDY 2016-055</td>
<td>Phase I</td>
<td>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</td>
</tr>
<tr>
<td>STUDY 2018-098</td>
<td>Phase I/II</td>
<td>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</td>
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**PROSTATE**

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<th>Study Code</th>
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<tr>
<td>STUDY 2013-108</td>
<td>NA</td>
<td>Immune Evaluation Study of Sipuleucel-T in African American and Non African American Men with Castrate Resistant Prostate Cancer</td>
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<tr>
<td>STUDY 2016-157</td>
<td>Phase I</td>
<td>Phase I Clinical Trial of VX-970 in Combination with the Topoisomerase I Inhibitor Irinotecan in Patients with Advanced Solid Tumors</td>
</tr>
<tr>
<td>STUDY 2019-029</td>
<td>Phase III</td>
<td>A Phase 3, Randomized Open-label Study of Pembrolizumab (MK-3475) Plus Olaparib Versus Abiraterone Acetate or Enzalutamide in Participants with Metastatic Castration-resistant Prostate Cancer (mCRPC) Who are Unselected for Homologous Recombination Repair Defects and Have Failed Prior Treatment with One Next-generation Hormonal Agent (NHA) and Chemotherapy(KEYLYNK-010)</td>
</tr>
<tr>
<td>STUDY 2018-170</td>
<td>NA</td>
<td>Genetic Counseling Processes and Outcomes Among Males with Prostate Cancer (ProGen)</td>
</tr>
<tr>
<td><strong>STUDY NEW 2019-027</strong></td>
<td>Phase II</td>
<td>IMPACT: Immunotherapy in Patients with Metastatic Cancers and CDK12 Mutations</td>
</tr>
<tr>
<td><strong>STUDY 2019-030</strong></td>
<td>Phase III</td>
<td>A Phase 3, Randomized, Double-blind Study of Pembrolizumab (MK-3475) Plus Docetaxel Plus Prednisone versus Placebo Plus Docetaxel Plus Prednisone in Participants with Chemotherapy-naïve Metastatic Castration-Resistant Prostate Cancer (mCRPC) who have Progressed on a Next Generation Hormonal Agent (NHA) (KEYNOTE-921)</td>
</tr>
</tbody>
</table>
STUDY 2019-045
Phase II
A Multicentre Phase Ib 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 2019-007
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 (PEMBO; Keytruda®) in Patients with Small Cell Neuroendocrine Prostate Cancer (SCNC; NEPC)

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 2017-092**  
**Phase II**  
A Single-arm, Open-label, Multicenter Study of Enfortumab Vedotin (ASG-22CE) for Treatment of Patients with Locally Advanced or Metastatic Urothelial Cancer who Previously Received Immune Checkpoint Inhibitor (CPI) Therapy

**STUDY 2015-167**  
**Phase II**  
A Randomized Phase 2 Trial of Ascorbic Acid in Combination with Docetaxel in Men with Metastatic Prostate Cancer

**STUDY 2017-046**  
**Phase I**  
A Phase IB Open-Label, Dose Escalation and Expansion Study to Investigate the Safety, Pharmacokinetics, Pharmacodynamics and Clinical Activity of GSK525762 in Combination with Androgen Deprivation Therapy and Other Agents in Subjects with Castrate Resistant Prostate Cancer (CRPC)

**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 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

**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 2018-017**  
**Phase II**  
A Phase 2 Study of Nivolumab in Combination with Either Rucaparib, Docetaxel, or Enzalutamide in Men with Castration Resistant Metastatic Prostate Cancer (CheckMate 9KD: CHECKpoint Pathway and NivoluMAb Clinical Trial Evaluation 9KD)

**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 Sitratavinib 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 2017-092
Phase II
A Single-arm, Open-label, Multicenter Study of Enfortumab Vedotin (ASG-22CE) for Treatment of Patients with Locally Advanced or Metastatic Urothelial Cancer who Previously Received Immune Checkpoint Inhibitor (CPI) Therapy

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 2016-175
Phase II
A Randomized Phase 2 Trial of Cisplatin/Gemcitabine with or without VX-970 in Metastatic Urothelial Carcinoma

STUDY 2016-157
Phase I
Phase I Clinical Trial of VX-970 in Combination with the Topoisomerase I Inhibitor Irinotecan in Patients with Advanced Solid Tumors

STUDY 2018-044
Phase II
Phase 2 Trial of Olaparib in Patients with Metastatic Urothelial Cancer Harboring DNA Damage Response Gene Alterations
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

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 NEW 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 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

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

Gynecologic Clinical Trials
For more information on Gynecologic 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 or fill out this online referral form.

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
<table>
<thead>
<tr>
<th>Study Code</th>
<th>Phase</th>
<th>Title</th>
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<tbody>
<tr>
<td>STUDY 2018-103</td>
<td>Phase III</td>
<td>A Phase 3 Randomized, Double-Blind, Placebo-Controlled Trial of Pembrolizumab (MK-3475) Plus Chemotherapy Versus Chemotherapy Plus Placebo for the First-Line Treatment of Persistent, Recurrent, or Metastatic Cervical Cancer (KEYNOTE-826)</td>
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<td>STUDY 2017-069</td>
<td>Phase I/II</td>
<td>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</td>
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<td>OVARY</td>
<td>STUDY GOG-3020</td>
<td>Phase III</td>
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<td>ATHENA: A Multicenter, Randomized, Double-Blind, Placebo-Controlled Phase 3 Study in Ovarian Cancer Patients Evaluating Rucaparib and Nivolumab as Maintenance Treatment Following Response to Front-Line Platinum-Based Chemotherapy</td>
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<td>STUDY GOG-3018</td>
<td>Phase III</td>
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<td>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</td>
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<td>STUDY 2018-043</td>
<td>Phase III</td>
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<td></td>
<td>A Phase 3, Randomized, Single Dose, Open-Label Study to Investigate the Safety and Efficacy of OTL38 Injection (OTL38) for Intra-operative Imaging of Folate Receptor Positive Ovarian Cancer</td>
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<td>STUDY 2018-159</td>
<td>Phase II</td>
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<tr>
<td></td>
<td>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</td>
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<td>STUDY NRG-GY005</td>
<td>Phase II/III</td>
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<td>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</td>
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<td>STUDY 2018-141</td>
<td>Phase I/II</td>
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<td>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</td>
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<td>STUDY 2017-064</td>
<td>Phase I/II</td>
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<td>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</td>
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<td>STUDY 2016-037</td>
<td>Phase I</td>
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<tr>
<td></td>
<td>A Phase 1 Study of ALKS 4230 in Subjects with Advanced Solid Tumors</td>
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<td>STUDY 2018-054</td>
<td>Phase I</td>
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<tr>
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<td>A Phase 1a/1b Study of FPA 150, an Anti-B7-H4 Antibody, in Patients With Solid Advanced Tumors</td>
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<td>STUDY 2018-015</td>
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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 NEW 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

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

STUDY NEW 2019-107  
Phase II  
A Phase II Study of the PARP inhibitor Olaparib in Combination with the DNA Damaging Agent Temozolomide for the Treatment of Advanced Uterine Leiomyosarcoma

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 NEW 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 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)
Head & Neck Clinical Trials

For more information on Head & Neck 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 or fill out this online referral form.

STAGES I/II/III

STUDY 2016-093
Phase I/II
A Phase 1b/2, Open-Label, Multicentre Study Assessing the Safety, Tolerability, Pharmacokinetics, and Preliminary Anti-tumor Activity of MEDI4736 in Combination With AZD9150 or AZD5069 in Patients With Advanced Solid Malignancies and Subsequently Comparing AZD9150 and AZD5069 Both as Monotherapy and in Combination With MEDI4736 as Second Line Treatment in Patients With Recurrent and/or Metastatic Squamous Cell Carcinoma of the Head and Neck

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 RTOG1008
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 NEW 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
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<thead>
<tr>
<th>STUDY</th>
<th>YEAR</th>
<th>PHASE</th>
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<tbody>
<tr>
<td>2016-212</td>
<td>Phase II</td>
<td>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</td>
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<tr>
<td>2017-107</td>
<td>Phase III</td>
<td>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</td>
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</tr>
<tr>
<td>2019-087</td>
<td>Phase I</td>
<td>A Phase 1, First-in-Human, Open-Label, Dose Escalation and Expansion Study of CUE-101 Monotherapy in Patients with HPV+ Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma (HNSCC)</td>
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<td>2018-076</td>
<td>Phase I/II</td>
<td>A Phase 1-2, First-in-Human Study of CX-2029 in Adults with Metastatic or Locally Advanced Unresectable Solid Tumors or Diffuse Large B-cell Lymphomas</td>
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<td>2017-069</td>
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<td>2016-017</td>
<td>Phase I/II</td>
<td>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</td>
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<tr>
<td>2018-098</td>
<td>Phase I/II</td>
<td>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</td>
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<tr>
<td>OTHER</td>
<td>2017-064</td>
<td>Phase I/II</td>
<td>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</td>
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<tr>
<td>2017-087</td>
<td>Phase I</td>
<td>A Phase 1, Open-Label, Dose-Escalation Study of SEA-CD40 in Adult Patients with Advanced Malignancies</td>
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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 2016-062**  
Phase I/II  
Phase 1/2 Trial of Idasanutlin in Combination with Ixazomib and Dexamethasone in Patients with 17p Deleted, Relapsed Phase I/II Multiple Myeloma

**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 2018-028**  
Phase II  
A Multicenter Phase 2 Study to Evaluate Subcutaneous Daratumumab in Combination with Standard Multiple Myeloma Treatment Regimens

**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 2018-026**  
Phase II  
A Phase II Study of CD38 Antibody Daratumumab in Patients with High-Risk MGUS and Low-Risk Smoldering 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 Daratumumab/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 Refactory 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 DouBody in Subjects with Relapsed or Refractory AML

**LUEKEMIA**  
**Acute Myeloid Leukemia (AML)**  
**STUDY BMTCN1506**  
**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 < or = 75 Years of Age with Relapsed/Refractory FLT3 Mutated Acute Myeloid Leukemia
<table>
<thead>
<tr>
<th>Study Number</th>
<th>Phase</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>STUDY 2015-093</td>
<td>Phase II</td>
<td>Randomized Phase II Study to Assess the Role of Nivolumab as Single Agent to Eliminate Minimal Residual Disease and Maintain Remission in Acute Myelogenous Leukemia (AML) Patients After Chemotherapy</td>
</tr>
<tr>
<td>STUDY 2019-023</td>
<td>Phase I</td>
<td>A Phase 1, First-in-Human, Dose Escalation Study of JNJ-67571244 (bispecif antibody targeting CD33 and CD3) in Subjects with Relapsed or Refractory Acute Myeloid Leukemia (AML) or Myelodysplastic Syndrome (MDS)</td>
</tr>
<tr>
<td>STUDY 2017-120</td>
<td>Phase III</td>
<td>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</td>
</tr>
<tr>
<td>STUDY 2016-035</td>
<td>Phase I</td>
<td>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</td>
</tr>
<tr>
<td><strong>Chronic Lymphocytic Leukemia (CLL)</strong></td>
<td></td>
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</tr>
<tr>
<td>STUDY 2014-132</td>
<td>Phase III</td>
<td>A Phase 3b, Multicenter, Open-label, PCI-32765 (Ibrutinib) Long-term Extension Study</td>
</tr>
<tr>
<td>STUDY EA9161</td>
<td>Phase III</td>
<td>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)</td>
</tr>
<tr>
<td>STUDY A041702</td>
<td>Phase III</td>
<td>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)</td>
</tr>
<tr>
<td><strong>Chronic Myeloid Leukemia (CML)</strong></td>
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</tr>
<tr>
<td>STUDY 2015-128</td>
<td>Phase II</td>
<td>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</td>
</tr>
<tr>
<td><strong>LYMPHOMA</strong></td>
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<tr>
<td><strong>Hodgkin's</strong></td>
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</tr>
<tr>
<td>STUDY 2017-132</td>
<td>Phase II</td>
<td>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)</td>
</tr>
<tr>
<td>STUDY 2019-074</td>
<td>Phase II</td>
<td>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)</td>
</tr>
<tr>
<td>STUDY 2016-033</td>
<td>Phase II</td>
<td>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</td>
</tr>
</tbody>
</table>
STUDY NEW S1826
Phase III
A Phase III, Randomized Study of Nivolumab (Opdivo) Plus AVD or Brentuximab Vedotin (Adcetris) Plus AVD in Patients (Age ≥ 12 Years) with Newly Diagnosed Advanced Stage Classical Hodgkin Lymphoma

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 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 2016-210
Phase I/II
An Open-Label, Dose-Finding And Proof Of Concept Study Of The PD-L1 Probody Therapeutic, CX-072, As Monotherapy And In Combination With Yervoy (Ipilimumab) Or With Zelboraf (Vemurafenib) In Subjects With Advanced Or Recurrent Solid Tumors Or Lymphomas

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  
A 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 (PD-1) 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

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 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-Requires Polycythemia Vera

STUDY NEW 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
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 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

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 or fill out this online referral form.

ADVANCED

STUDY 2016-210
Phase I/II
An Open-Label, Dose-Finding And Proof Of Concept Study Of The PD-L1 Probody Therapeutic, CX-072, As Monotherapy And In Combination With Yervoy (Ipilimumab) Or With Zelboraf (Vemurafenib) In Subjects With Advanced Or Recurrent 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 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 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 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 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 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

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

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.

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. 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 I  
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/II, 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 2016-210**  
Phase I/II  
An Open-Label, Dose-Finding And Proof Of Concept Study Of The PD-L1 Probody Therapeutic, CX-072, As Monotherapy And In Combination With Yervoy (Ipilimumab) Or With Zelboraf (Vemurafenib) In Subjects With Advanced Or Recurrent Solid Tumors Or Lymphomas

**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 2016-157**  
Phase I  
Phase I Clinical Trial of VX-970 in Combination with the Topoisomerase I Inhibitor Irinotecan in Patients with Advanced Solid Tumors

**STUDY 2018-154**  
Phase I  
A Phase 1/1b Open-Label Multi-Center to Characterize the Safety and Tolerability of TRQ15-01 in Patients with Relapsed/Refractory Metastatic or Locally-Advanced Solid Tumor or Lymphoma

**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 2018-109
Phase I/II
A Phase 1/2 Study of Oral LOXO-292 in Patients with Advanced Solid Tumors, Including RET Fusion-Positive Solid Tumors, Medullary Thyroid Cancer, and Other Tumors with RET Activation (LIBRETTO-001)

STUDY NEW 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 2016-210
Phase I/II
An Open-Label, Dose-Finding And Proof Of Concept Study Of The PD-L1 Probody Therapeutic, CX-072, As Monotherapy And In Combination With Yervoy (Ipilimumab) Or With Zelboraf (Vemurafenib) In Subjects With Advanced Or Recurrent Solid Tumors Or Lymphomas

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 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 2017-064
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 2018-076
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 (PEMBO; Keytruda®) in Patients with Small Cell Neuroendocrine Prostate Cancer (SCNC; NEPC)

STUDY 2018-138
Phase I/II
An Open-Label Phase 1B/2 Study to Evaluate the Safety and Efficacy of Tabeleclucel in Combination with Pembrolizumab in Subjects with Platinumpretreated, Recurrent/Metastatic Epstein-Barr Virus-Associated Nasopharyngeal Carcinoma

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 2018-120
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 2016-037
Phase I
A Phase 1 Study of ALKS 4230 in Subjects with 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 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 2018-015
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

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 NEW 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 2019-047
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, Gastic/Gastroesophageal Junction Cancer and other Locally Advanced/Metastatic Solid Tumors

GENOMIC TESTING SPECIFIC
STUDY 2016-157
Phase I
Phase I Clinical Trial of VX-970 in Combination with the Topoisomerase I Inhibitor Irinotecan 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 2018-015
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 Or Metastatic Solid Tumors
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.

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 or fill out this online referral form.

**ADJUVENT**

**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

**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 2016-110**
Phase II
A Phase II, Open-label, Multicenter, Single-arm Study To Investigate The Efficacy And Safety Of Atezolizumab As Neoadjuvant And Adjuvant Therapy In Patients With Stage IB, II, Or IIIA Resectable And Untreated Non-Small Cell Lung Cancer

**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 2016-110
Phase II
A Phase II, Open-label, Multicenter, Single-arm Study To Investigate The Efficacy And Safety Of Atezolizumab As Neoadjuvant And Adjuvant Therapy In Patients With Stage IB, II, Or IIIA Resectable And Untreated Non-Small Cell Lung Cancer

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 2018-015
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 Or Metastatic 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
<table>
<thead>
<tr>
<th>Study ID</th>
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<tr>
<td>2018-080</td>
<td>Brigatinib in Patients With Anaplastic Lymphoma Kinase-Positive (ALK+), Advanced Non-Small Cell Lung Cancer (NSCLC) Progressed on Alectinib or Ceritinib</td>
<td>Phase II</td>
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<td>2017-145</td>
<td>A Phase 2 Study of Poziotinib in Patients with Non-Small Cell Lung Cancer, Locally Advanced or Metastatic, with EGFR or HER2 Exon 20 Insertion Mutation (POZITIVE20-1)</td>
<td>Phase II</td>
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<td>2017-145</td>
<td>A Phase 2 Study of Poziotinib in Patients with Non-Small Cell Lung Cancer, Locally Advanced or Metastatic, with EGFR or HER2 Exon 20 Insertion Mutation (POZITIVE20-1)</td>
<td>Pilot</td>
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<tr>
<td>2018-120</td>
<td>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</td>
<td>Phase I/II</td>
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<td>2017-111</td>
<td>A Phase 1b Dose-Escalation Study of Cabozantinib (XL184) Administered in Combination with Atezolizumab to Subjects with Locally Advanced or Metastatic Solid Tumors</td>
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<td>2016-017</td>
<td>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</td>
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<td>2016-055</td>
<td>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</td>
<td>Phase I</td>
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<td>2014-002</td>
<td>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</td>
<td>Phase II</td>
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<td>2016-037</td>
<td>A Phase 1 Study of ALKS 4230 Administered Intravenously as Monotherapy and in Combination with Pembrolizumab in Subjects with Advanced Solid Tumors</td>
<td>Phase I</td>
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<td>Phase II</td>
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<td>STUDY 2018-015</td>
<td>Phase I/II</td>
<td>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 Or Metastatic Solid Tumors</td>
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<td>STUDY 2017-129</td>
<td>NA</td>
<td>Improving Treatment Cost Discussions between Cancer Patients and their Oncologists: Feasibility and Utilization of an Application-based Question Prompt List</td>
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<td>STUDY 2018-053</td>
<td>Phase III</td>
<td>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)</td>
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<td>STUDY 2018-098</td>
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<td>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</td>
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<td>RECURRENT ALK</td>
<td>STUDY 2017-106</td>
<td>Phase II</td>
<td>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)</td>
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<td>EGFR</td>
<td>STUDY 2017-106</td>
<td>Phase II</td>
<td>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)</td>
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<td>Other Genetic Marker</td>
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<td>Phase I/II</td>
<td>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 Or Metastatic Solid Tumors</td>
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<td>SCLC LIMITED</td>
<td>STUDY NRG-LU005</td>
<td>Phase I/II</td>
<td>Limited Stage Small Cell Lung Cancer (LS-SCLC): A Phase II/III Randomized Study of Chemoradiation Versus Chemoradiation Plus Atezolizumab</td>
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</table>
**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 NEW 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

STUDY 2018-167
Phase I
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