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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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 2015-098**

Phase I
A Phase 1 Dose Escalation and Cohort Expansion Study of the Safety, Tolerability, and Efficacy of Anti-LAG-3 (BMS-986016) in Relapsed or Refractory Chronic Lymphocytic Leukemia and Lymphomas

**STUDY 2015-115**

Phase II
A Phase 2 Multicenter Study Evaluating the Efficacy of KTE-C19 in Subjects with Relapsed/Refractory Mantle Cell Lymphoma (r/r MCL)

**STUDY 2016-109**

Phase II
A Multi-Center, Phase II Trial of HLA-Mismatched Unrelated Donor Bone Marrow Transplantation with Post-Transplantation Cyclophosphamide for Patients with Hematologic Malignancies (Protocol Number 15-MMUD).
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 BMTCTN1302  
**Phase II**  
Multicenter Phase II, Double-blind Placebo Controlled Trial of Maintenance Ixazomib After Allogeneic Hematopoietic Stem Cell Transplantation for High Risk Multiple Myeloma.

STUDY BMTCTN1102  
**Phase III**  
A Multi-Center Biologic Assignment Trial Comparing Reduced Intensity Allogeneic Hematopoietic Cell Transplant to Hypomethylating Therapy or Best Supportive Care in Patients Aged 50-75 with Intermediate-2 and High Risk Myelodysplastic Syndrome.

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 2011-203  
**Phase I/II**  
Phase I/II Study of Dasatinib in Recipients of Autologous Stem Cell Transplantation for Hematologic Malignancies.

STUDY 2016-032  
**Phase II**  
A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Tolerability of Entosplatinib, a Selective SYK Inhibitor, in Combination with Systemic Corticosteroids as First-Line Therapy in Subjects with Chronic Graft Versus Host Disease (cGVHD)

STUDY 2016-194  
**Phase III**  
A Randomized, Double-Blind Phase 3 Study of Ibrutinib in Combination With Corticosteroids versus Placebo in Combination With Corticosteroids in Subjects with New Onset Chronic Graft Versus Host Disease (cGVHD)

STUDY 2016-049  
**Phase I/II**  
A Phase 1 Non-randomized/2 Randomized Study of ProTmune (ex vivo Programmed Mobilized Peripheral Blood Cells) for Allogeneic Hematopoietic Cell Transplantation in Adult Patients with Hematologic Malignancies.

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.

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**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 S1207**  
**Phase III**  
Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients with High-Risk, Hormone Receptor-Positive and HER2/neu Negative Breast Cancer - e3 Breast Cancer Study - evaluating Everolimus with Endocrine Therapy.
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 A011202
Phase III
A Randomized Phase III Trial Comparing Axillary Lymph Node Dissection to Axillary Radiation In Breast Cancer Patients (cT1-3 N1) Who Have Positive Sentinel Lymph Node Disease After Neoadjuvant Chemotherapy

ADJUVANT HORMONAL
STUDY 2016-016
Phase I/II
A Phase I/II Multicenter Study of the Combination of AZD2014 and Palbociclib on a Background of Hormonal Therapy in Patients with Locally Advanced/Metastatic Estrogen Receptor Positive Breast Cancer Comprising a Safety, Pharmacokinetic and Preliminary Efficacy Evaluation followed by a Randomized, Double-Blind, Placebo-controlled, Parallel Group Extension (PASTOR)

NEOADJUVANT
STUDY 2015-137
Phase I
A Phase 1b, Open-Label, Two-Arm Study Evaluating the Safety and Pharmacokinetics of Atezolizumab (Anti-PD-L1 Antibody) in Combination with Trastuzumab Emtansine or with Trastuzumab and Pertuzumab in Patients with HER-Positive Breast Cancer

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 Basal-Like Breast Cancer following Neo-adjuvant Chemotherapy

STUDY 2016-002
Phase II
A Randomized Multi-center Phase II Trial to Evaluate the Safety and Immunogenicity of Two Doses of Vaccination with Folate Receptor Alpha Peptides with GM-CSF in Patients with Triple Negative Breast Cancer

ADVANCED (STAGE IV) CHEMOTHERAPY
STUDY 2013-120
Phase I
A Phase 1b Open-Label Three-Arm Multi-Center Study to Assess the Safety and Tolerability of PF-05212384 (PI3K/mTOR Inhibitor) in Combination with Other Anti-Tumor Agents

STUDY 2016-030
Phase I
Phase Ib Study to Assess the Safety, Tolerability, and Clinical Activity of Gedatolisib in Combination with Palbociclib and Either Letrozole or Fulvestrant in Women with Metastatic or Locally Advanced/Recurrent Breast Cancer (MBC)

STUDY 2016-050
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<th><strong>Phase I</strong></th>
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<td>A Phase I, First-in-Human, Dose Escalation Trial of MSC2363318A, a Dual p70S6K/Akt Inhibitor, in Subjects with Advanced Malignancies</td>
<td>A Phase 1b, Open-Label, Two-Arm Study Evaluating the Safety and Pharmacokinetics of Atezolizumab (Anti-PD-L1 Antibody) in Combination with Trastuzumab Emtansine or with Trastuzumab and Pertuzumab in Patients with HER2-Positive Breast Cancer</td>
<td>A Phase I, Multicenter, Open-Label, Two-Part, Dose-escalation Study of RAD1901 in Postmenopausal Women with Advanced Estrogen Receptor Positive and HER2-Negative Breast Cancer</td>
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<td>A Phase 1b Study of Abemaciclib in Combination with Pembrolizumab for Patients with Stage IV Non-Small Cell Lung Cancer or Hormone Receptor Positive, HER2 Negative Breast Cancer</td>
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<td>STUDY 2015-046</td>
<td>Phase I</td>
<td>A Phase 1b, Open-Label, Two-Arm Study Evaluating the Safety and Pharmacokinetics of Atezolizumab (Anti-PD-L1 Antibody) in Combination with Trastuzumab Emtansine or with Trastuzumab and Pertuzumab in Patients with HER2-Positive Breast Cancer</td>
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<td>STUDY 2016-055</td>
<td>STUDY 2016-123</td>
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<td>STUDY 2016-055</td>
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<td>Phase I</td>
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<td>Phase III</td>
<td>STUDY 2016-025</td>
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<td>A Phase 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>A Randomized, Double-Blind, Phase III Study of Pembrolizumab (MK-3475) plus Chemotherapy vs Placebo plus Chemotherapy for Previously Untreated Locally Recurrent Inoperable or Metastatic Triple Negative Breast Cancer - (KEYNOTE-355)</td>
<td>A Phase 1, Multicenter, Open-Label, Dose-Escalation Study of SGN-2FF in Patients with Advanced Solid Tumors</td>
<td>A Multi-Center Study of hTERT Immunotherapy Alone or in Combination with IL-12 DNA followed by Electroporation in Adults with Solid Tumors at High Risk of Relapse Post Definitive Surgery and Standard Therapy</td>
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STUDY 2015-157
Phase I/II
Phase 1/2 Clinical Study of Niraparib in Combination with Pembrolizumab in Patients with Advanced or Metastatic Triple-Negative Breast Cancer and in Patients with Recurrent Ovarian 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 2016-116
Phase II
A Phase 2 Study of Cediranib in Combination with Olaparib in Advanced Solid Tumors

STUDY NEW 2016-152
Phase I
A Phase 1b Study to Evaluate TAK-659 in Combination With Nivolumab in Patients With Advanced Solid Tumors

STUDY NEW 2016-018
Phase I
A Phase 1, First-in-Human, Multi-Part Study of RAD140 in Postmenopausal Women with Hormone Receptor Positive Breast Cancer

STUDY 2015-086
Phase I
A First-in-Human Study of Repeat Dosing with REGN2810, a Monoclonal, Fully Human Antibody to Programmed Death-1(PD-1), as Single Therapy and in Combination with Other Anti-Cancer Therapies, in Patients with Advanced Malignancies

STUDY 2014-100
Phase II
Cryoablation of Low Risk Breast Cancers less than 1.5 cm: An Evaluation of Local Recurrence (Ice3 Trial)

STUDY EAY131
Phase II
Molecular Analysis for Therapy Choice (MATCH)

Gastrointestinal Clinical Trials

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ESOPHAGUS

Metastatic
STUDY 2016-050
Phase I
A Phase 1 Dose Escalation and Cohort Expansion Study of ERY974, an Anti-Glypican 3 (GPC3)/CD3 Bispecific Antibody, 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 2016-025
Phase I/II
A Multi-Center Study of hTERT Immunotherapy Alone or in Combination with IL-12 DNA followed by Electroporation in Adults with Solid Tumors at High Risk of Relapse Post Definitive Surgery and Standard Therapy

**GASTRIC AND GASTROESOPHAGEAL JUNCTION**

**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 2015-047**

**Phase I**

A Phase 1 Open-Label, Dose-Finding Study Evaluating Safety and Pharmacokinetics of FPA144 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 2017-029**

**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 2015-103**

**Phase I**

A Phase 1b Open-Label Study of PEGylated Recombinant Human Hyaluronidase (PEGPH20) Combined with Pembrolizumab in Subjects with Selected Hyaluronan-High Solid Tumors

**STUDY 2016-050**

**Phase I**

A Phase 1 Dose Escalation and Cohort Expansion Study of ERY974, an Anti-Glypican 3 (GPC3)/CD3 Bispecific Antibody, in Patients with Advanced Solid Tumors.

**STUDY 2015-156**

**Phase I**

A Phase 1 Dose Escalation and Cohort Expansion Study of the Safety, Tolerability, and Efficacy of Anti-LAG-3 Monoclonal Antibody (BMS-986016) Administered Alone and in Combination with Anti-PD-1 Monoclonal Antibody (Nivolumab, BMS-936558) in Advanced Solid Tumors

**STUDY 2016-003**

**Phase I/II**

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

**STUDY 2016-025**

**Phase I/II**

A Multi-Center Study of hTERT Immunotherapy Alone or in Combination with IL-12 DNA followed by Electroporation in Adults with Solid Tumors at High Risk of Relapse Post Definitive Surgery and Standard Therapy

**PANCREAS**

**Adenocarcinoma**

**Borderline Resectable**

**STUDY A021501**

**Phase III**

Preoperative Extended Chemotherapy vs. Chemotherapy Plus Hypofractionated Radiation Therapy for Borderline Resectable Adenocarcinoma of the Head of the Pancreas
**Metastatic**

**STUDY S1513**  
**Phase II**  
Randomized Phase II Study of 2nd Line FOLFIRI versus Modified FOLFIRI with PARP Inhibitor ABT-888 (Veliparib) (NSC-737664) in Metastatic Pancreatic Cancer

**STUDY S1505**  
**Phase II**  
A Randomized Phase II Study of Perioperative mFOLFIROX versus Gemcitabine/NAB-Paclitaxel as Therapy for Resectable Pancreatic Adenocarcinoma

**STUDY NEW 2016-011**  
**Phase III**  
A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study of PEGylated Recombinant Human Hyaluronidase (PEGPH20) in Combination with nab-Paclitaxel Plus Gemcitabine Compared with Placebo Plus nab- Paclitaxel and Gemcitabine in Subjects with Hyaluronan-High Stage IV Previously Untreated Pancreatic Ductal Adenocarcinoma

**Neuroendocrine**

**STUDY EA2142**  
**Phase II**  
Randomized Phase II Study of Cisplatin and Etoposide versus Temozolomide and Capecitabine in Patients with Advanced G3 Non-Small Cell Gastroenteropancreatic Neuroendocrine Carcinomas

**STUDY EA2161**  
**Phase II**  
A Phase II Study of MLN0128 (TAK-228) in Rapalog-Resistant Advanced Pancreatic Neuroendocrine Tumors (PNET)

**STUDY 2016-025**  
**Phase I/II**  
A Multi-Center Study of hTERT Immunotherapy Alone or in Combination with IL- 12 DNA followed by Electroporation in Adults with Solid Tumors at High Risk of Relapse Post Definitive Surgery and Standard Therapy

**STUDY NEW 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 2016-116**  
**Phase II**  
A Phase 2 Study of Cediranib in Combination with Olaparib in Advanced Solid Tumors

**STUDY RTOG0848**  
**Phase III**  
A Phase II-R and a Phase III Trial Evaluating Both Erlotinib (PH II-R) and Chemoradiation (PH III) as Adjuvant Treatment for Patients with Resected Head of Pancreas Adenocarcinoma

**HCC**

**Metastatic**

**STUDY 2016-025**  
**Phase I/II**  
A Multi-Center Study of hTERT Immunotherapy Alone or in Combination with IL-12 DNA followed by Electroporation in Adults with Solid Tumors at High Risk of Relapse Post Definitive Surgery and Standard Therapy

**STUDY 2015-086**
Phase I
A First-in-Human Study of Repeat Dosing with REGN2810, a Monoclonal, Fully Human Antibody to Programmed Death-1 (PD-1), as Single Therapy and in Combination with Other Anti-Cancer Therapies, in Patients with Advanced Malignancies

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 2016-064
Phase III
A Phase III Study of Pembrolizumab (MK-3475) vs. Best Supportive Care as Second-Line Therapy in Subjects with Previously Systemically Treated Advanced Hepatocellular Carcinoma (KEYNOTE-240)

STUDY 2017-034
Phase I
A Phase Ib Study Of PDR001 In Combination With Sorafenib In Patients With Advanced Hepatocellular Carcinoma (HCC)

STUDY 2016-039
Phase I/II
A Phase Ib/II Clinical Study of BBI608 in Combination with Sorafenib or BBI503 in Combination with Sorafenib in Adult Patients with Hepatocellular Carcinoma

STUDY 2016-079
Phase I
An Open-Label Multicenter Phase 1 Study to Evaluate the Safety, Pharmacokinetics and Pharmacodynamics of H3B-6527 in Subjects With Advanced Hepatocellular Carcinoma or Intrahepatic Cholangiocarcinoma

BILIARY/GALL BLADDER
Metastatic
STUDY 2016-186
Phase II
A Phase 2, Open-Label, Single-Arm, Multicenter Study to Evaluate the Efficacy and Safety of INCB054828 in Subjects With Advanced/Metastatic or Surgically Unresectable Cholangiocarcinoma Including FGFR2 Translocations Who Failed Previous Therapy

STUDY 2014-081
Phase II
A Phase II Multicenter, Single Arm Study of Oral BQJ398 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

Metastatic (Includes Rectal)
1st Line
STUDY 2015-086
Phase I
A First-in-Human Study of Repeat Dosing with REGN2810, a Monoclonal, Fully Human Antibody to Programmed Death-1 (PD-1), as Single Therapy and in Combination with Other Anti-Cancer Therapies, in Patients with Advanced Malignancies

2nd Line
STUDY 2015-086
Phase I
A First-in-Human Study of Repeat Dosing with REGN2810, a Monoclonal, Fully Human Antibody to Programmed Death-1 (PD-1), as Single Therapy and in Combination with Other Anti-Cancer Therapies, in Patients with Advanced 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 2015-131
Phase II
An Open-Label, Multicenter, Global Phase 2 Basket Study of Entrectinib for the Treatment of Patients with Locally Advanced or Metastatic Solid Tumors that Harbor NTRK1/2/3, ROS1, or ALK Gene Rearrangements

STUDY 2016-050
Phase I
A Phase 1 Dose Escalation and Cohort Expansion Study of ERY974, an Anti-Glypican 3 (GPC3)/CD3 Bispecific Antibody, in Patients with Advanced Solid Tumors.

STUDY 2015-110
Phase I/II
A Phase I/II, Dose-escalation and Cohort Expansion Study of the Safety, Tolerability and Efficacy of Anti-CD27 antibody (Varilumab) Administered in Combination with Anti-PD-1 (Nivolumab) in Advanced Refractory 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 NEW 2016-185
Phase I/II
A Phase 1b/2 Trial of Hu5F9-G4 in Combination with Cetuximab in Patients with Solid Tumors and Advanced Colorectal Cancer

STUDY NEW 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 2016-063
Phase III
A Phase III Study of Pembrolizumab (MK-3475) vs. Chemotherapy in Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Stage IV Colorectal Carcinoma (KEYNOTE-177)

STUDY 2016-003
Phase I/II
A Phase 1b/2 Study of Ibrutinib Combination Therapy in Selected Advanced Gastrointestinal And Genitourinary Tumors

STUDY 2016-025
Phase I/II
A Multi-Center Study of hTERT Immunotherapy Alone or in Combination with IL-12 DNA followed by Electroporation in Adults with Solid Tumors at High Risk of Relapse Post Definitive Surgery and Standard Therapy

RECTUM
STUDY 2016-025
Phase I/II
A Multi-Center Study of hTERT Immunotherapy Alone or in Combination with IL-12 DNA followed by Electroporation in Adults with Solid Tumors at High Risk of Relapse Post Definitive Surgery and Standard Therapy

STUDY 2016-063
TITLE
A Phase III Study of Pembrolizumab (MK-3475) vs. Chemotherapy in Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Stage IV Colorectal Carcinoma (KEYNOTE-177)

STUDY NEW NRG-GI002
Phase II
A Phase II Clinical Trial Platform of Sensitization Utilizing Total Neoadjuvant Therapy (TNT) Phase II in Rectal Cancer
STUDY 2016-189
Phase I
A Phase 1, Multicenter, Open-Label, Dose-Escalation Study of SGN-2FF in Patients with Advanced Solid Tumors

OTHER
STUDY EAY131
Phase II
Molecular Analysis for Therapy Choice (MATCH)

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 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 2016-037
Phase I
A Phase 1 Study of ALKS 4230 in Subjects with Advanced Solid Tumors

STUDY 2016-003
Phase I/II
A Phase 1b/2 Study of Ibrutinib Combination Therapy in Selected Advanced Gastrointestinal And Genitourinary Tumors

STUDY 2015-168
Phase III
A Phase 3, Randomized, Controlled, Multi-Center, Open-Label Study to Compare Tivozanib Hydrochloride to Sorafenib in Subjects With Refractory Advanced Renal Cell Carcinoma

STUDY NEW 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 2016-201
Phase III
A Multicenter, Open-label, Randomized, Phase 3 Trial to Compare the Efficacy and Safety of Lenvatinib in Combination with Everolimus or Pembrolizumab Versus Sunitinib Alone in First-Line Treatment of Subjects with Advanced Renal Cell Carcinoma (CLEAR).

STUDY 2017-013
Phase I
A Phase 1, Multiple-Dose, Dose-Escalation Trial of PT2385 Tablets, a HIF-2a Inhibitor in Patients with Advanced Clear Cell Renal Cell
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<tr>
<th>Study ID</th>
<th>Phase</th>
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<td>STUDY 2016-126</td>
<td>Phase II</td>
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<td>STUDY 2016-050</td>
<td>Phase I</td>
<td>A Phase 1 Dose Escalation and Cohort Expansion Study of ERY974, an Anti-Glypican 3 (GPC3)/CD3 Bispecific Antibody, in Patients with Advanced Solid Tumors.</td>
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<tr>
<td>STUDY 2017-036</td>
<td>Phase I</td>
<td>A Phase I Open-Label Pharmacokinetics and Safety Study of Talazoparib (MDV3800) in Patients With Advanced Solid Tumors and Normal or Varying Degrees of Renal Impairment</td>
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<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 2017-029</td>
<td>Phase I</td>
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<td>STUDY EA8143</td>
<td>Phase III</td>
<td>A Phase 3 Randomized Study Comparing PERioperative Nivolumab vs. Observation in Patients with Localized Renal Cell Carcinoma Undergoing Nephrectomy (PROSPER RCC)</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>
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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>
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<tr>
<td>STUDY 2009-139</td>
<td>Phase I</td>
<td>Phase I Safety, Pharmacokinetic and Pharmacodynamic Study of PF-02341066, A C-Met/HGFR Selective Tyrosine Kinase Inhibitor, Administered Orally to Patients with Advanced Cancer</td>
</tr>
<tr>
<td>STUDY 2014-010</td>
<td>Phase I</td>
<td>A Phase 1 Study of the Safety and Pharmacokinetics of Escalating Doses of ASG-22CE Given as Monotherapy in Subjects with Metastatic Urothelial Cancer and other Malignant Solid Tumors that Express Nectin-4</td>
</tr>
<tr>
<td>STUDY 2015-156</td>
<td>Phase I</td>
<td>A Phase 1 Dose Escalation and Cohort Expansion Study of the Safety, Tolerability, and Efficacy of Anti-LAG-3 Monoclonal Antibody (BMS-986016) Administered Alone and in Combination with Anti-PD-1 Monoclonal Antibody (Nivolumab, BMS-936558) in Advanced Solid Tumors</td>
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<tr>
<td>PROSTATE</td>
<td>STUDY 2013-108</td>
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<tr>
<td></td>
<td></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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STUDY 2014-075
Phase I
Targeting the Prostatic Tumor Microenvironment with PLX3397, a Tumor-associated Macrophage Inhibitor, in Men with Unfavorable Risk Prostate Cancer Treated with Radiation and Androgen Deprivation Therapy

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 2015-059
Phase I/II
A Phase Ib/II, Multicentre, Open Label, Randomised Study of BI 836845 in Combination with Enzalutamide, versus Enzalutamide alone, in Metastatic Castration-Resistant Prostate Cancer (CRPC) Following Disease Progression on Docetaxel-Based Chemotherapy and Abiraterone

STUDY 2016-153
Phase I
A Phase I Safety and Tolerability Study of ZEN003694 in Combination with Enzalutamide in Patients with Metastatic Castration-Resistant Prostate Cancer

STUDY NEW 2016-069
Phase II
Phase II Trial of Pembrolizumab (MK-3475) in Subjects with Metastatic Castration-Resistant Prostate Cancer (mCRPC) Previously Treated with Chemotherapy (KEYNOTE-199)

STUDY NEW 2016-178
Phase I
A Phase 1, Dose-Finding and Signal-Seeking Study of the Safety and Efficacy of Intravenous CAVATAK(TM) (coxsackievirus A21, CVA21) Alone and in Combination with Pembrolizumab in Patients with Late Stage Solid Tumours (NSCLC, Castrate-Resistant Prostate Cancer, Melanoma and Bladder Cancer)

STUDY NEW 2017-015
Phase I
A Phase 1 Study of a Prostate-Specific Membrane Antigen Targeting-Tubulysin Conjugate EC1169 in Patients with Recurrent Metastatic, Castration-Resistant, Prostate Cancer (mCRPC)

STUDY NEW 2017-051
Phase I
A Phase I Study of PCUR-101 in Combination with Androgen Suppression Therapy in the Treatment of Patients with Metastatic Castration-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 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 2015-033
Phase III
A Randomized, Double Blind, Multicenter, Parallel-Group, Phase III Study to Evaluate Efficacy and Safety of DCVAC/PCa Versus Placebo in Men with Metastatic Castration Resistant Prostate Cancer Eligible for 1st Line Chemotherapy
STUDY 2015-086
Phase I
A First-in-Human Study of Repeat Dosing with REGN2810, a Monoclonal, Fully Human Antibody to Programmed Death-1 (PD-1), as Single Therapy and in Combination with Other Anti-Cancer Therapies, in Patients with Advanced Malignancies

STUDY 2015-057
Phase I
A Phase I, Open-label, Multicenter Study to Assess the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Preliminary Anti-tumor Activity of AZD8186 in Patients with Advanced Castration-resistant Prostate Cancer (CRPC), Squamous Non-Small Cell Lung Cancer (sqNSCLC), Triple Negative Breast Cancer (TNBC) and Patients with Known PTEN-deficient/mutated or PIK3CB Mutated/amplified Advanced Solid Malignancies, as Monotherapy and in Combination with Abiraterone Acetate or AZD2014

STUDY 2015-050
Phase II
A Single-arm, Phase 2 Study to Evaluate the Safety and Efficacy of VT-464 in Patients with Castration-Resistant Prostate Cancer Progressing on Enzalutamide or Abiraterone.

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 2016-050
Phase I
A Phase 1 Dose Escalation and Cohort Expansion Study of ERY974, an Anti-Glypican 3 (GPC3)/CD3 Bispecific Antibody, in Patients with 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 2015-084
Phase III
A Phase III, Open-Label, Multicenter, Randomized Study of Atezolizumab (Anti- PD-L1 Antibody) Versus Observation as Adjuvant Therapy in Patients With, High-Risk Muscle-Invasive Urothelial Carcinoma After Surgical Resection

STUDY 2016-003
Phase I/II
A Phase 1b/2 Study of Ibrutinib Combination Therapy in Selected Advanced Gastrointestinal And Genitourinary Tumors

STUDY S1314
Phase II
A Randomized Phase II Study of Co-Expression Extrapolation (COXEN) with Neoadjuvant Chemotherapy for Localized, 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 NEW 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 2016-178
Phase I
A Phase 1, Dose-Finding and Signal-Seeking Study of the Safety and Efficacy of Intravenous CAVATAK(TM) (coxsackievirus A21, CVA21) Alone and in Combination with Pembrolizumab in Patients with Late Stage Solid Tumours (NSCLC, Castrate-Resistant Prostate Cancer, Melanoma and Bladder Cancer)

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 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 2014-010
Phase I
A Phase 1 Study of the Safety and Pharmacokinetics of Escalating Doses of ASG-22CE Given as Monotherapy in Subjects with Metastatic Urothelial Cancer and other Malignant Solid Tumors that Express Nectin-4

STUDY 2015-072
Phase II
A Multicenter, Non-Randomized, Phase II Study of Regorafenib for Advanced Urothelial Cancer Following Prior Chemotherapy

STUDY 2013-120
Phase I
A Phase 1b Open-Label Three-Arm Multi-Center Study to Assess the Safety and Tolerability of PF-05212384 (PI3K/mTOR Inhibitor) in Combination with Other Anti-Tumor Agents

OTHER
STUDY EAY131
Phase II
Molecular Analysis for Therapy Choice (MATCH)

STUDY 2016-189
Phase I
A Phase 1, Multicenter, Open-Label, Dose-Escalation Study of SGN-2FF in Patients with Advanced Solid Tumors

STUDY 2015-156
Phase I
A Phase 1 Dose Escalation and Cohort Expansion Study of the Safety, Tolerability, and Efficacy of Anti-LAG-3 Monoclonal Antibody (BMS-986016) Administered Alone and in Combination with Anti-PD-1 Monoclonal Antibody (Nivolumab, BMS-936558) in Advanced Solid Tumors

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Gynecologic Clinical Trials
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CERVIX
STUDY GOG-3009
Phase III
Phase 3 Study of ADXS11-001 Administered Following Chemoradiation as Adjuvant Treatment for High Risk Locally Advanced Cervical Cancer: AIM2CERV

**STUDY 2016-081**  
Phase I/II  
Phase 1-2 Study of MEDI4736 Alone or In Combination with ADXS11-001 In Recurrent/Persistent or Metastatic Cervical or HPV+ Phase I/II Head & Neck Cancer

**STUDY NEW 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 2017-064**  
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

**OVARY**  
**STUDY 2015-110**  
Phase I/II  
A Phase I/II, Dose-escalation and Cohort Expansion Study of the Safety, Tolerability and Efficacy of Anti-CD27 antibody (Varilumab) Administered in Combination with Anti-PD-1 (Nivolumab) in Advanced Refractory Solid Tumors

**STUDY 2015-157**  
Phase I/II  
Phase 1/2 Clinical Study of Niraparib in Combination with Pembrolizumab in Patients with Advanced or Metastatic Triple-Negative Breast Cancer and in Patients with Recurrent Ovarian 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 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 2017-023**  
Phase I/II  
PiSARRO: p53 Suppressor Activation in Recurrent High Grade Serous Ovarian Cancer, a Phase Ib/II Study of Systemic Carboplatin/Pegylated Liposomal Doxorubicin Combination Chemotherapy With or Without APR-246

**STUDY 2016-025**  
Phase I/II  
A Multi-Center Study of hTERT Immunotherapy Alone or in Combination with IL-12 DNA followed by Electroporation in Adults with Solid Tumors at High Risk of Relapse Post Definitive Surgery and Standard Therapy

**STUDY NRG-GY004**  
Phase III  
Phase III Study Comparing Single Agent Olaparib or the Combination of Cediranib and Olaparib to Standard Platinum-based Chemotherapy in Women with Recurrent Platinum-Sensitive Ovarian, Fallopian Tube or Primary Peritoneal Cancer

**STUDY 2016-037**  
Phase I  
A Phase 1 Study of ALKS 4230 in Subjects with Advanced Solid Tumors

**STUDY 2016-204**  
Phase II
Non-Randomized, Open-Label Phase II Study to Assess Olaparib Tablets as a Treatment for Subjects with Different HRD Tumor Status and with Platinum-Sensitive, Relapsed, High-Grade Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer That Have Received at Least 2 Prior Lines of Chemotherapy

**STUDY NEW GOG-3015**
Phase III
A Phase III, Multicenter, Randomized, Study of Atezolizumab Versus Placebo Administered in Combination with Paclitaxel, Carboplatin, and Bevacizumab to Patients with Newly-Diagnosed Stage III or Stage IV Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

**STUDY 2016-128**
Phase III
ARIEL4 (Assessment of Rucaparib In Ovarian CancEr Trial): A Phase 3 Multicenter, Randomized Study of Rucaparib versus Chemotherapy in Patients with Relapsed, BRCA-Mutant, High-Grade Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

**STUDY 2013-120**
Phase I
A Phase 1b Open-Label Three-Arm Multi-Center Study to Assess the Safety and Tolerability of PF-05212384 (PI3K/mTOR Inhibitor) in Combination with Other Anti-Tumor Agents

**STUDY 2015-066**
Phase III
A Phase III, Open Label, Randomised, Controlled, Multi-centre Study to assess the efficacy and safety of Olaparib Monotherapy versus Physician's Choice Single Agent Chemotherapy in the Treatment of Platinum Sensitive Relapsed Ovarian Cancer in Patients carrying germline BRCA1/2 Mutations

**UTERUS**

**STUDY GOG-0238**
Phase II
A Randomized Trial of Pelvic Irradiation with or without Concurrent Weekly Cisplatin in Patients with Pelvic-Only Recurrence of Carcinoma of the Uterine Corpus

**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 2015-086**
Phase I
A First-in-Human Study of Repeat Dosing with REGN2810, a Monoclonal, Fully Human Antibody to Programmed Death-1(PD-1), as Single Therapy and in Combination with Other Anti-Cancer Therapies, in Patients with Advanced Malignancies

**VULVAR**

**STUDY GOG-0279**
Phase II
A Phase II Trial Evaluating Cisplatin and Gemcitabine Concurrent with Intensity-Modulated Radiation Therapy (IMRT) for the Treatment of Locally-Advanced Squamous Cell Carcinoma of the Vulva

**OTHER**

**STUDY 2017-023**
Phase I/II
PiSARRO: p53 Suppressor Activation in Recurrent High Grade Serous Ovarian Cancer, a Phase Ib/II Study of Systemic Carboplatin/Pegylated Liposomal Doxorubicin Combination Chemotherapy With or Without APR-246

**STUDY 2016-204**
Phase II
Non-Randomized, Open-Label Phase II Study to Assess Olaparib Tablets as a Treatment for Subjects with Different HRD Tumor Status and with Platinum-Sensitive, Relapsed, High-Grade Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer That Have
Received at Least 2 Prior Lines of Chemotherapy

**STUDY NEW GOG-3015**  
Phase III  
A Phase III, Multicenter, Randomized, Study of Atezolizumab Versus Placebo Administered in Combination with Paclitaxel, Carboplatin, and Bevacizumab to Patients with Newly-Diagnosed Stage III or Stage IV Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

**STUDY EAY131**  
Phase II  
Molecular Analysis for Therapy Choice (MATCH)

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### Head & Neck Clinical Trials

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**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 2016-174**  
Phase I/II  
Phase I/II Clinical Trial of NC-6004 in Combination with 5-FU and Cetuximab as First-line Treatment in Patients with Recurrent or Metastatic Squamous Cell Carcinoma of The Head and Neck

**STUDY 2017-027**  
Phase II  
A Phase II, Open-label, Randomized Controlled Study of PDR001 in Patients with Moderately Differentiated/Undifferentiated Locally Advanced Recurrent or Metastatic Nasopharyngeal Carcinoma who Progressed on Standard Treatment

**STUDY 2017-003**  
Phase III  
A Randomized Phase III Study of Pembrolizumab Given Concomitantly with Chemoradiation and as Maintenance Therapy versus Chemoradiation Alone in Subjects with Locally Advanced Head and Neck Squamous Cell Carcinoma

**STUDY 2016-165**  
**TITLE**  
A Randomized Double-Blind Phase 3 Study of Avelumab in Combination with Standard of Care Chemoradiotherapy (Cisplatin Plus Definitive Radiation Therapy) Versus Standard of Care Chemoradiotherapy in the Front-Line Treatment of Patients with Locally Advanced Squamous Cell Carcinoma of the Head and Neck

**STAGES I - IV**  
**STUDY 2016-050**  
Phase I  
A Phase 1 Dose Escalation and Cohort Expansion Study of ERY974, an Anti-Glypican 3 (GPC3)/CD3 Bispecific Antibody, in Patients with Advanced Solid Tumors.

**STUDY 2016-189**  
Phase I
A Phase 1, Multicenter, Open-Label, Dose-Escalation Study of SGN-2FF in Patients with Advanced Solid Tumors

**ANY STAGE**

**STUDY 2009-139**

**Phase I**

Phase I Safety, Pharmacokinetic and Pharmacodynamic Study of PF-02341066, A C-Met/HGFR Selective Tyrosine Kinase Inhibitor, Administered Orally to Patients with Advanced Cancer

**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 2015-156**

**Phase I**

A Phase 1 Dose Escalation and Cohort Expansion Study of the Safety, Tolerability, and Efficacy of Anti-LAG-3 Monoclonal Antibody (BMS-986016) Administered Alone and in Combination with Anti-PD-1 Monoclonal Antibody (Nivolumab, BMS-936558) in Advanced Solid Tumors

**STUDY NEW 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 2016-149**

**Phase I/II**

A Phase 1b/2, Open-label, Multicenter, Dose-escalation and Expansion Trial of Intratumoral SD-101 in Combination With Pembrolizumab in Patients With Metastatic Melanoma or Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma

**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

**OTHER**

**STUDY 2015-110**

**Phase I/II**

A Phase I/II, Dose-escalation and Cohort Expansion Study of the Safety, Tolerability and Efficacy of Anti-CD27 antibody (Varlilumab) Administered in Combination with Anti-PD-1 (Nivolumab) in Advanced Refractory Solid Tumors

**STUDY EAY131**

**Phase II**

Molecular Analysis for Therapy Choice (MATCH)

**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 2017-064**

**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 2016-152**

**Phase I**

A Phase 1b Study to Evaluate TAK-659 in Combination With Nivolumab in Patients With Advanced Solid Tumors

**STUDY 2016-025**
Phase I/II
A Multi-Center Study of hTERT Immunotherapy Alone or in Combination with IL-12 DNA followed by Electroporation in Adults with Solid Tumors at High Risk of Relapse Post Definitive Surgery and Standard Therapy

STUDY 2015-086
Phase I
A First-in-Human Study of Repeat Dosing with REGN2810, a Monoclonal, FullyHuman Antibody to Programmed Death-1 (PD-1), as Single Therapy and in Combination with Other Anti-Cancer Therapies, in Patients with Advanced Malignancies

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Hematology Clinical Trials

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MULTIPLE MYELOMA
STUDY 2015-129
Phase I/II
A Phase 1/2 Open label Study of SL-401 in combination with Pomalidomide and Dexamethasone in Relapsed or Relapsed and Refractory Multiple Myeloma

STUDY 2015-008
Phase I/II
Investigator-initiated Phase I/II Clinical Trial of Selinexor (KPT-330) and Pegylated Liposomal Doxorubicin for Relapsed and Refractory Multiple Myeloma

STUDY 2016-146
Phase I
Phase 1 Study of SGN-CD352A in Patients with Relapsed or Refractory Multiple Myeloma

STUDY 2017-005
Phase I/II
A Phase 1/2, Open-Label Safety, Pharmacokinetic, and Efficacy Study of TAS4464 in Patients with Multiple Myeloma or Lymphoma

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 2016-119
Phase I
An Open-label, Dose-escalation and Multi-center Study to Evaluate the Safety, Pharmacokinetics and Efficacy of SAR650984 (Isatuximab) in Patients with Relapsed/Refractory Multiple Myeloma

STUDY 2014-054
Phase I/II
A Phase 1/2 Dose Escalation Safety, Pharmacokinetic and Efficacy Study of Multiple Intravenous Administrations of a Humanized Monoclonal Antibody (SAR650984) Against CD38 In Patients with Selected CD38+ Hematological Malignancies

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 NEW 2017-024
Phase II
A Single Arm, Open-Label, Phase 2 Study of Melflufen in Combination with Dexamethasone in Patients with Relapsed Refractory Multiple Myeloma who are Refractory to Pomalidomide and/or Daratumumab

STUDY 2010-106
Phase III
A Randomized Phase III Study Comparing Conventional Dose Treatment Using a Combination of Lenalidomide, Bortezomib and Dexamethasone (RVD) to High-Dose Treatment with Peripheral Stem Cell Transplant in the Initial Management of Myeloma in Patients up to 65 Years of Age

STUDY 2016-179
Phase II
Phase 2, Randomized, Open-Label Study Comparing Daratumumab, Lenalidomide, Bortezomib and Dexamethasone (D-RVd) Versus Lenalidomide, Bortezomib, and Dexamethasone (RVd) in Subjects With Newly Diagnosed Multiple Myeloma Eligible for High-Dose Chemotherapy and Autologous Stem Cell Transplantation

STUDY 2016-062
Phase I/II
Phase 1/2 Trial of Idasanutlin in Combination with Ixazomib and Dexamethasone in Patients with 17p Deleted, Relapsed Multiple Myeloma

AMYLOIDOSIS or LIGHT CHAIN DEPOSITION DISEASE
STUDY 2012-066
Phase III
A Phase 3, Randomized, Controlled, Open-Label, Multicenter, Safety and Efficacy Study of Dexamethasone Plus MLN9708 or Physicians Choice of Treatment Administered to Patients With Relapsed or Refractory Systemic Light Chain (AL) Amyloidosis

STUDY NEW 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 CD123 x CD3 DuoBody in Subjects with Relapsed or Refractory AML

LEUKEMIA
Acute Lymphoblastic Leukemia (ALL)
STUDY E1910
Phase III
A Phase III Randomized Trial of Blinatumomab for Newly Diagnosed BCR-ABLnegative B lineage Acute Lymphoblastic Leukemia in Adults

Acute Myeloid Leukemia (AML)
STUDY 2017-006
Phase I/II
A Phase 1b/2 Study of Entospletinib (GS-9973) Monotherapy and in Combination with Chemotherapy in Patients with Acute Myeloid Leukemia (AML)

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 2016-140
Phase III
A Phase 3 Open-label, Multicenter, Randomized Study of ASP2215 versus Salvage Chemotherapy in Patients with Relapsed or Refractory Acute Myeloid Leukemia (AML) with FLT3 Mutation

STUDY 2016-169
Phase II
A Randomized, Phase II Study of CX-01 Combined With Standard Induction Therapy for Newly Diagnosed Acute Myeloid Leukemia

STUDY 2016-103
Phase I
An Open-label, Multicenter Phase 1 Trial to Evaluate the Safety, Pharmacokinetics and Pharmacodynamics of Splicing Modulator H3B-8800 for Subjects With Myelodysplastic Syndromes, Acute Myeloid Leukemia, and Chronic Myelomonocytic Leukemia

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 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 016-058
Phase III
A Phase III, Randomized, Open-label, Clinical Trial to Compare Pembrolizumab with Brentuximab Vedotin in Subjects with Relapsed or Refractory Classical Hodgkin Lymphoma

Non-Hodgkin’s

Aggressive (Mantle Cell, Large B-Cell Lymphoma)

STUDY 2017-025
Phase III
Phase 3 Study of Ibrutinib in Combination with Venetoclax in Subjects with Mantle Cell Lymphoma

STUDY 2013-178
Phase I/II
A Multicenter Open-Label, Randomized Phase 1b/2, Study of the Bruton's Tyrosine Kinase (BTK) Inhibitor, Ibrutinib, in Combination with Lenalidomide, with and without Rituximab in Subjects with Relapsed or Refractory Diffuse Large B-Cell Lymphoma

STUDY 2017-007
Phase I
A Multi-Center, Open label, Dose Escalation, Phase I/ib Study to Evaluate the Safety and Efficacy of RP4010, a Calcium Release Activated Calcium (CRAC) Channel Inhibitor, in Patients with Relapsed or Refractory Non-Hodgkin 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 2016-176
Phase II
A Phase 2, Multicenter, International, Open-Label, Safety and Efficacy Study of INCB050465 in Subjects With Relapsed or Refractory Diffuse Large B-Cell Lymphoma (CITADEL-202)

STUDY 2016-147
Phase II
<table>
<thead>
<tr>
<th>Study</th>
<th>Title</th>
<th>Phase</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>STUDY 2015-150</td>
<td>A Phase 2, Open-label, Single-arm, Two-cohort Study of Nivolumab in Relapsed/Refractory Primary Central Nervous System Lymphoma (PCNSL) or Relapsed/Refractory Primary Testicular Lymphoma (PTL)</td>
<td>I/II</td>
<td></td>
</tr>
<tr>
<td>STUDY 2015-100</td>
<td>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 Or Diffuse Large B-Cell Lymphoma</td>
<td>I/II</td>
<td></td>
</tr>
<tr>
<td>STUDY 2016-109</td>
<td>T cell</td>
<td>I</td>
<td>Phase I Safety, Pharmacokinetic and Pharmacodynamic Study of PF-02341066, A C-Met/HGFR Selective Tyrosine Kinase Inhibitor, Administered Orally to Patients with Advanced Cancer</td>
</tr>
<tr>
<td>STUDY 2016-139</td>
<td>A Phase I/Ib, Dose Escalation Study to Evaluate Safety and Efficacy of RP6530, a dual PI3K δ/γ inhibitor, in Patients with Relapsed or Refractory T-cell Lymphoma</td>
<td>I/I</td>
<td></td>
</tr>
<tr>
<td>STUDY 2016-125</td>
<td>A Phase 1b/2 Investigator Initiated Study of RCHOP in Combination with Selinexor (KPT-330) in B Cell Non Phase I/II Hodgkin's Lymphoma</td>
<td>I/I</td>
<td></td>
</tr>
<tr>
<td>STUDY 2016-210</td>
<td>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</td>
<td>I/I</td>
<td></td>
</tr>
<tr>
<td>STUDY NEW 2017-069</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>
<td>I/I</td>
<td></td>
</tr>
<tr>
<td>STUDY 2017-008</td>
<td>A Phase 1, Open-Label, Dose Escalation and Dose Expansion Trial Evaluating the Safety, Pharmacokinetics, Pharmacodynamics, and Clinical Effects of Orally Administered CA-170 in Patients with Advanced Tumors and Lymphomas</td>
<td>I</td>
<td></td>
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<tr>
<td>MYELODYSPLASTIC SYNDROME (MDS)</td>
<td>A Phase 1 Study to Evaluate the Safety and Tolerability of MEDI4736 in Subjects with Myelodysplastic Syndrome after Treatment with Hypomethylating Agents</td>
<td>I</td>
<td></td>
</tr>
<tr>
<td>STUDY 2014-037</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>
<td>I</td>
<td></td>
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<tr>
<td>OTHER</td>
<td>Phase 1b Trial of Pembrolizumab (MK-3475) in Combination with Dinaciclib (MK-7965) in Subjects with Hematologic Malignancies (KEYNOTE-155)</td>
<td>I</td>
<td></td>
</tr>
<tr>
<td>STUDY 2016-148</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Phase I/II
A Phase 1-2 Dose-Escalation and Cohort-Expansion Study of Oral eFT508 in Subjects with Hematological Malignancies

STUDY EAY131
Phase II
Molecular Analysis for Therapy Choice (MATCH)

Immunotherapy 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.

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 2015-034
Phase I/II
A Phase 1/2a Study to Assess the Safety, Pharmacokinetics, and Pharmacodynamics of PLX8394 in Patients with Advanced, Unresectable Solid Tumors

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 2017-053
Phase I/II
A Study to Evaluate the Safety and Efficacy of the CD40 Agonistic Antibody APX005M Administered in Combination with Nivolumab in Subjects with Nonsmall Cell Lung Cancer and Subjects with Metastatic Melanoma

STUDY 2016-015
Phase II
A Phase 2 Study of REGN2810, a Fully Human Monoclonal Antibody to Programmed Death-1 (PD-1), in Patients with Advanced Cutaneous Squamous Cell Carcinoma (CSCC)

STUDY NEW 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 2015-004
Phase II
A Multi-Center Phase 2 Open Label Study to Evaluate Safety and Efficacy in Subjects with Melanoma Metastatic to the Brain treated with Nivolumab in Combination with Ipilimumab followed by Nivolumab Monotherapy

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 2009-139
Phase I
Phase I Safety, Pharmacokinetic and Pharmacodynamic Study of PF-02341066, A C-Met/HGFR Selective Tyrosine Kinase Inhibitor, Administered Orally to Patients with Advanced Cancer

STUDY S1320
Phase II
A Randomized, Phase II Trial of Intermittent Versus Continuous Dosing of Dabrafenib (NSC-763760) and Trametinib (NSC-763093) in BRAFV600E/K Mutant Melanoma

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

OTHER
STUDY 2015-086
Phase I
A First-in-Human Study of Repeat Dosing with REGN2810, a Monoclonal, Fully Human Antibody to Programmed Death-1(PD-1), as Single Therapy and in Combination with Other Anti-Cancer Therapies, in Patients with Advanced Malignancies

STUDY 2015-117
Phase III
A Phase 1b/3, Multicenter, Trial of Talimogene Laherparepvec in Combination with Pembrolizumab (MK-3475) for Treatment of Unresectable, Stage IIIIB to IVM1c Melanoma (MASTERKEY-265)

STUDY 2015-156
Phase I
A Phase 1 Dose Escalation and Cohort Expansion Study of the Safety, Tolerability, and Efficacy of Anti-LAG-3 Monoclonal Antibody (BMS-986016) Administered Alone and in Combination with Anti-PD-1 Monoclonal Antibody (Nivolumab, BMS-936558) in 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 2017-029
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 2016-149
Phase I/II
A Phase 1b/2, Open-label, Multicenter, Dose-escalation and Expansion Trial of Intratumoral SD-101 in Combination With Pembrolizumab in Patients With Metastatic Melanoma or Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma

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 EAY131
Phase II
Molecular Analysis for Therapy Choice (MATCH)

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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. 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 2012-069
Phase I
A Phase 1, Open-Label, Non-Randomized, Dose-Escalating Safety, Tolerability, And Pharmacokinetic Study Of TAS-114 In Combination With Capecitabine In Patients With Advanced Solid Tumors TAS-114

STUDY 2011-166
Phase I
A Phase 1 and Pharmacokinetic Single Agent Study of Romidepsin in Patients with Lymphomas, Chronic Lymphocytic Leukemia and Select Solid Tumors and Varying Degrees of Liver Dysfunction

STUDY 2015-005
Phase I
A Phase 1A Dose-Escalation Study of OBP-801 in Patients with Advanced Solid Tumors.

STUDY 2016-050
Phase I
A Phase 1 Dose Escalation and Cohort Expansion Study of ERY974, an Anti-Glypican 3 (GPC3)/CD3 Bispecific Antibody, in Patients 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 2016-189
Phase I
A Phase 1, Multicenter, Open-Label, Dose-Escalation Study of SGN-2FF in Patients with Advanced Solid Tumors

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 NEW 2016-185
Phase I/II
A Phase 1b/2 Trial of Hu5F9-G4 in Combination with Cetuximab in Patients with Solid Tumors and Advanced Colorectal Cancer

STUDY 2017-036
Phase I
A Phase I Open-Label Pharmacokinetics and Safety Study of Talazoparib (MDV3800) in Patients With Advanced Solid Tumors and Normal or Varying Degrees of Renal Impairment

STUDY NEW 2016-152
Phase I
A Phase 1b Study to Evaluate TAK-659 in Combination With Nivolumab in Patients With Advanced Solid Tumors

STUDY 2016-135
Phase I/II
A Phase 1b/2 Study of ARRY-382 in Combination with Pembrolizumab, a Programmed Cell Death Receptor 1 (PD-1) Antibody, for the Treatment of Patients with Advanced Solid Tumors

STUDY NEW 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 2015-156
Phase I
A Phase 1 Dose Escalation and Cohort Expansion Study of the Safety, Tolerability, and Efficacy of Anti-LAG-3 Monoclonal Antibody (BMS-986016) Administered Alone and in Combination with Anti-PD-1 Monoclonal Antibody (Nivolumab, BMS-936558) in Advanced Solid Tumors

STUDY 2015-011
Phase I
A Phase 1b Study to Assess Safety, Pharmacokinetics, Pharmacodynamics, and Preliminary Efficacy of PLX9486 as a Single Agent and in Combination with PLX3397 in Patients with Advanced Solid Tumors and Patients with Locally Advanced, Unresectable, or Metastatic Gastrointestinal Stromal Tumor (GIST) Who Have Been Previously Treated with Imatinib Mesylate, Sunitinib Malate, and Regorafenib

STUDY 2015-034
Phase I/II
A Phase 1/2a Study to Assess the Safety, Pharmacokinetics, and Pharmacodynamics of PLX8394 in Patients with Advanced, Unresectable Solid Tumors
STUDY 2015-149
Phase I
A Phase I Open-Label, Dose Escalation Study to Investigate the Safety, Pharmacokinetics, Pharmacodynamics, and Clinical Activity of GSK2820151 in Subjects with Advanced or Recurrent Solid Tumors

STUDY 2016-037
Phase I
A Phase 1 Study of ALKS 4230 in Subjects with Advanced Solid Tumors

STUDY 2009-139
Phase I
Phase I Safety, Pharmacokinetic and Pharmacodynamic Study of PF-02341066, A C-Met/HGFR Selective Tyrosine Kinase Inhibitor, Administered Orally to Patients with Advanced Cancer

STUDY 2013-119
Phase I
A Phase I, First-in-Human, Dose Escalation Trial of MSC2363318A, a Dual p70S6K/Akt Inhibitor, in Subjects with Advanced Malignancies

STUDY 2011-082
Phase I
An Early Phase 1 Study of ABT-888 in Combination with Carboplatin and Paclitaxel in Patients with Hepatic or Renal Dysfunction and Solid Tumors (NCI# 8808, UPCI# 10-115)

STUDY 2015-086
Phase I
A First-in-Human Study of Repeat Dosing with REGN2810, a Monoclonal, Fully Human Antibody to Programmed Death-1(PD-1), as Single Therapy and in Combination with Other Anti-Cancer Therapies, in Patients with Advanced Malignancies

STUDY 2016-075
Phase I/II
A Phase 1/2 Study of the Safety, Pharmacokinetics, and Pharmacodynamics of the Glutaminase Inhibitor CB-839 in Combination with Nivolumab in Patients with Clear Cell Renal Cell Carcinoma and Other Solid Tumors

STUDY 2011-002
Phase I
Phase I Pharmacokinetic Study of Belinostat for Solid Tumors and Lymphomas in Patients with Varying Degrees of Hepatic Dysfunction

TUMOR SPECIFIC

STUDY 2015-110
Phase I/II
A Phase I/II, Dose-escalation and Cohort Expansion Study of the Safety, Tolerability and Efficacy of Anti-CD27 antibody (Varilumab) Administered in Combination with Anti-PD-1 (Nivolumab) in Advanced Refractory 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 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 2017-053
Phase I/II
A Study to Evaluate the Safety and Efficacy of the CD40 Agonistic Antibody APX005M Administered in Combination with Nivolumab in Subjects with Nonsmall Cell Lung Cancer and Subjects with Metastatic Melanoma
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 2015-157
Phase I/II
Phase 1/2 Clinical Study of Niraparib in Combination with Pembrolizumab in Patients with Advanced or Metastatic Triple-Negative Breast Cancer and in Patients with Recurrent Ovarian Cancer

STUDY 2015-034
Phase I/II
A Phase 1/2a Study to Assess the Safety, Pharmacokinetics, and Pharmacodynamics of PLX8394 in Patients with Advanced, Unresectable Solid Tumors

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 NEW 2016-152
Phase I
A Phase 1b Study to Evaluate TAK-659 in Combination With Nivolumab in Patients With Advanced Solid Tumors

STUDY NEW 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 2016-081
Phase I/II
Phase 1-2 Study of MEDI4736 Alone or In Combination with ADXS11-001 In Recurrent/Persistent or Metastatic Cervical or HPV+ Head & Neck Cancer

STUDY 2013-120
Phase I
A Phase 1b Open-Label Three-Arm Multi-Center Study to Assess the Safety and Tolerability of PF-05212384 (PI3K/mTOR Inhibitor) in Combination with Other Anti-Tumor Agents

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 2015-046
Phase I
A Phase I, Multicenter, Open-Label, Two-Part, Dose-escalation Study of RAD1901 in Postmenopausal Women with Advanced Estrogen Receptor Positive and HER2-Negative Breast Cancer

STUDY 2015-047
Phase I
A Phase 1 Open-Label, Dose-Finding Study Evaluating Safety and Pharmacokinetics of FPA144 in Patients with Advanced Solid Tumors

STUDY 2013-119
Phase I
A Phase I, First-in-Human, Dose Escalation Trial of MSC2363318A, a Dual p70S6K/Akt Inhibitor, in Subjects with Advanced Malignancies

STUDY 2015-137
Phase I
A Phase 1b, Open-Label, Two-Arm Study Evaluating the Safety and Pharmacokinetics of Atezolizumab (Anti-PD-L1 Antibody) in Combination with Trastuzumab Emtansine or with Trastuzumab and Pertuzumab in Patients with HER2-Positive Breast Cancer

STUDY 2016-079
Phase I
An Open-Label Multicenter Phase 1 Study to Evaluate the Safety, Pharmacokinetics and Pharmacodynamics of H3B-6527 in Subjects With Advanced Hepatocellular Carcinoma or Intrahepatic Cholangiocarcinoma

STUDY 2016-016
Phase I/II
A Phase I/II Multicenter Study of the Combination of AZD2014 and Palbociclib on a Background of Hormonal Therapy in Patients with Locally Advanced/Metastatic Estrogen Receptor Positive Breast Cancer Comprising a Safety, Pharmacokinetic and Preliminary Efficacy Evaluation followed by a Randomized, Double-Blind, Placebo-controlled, Parallel Group Extension (PASTOR)

STUDY 2016-037
Phase I
A Phase 1 Study of ALKS 4230 in Subjects with Advanced Solid Tumors

GENOMIC TESTING SPECIFIC
STUDY 2015-047
Phase I
A Phase 1 Open-Label, Dose-Finding Study Evaluating Safety and Pharmacokinetics of FPA144 in Patients with Advanced Solid Tumors

STUDY 2016-050
Phase I
A Phase 1 Dose Escalation and Cohort Expansion Study of ERY974, an Anti-Glypican 3 (GPC3)/CD3 Bispecific 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 2015-137
Phase I
A Phase 1b, Open-Label, Two-Arm Study Evaluating the Safety and Pharmacokinetics of Atezolizumab (Anti-PD-L1 Antibody) in Combination with Trastuzumab Emtansine or with Trastuzumab and Pertuzumab in Patients with HER2-Positive Breast Cancer

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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 or fill out this online referral
**ADJUVANT**

**STUDY 2015-080**
Phase III
A Phase III, Open-Label, Randomized Study to Investigate the Efficacy and Safety of MPDL3280A (ANTI-PD-L1 ANTIBODY) Compared with Best Supportive Care Following Adjuvant Cisplatin-Based Chemotherapy in PD-L1-Selected Patients with Completely Resected Stage IB-III A Non-Small Cell Lung Cancer

**STUDY 2017-053**
Phase I/II
A Study to Evaluate the Safety and Efficacy of the CD40 Agonistic Antibody APX005M Administered in Combination with Nivolumab in Subjects with Nonsmall Cell Lung Cancer and Subjects with Metastatic Melanoma

**STAGE I/II**

**STUDY E4512**
Phase III
A Phase III Double-Blind Trial for Surgically Resected Early Stage Non-Small Cell Lung Cancer: Crizotinib versus Placebo for Patients with Tumors Harboring the Anaplastic Lymphoma Kinase (ALK) Fusion Protein

**STUDY 2017-053**
Phase I/II
A Study to Evaluate the Safety and Efficacy of the CD40 Agonistic Antibody APX005M Administered in Combination with Nivolumab in Subjects with Nonsmall Cell Lung Cancer and Subjects with Metastatic Melanoma

**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 A081105**
Phase III
Randomized Double Blind Placebo Controlled Study of Erlotinib or Placebo in Patients with Completely Resected Epidermal Growth Factor Receptor (EGFR) Mutant Non-Small Cell Lung Cancer (NSCLC)

**STAGE III A/B**

**STUDY 2015-103**
Phase I
A Phase 1b Open-Label Study of PEGylated Recombinant Human Hyaluronidase (PEGPH20) Combined with Pembrolizumab in Subjects with Selected Hyaluronan-High Solid Tumors

**STUDY S1206**
Phase I/II
A Dose Finding Study Followed by Phase II Randomized Placebo-Controlled Study of Veliparib (ABT-888) Added to Chemoradiotherapy with Carboplatin and Paclitaxel for Unresectable Stage III Non-Small Cell Lung Cancer (NSCLC). (NCI STUDY NUMBER 8811)

**STUDY 2017-053**
Phase I/II
A Study to Evaluate the Safety and Efficacy of the CD40 Agonistic Antibody APX005M Administered in Combination with Nivolumab in Subjects with Nonsmall Cell Lung Cancer and Subjects with Metastatic Melanoma

**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 S1400**
Phase II/III
A Biomarker-Driven Master Protocol for Previously Treated Squamous Cell Lung Cancer (Lung-MAP)

**STAGE IV**

**ALK**

**STUDY 2014-071**
Phase I/II
Phase 1/2 Study of PF-06463922 (An ALK/ROS1 Tyrosine Kinase Inhibitor) in Patients with Advanced Non-Small Cell Lung Cancer Harboring Specific Molecular Alterations

**STUDY 2009-139**
Phase I
Phase I Safety, Pharmacokinetic and Pharmacodynamic Study of PF-02341066, A C-Met/HGFR Selective Tyrosine Kinase Inhibitor, Administered Orally to Patients with Advanced Cancer

**STUDY 2015-131**
Phase II
An Open-Label, Multicenter, Global Phase 2 Basket Study of Entrectinib for the Treatment of Patients with Locally Advanced or Metastatic Solid Tumors that Harbor NTRK1/2/3, ROS1, or ALK Gene Rearrangements

**EGFR**

**STUDY 2015-133**
Phase II
A Phase II, Multicenter, Three-cohort Study of Oral cMET Inhibitor INC280 in Adult Patients with EGFR wild-type (wt), Advanced Non-Small Cell Lung Cancer (NSCLC) who have Received One or Two Prior Lines of Systemic Therapy for Advanced/Metastatic Disease

**Other Genetic Marker**

**STUDY S1400**
Phase II/III
A Biomarker-Driven Master Protocol for Previously Treated Squamous Cell Lung Cancer (Lung-MAP)

**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 NEW 2017-093**
Phase II
A Phase 2 Study of MEDI4736 (durvalumab) and Tremelimumab Alone or in Combination with High or Low-Dose Radiation in Metastatic Colorectal and NSCLC

**STUDY 2015-103**
Phase I
A Phase 1b Open-Label Study of PEGylated Recombinant Human Hyaluronidase (PEGPH20) Combined with Pembrolizumab in Subjects with Selected Hyaluronan-High Solid Tumors

**STUDY 2017-053**
Phase I/II
A Study to Evaluate the Safety and Efficacy of the CD40 Agonistic Antibody APX005M Administered in Combination with Nivolumab in Subjects with Nonsmall Cell Lung Cancer and Subjects with Metastatic Melanoma

**STUDY NEW 2016-178**
Phase I
A Phase 1, Dose-Finding and Signal-Seeking Study of the Safety and Efficacy of Intravenous CAVATAK(TM) (coxsackievirus A21, CVA21) Alone and in Combination with Pembrolizumab in Patients with Late Stage Solid Tumours (NSCLC, Castrate-Resistant Prostate Cancer, Melanoma and Bladder Cancer)

**STUDY NEW S1507**
Phase II
A Phase II Trial of Trametinib with Docetaxel in Patients with Kras Mutation Positive Non-Small Cell Lung Cancer (NSCLC) and Progressive Disease Following One or Two Prior Systemic Therapies

**STUDY 2016-034**
Phase I
A Phase 1b Study of Abemaciclib in Combination with Pembrolizumab for Patients with Stage IV Non-Small Cell Lung Cancer or Hormone Receptor Positive, HER2 Negative Breast Cancer

**STUDY 2016-134**
Phase II
A Phase 2, Fast Real-time Assessment of Combination Therapies in Immuno-Oncology Study in Subjects with Advanced Non-small Cell Lung Cancer (FRACTION-Lung)

**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 2015-086**
Phase I
A First-in-Human Study of Repeat Dosing with REGN2810, a Monoclonal, Fully Human Antibody to Programmed Death-1(PD-1), as Single Therapy and in Combination with Other Anti-Cancer Therapies, in Patients with Advanced Malignancies

**STUDY 2009-139**
Phase I
Phase I Safety, Pharmacokinetic and Pharmacodynamic Study of PF-02341066, A C-Met/HGFR Selective Tyrosine Kinase Inhibitor, Administered Orally to Patients with Advanced Cancer

**STUDY 2015-131**
Phase II
An Open-Label, Multicenter, Global Phase 2 Basket Study of Entrectinib for the Treatment of Patients with Locally Advanced or Metastatic Solid Tumors that Harbor NTRK1/2/3, ROS1, or ALK Gene Rearrangements

**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 2013-120**
Phase I
A Phase 1b Open-Label Three-Arm Multi-Center Study to Assess the Safety and Tolerability of PF-05212384 (PI3K/mTOR Inhibitor) in Combination with Other Anti-Tumor Agents

**RECURRENT ALK**
**STUDY 2009-139**
Phase I
Phase I Safety, Pharmacokinetic and Pharmacodynamic Study of PF-02341066, A C-Met/HGFR Selective Tyrosine Kinase Inhibitor, Administered Orally to Patients with Advanced Cancer

**Other Genetic Marker**
**STUDY 2009-139**
Phase I
Phase I Safety, Pharmacokinetic and Pharmacodynamic Study of PF-02341066, A C-Met/HGFR Selective Tyrosine Kinase Inhibitor, Administered Orally to Patients with Advanced Cancer

**STUDY NEW S1507**
Phase II
A Phase II Trial of Trametinib with Docetaxel in Patients with Kras Mutation Positive Non-Small Cell Lung Cancer (NSCLC) and
Progressive Disease Following One or Two Prior Systemic Therapies

**SCLC EXTENSIVE**

**STUDY 2016-099**  
Phase I  
An Intensive QT/QTc Study to Investigate the Effects of Rovalpituzumab Tesirine on Cardiac Ventricular Repolarization in Subjects with Small Cell Lung 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

**MESOTHELIOMA**

**STUDY 2015-010**  
Phase II  
A Phase II Trial of BIBF 1120 (Nintedanib) in Recurrent Malignant Pleural 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

**STUDY 2016-172**  
Phase III  
A Phase III, Randomized, Open Label Trial of Nivolumab in Combination with Ipilimumab versus Pemetrexed with Cisplatin or Carboplatin as First Line Therapy in Unresectable Pleural Mesothelioma

**SARCOMA**

**STUDY 2009-139**  
Phase I  
Phase I Safety, Pharmacokinetic and Pharmcodynamic Study of PF-02341066, A C-Met/HGFR Selective Tyrosine Kinase Inhibitor, Administered Orally to Patients with Advanced Cancer

**OTHER**

**STUDY 2009-139**  
Phase I  
Phase I Safety, Pharmacokinetic and Pharmcodynamic Study of PF-02341066, A C-Met/HGFR Selective Tyrosine Kinase Inhibitor, Administered Orally to Patients with Advanced Cancer

**STUDY EAY131**  
Phase II  
Molecular Analysis for Therapy Choice (MATCH)

**STUDY 2016-189**  
Phase I  
A Phase 1, Multicenter, Open-Label, Dose-Escalation Study of SGN-2FF in Patients with Advanced Solid Tumors

**STUDY S1403**  
Phase II/III  
A Randomized Phase II/III Trial of Afatinib plus Cetuximab versus Afatinib Alone in Treatment-Naive Patients with Advanced, EGFR Mutation Positive Non-Small Cell Lung Cancer (NSCLC)(BI 1200.124)

**STUDY 2016-116**  
Phase II  
A Phase 2 Study of Cediranib in Combination with Olaparib in Advanced Solid Tumors
STUDY NEW 2016-152
Phase I
A Phase 1b Study to Evaluate TAK-659 in Combination With Nivolumab 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 NEW 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 2015-156
Phase I
A Phase 1 Dose Escalation and Cohort Expansion Study of the Safety, Tolerability, and Efficacy of Anti-LAG-3 Monoclonal Antibody (BMS-986016) Administered Alone and in Combination with Anti-PD-1 Monoclonal Antibody (Nivolumab, BMS-936558) in Advanced Solid Tumors

STUDY 2016-025
Phase I/II
A Multi-Center Study of hTERT Immunotherapy Alone or in Combination with IL-12 DNA followed by Electroporation in Adults with Solid Tumors at High Risk of Relapse Post Definitive Surgery and Standard Therapy

STUDY 2015-086
Phase I
A First-in-Human Study of Repeat Dosing with REGN2810, a Monoclonal, Fully Human Antibody to Programmed Death-1(PD-1), as Single Therapy and in Combination with Other Anti-Cancer Therapies, in Patients with Advanced Malignancies