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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<th>Immunotherapy</th>
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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 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 NEW 2017-001
Phase III
A Single-Arm Study of the Effect of a 5-day Regimen of Tbo-Filgrastim 10 mcg/kg of Body Weight Administered Subcutaneously on Peripheral Stem Cell Mobilization in Healthy Donors.

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 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 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 Entospletinib, 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.

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

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 NEW 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
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 NEW 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 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
TITLE
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

HORMONAL
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 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 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 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

OTHERS
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 2016-055
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 2016-123
Phase III
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)

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

**STUDY 2015-157**  
**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 NEW 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 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)

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### 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 NEW 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

**Metastatic**

**STUDY 2013-162**
Phase I
A Phase I, Open-label, Multiple-ascending Dose Trial to Investigate the Safety, Tolerability, Pharmacokinetics, Biological and Clinical Activity of MSB0010718C in Subjects with Metastatic or Locally Advanced Solid Tumors and Expansion to Selected Indications

**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 NEW 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 2017-029**
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

**STUDY 2015-161**
Phase I/II
A Phase 1b/2, Open Label, Dose Escalation Study of Margetuximab in Combination with Pembrolizumab in Patients with Relapsed/Refractory Advanced HER2+ Gastroesophageal Junction or Gastric Cancer
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 NEW S1505
Phase II
A Randomized Phase II Study of Perioperative mFOLFIRINOX versus Gemcitabine/NAB-Paclitaxel as Therapy for Resectable Pancreatic Adenocarcinoma

STUDY 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 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 NEW 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 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 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

STUDY 2016-041
Phase II
Randomized, Double-Blind, Phase 2 Study of Ramucirumab or Merestinib or Placebo plus Cisplatin and Gemcitabine as First-Line Treatment in Patients with Advanced or Metastatic Biliary Tract Cancer

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
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<tr>
<th>STUDY 2015-131</th>
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<tr>
<td>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</td>
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<th>STUDY 2016-050</th>
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<tr>
<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>
<th>STUDY 2015-110</th>
<th>Phase I/II</th>
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<tbody>
<tr>
<td>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</td>
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<tr>
<th>STUDY 2016-157</th>
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<tbody>
<tr>
<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>
<th>STUDY 2016-063</th>
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<tbody>
<tr>
<td>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)</td>
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<th>STUDY 2016-092</th>
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<tr>
<td>An Open-Label, Phase 1/1b, Single-Agent Study of RXDX-105 in Patients With Advanced Solid Tumors</td>
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<thead>
<tr>
<th>STUDY 2016-003</th>
<th>Phase I/II</th>
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<tbody>
<tr>
<td>A Phase 1b/2 Study of Ibrutinib Combination Therapy in Selected Advanced Gastrointestinal And Genitourinary Tumors</td>
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<th>STUDY 2016-025</th>
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<tr>
<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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| RECTUM |

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

ANAL
Localized
STUDY EA2133
Phase II
InterAACT: An International Multicentre Open Label Randomised Phase II Advanced Anal Cancer Trial Comparing Cisplatin plus 5-fluorouracil versus Carboplatin plus Weekly Paclitaxel in Patients with Inoperable Locally Recurrent or Metastatic Disease

Metastatic
STUDY EA2133
Phase II
InterAACT: An International Multicentre Open Label Randomised Phase II Advanced Anal Cancer Trial Comparing Cisplatin plus 5-fluorouracil versus Carboplatin plus Weekly Paclitaxel in Patients with Inoperable Locally Recurrent or Metastatic Disease

STUDY 2015-108
Phase II
Phase 2 Study of ADXS11-001 in Subjects with Persistent/Recurrent, Loco-Regional or Metastatic Squamous Cell Carcinoma of the Anorectal Canal

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

STUDY NEW 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

RETURN TO TOP

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
<table>
<thead>
<tr>
<th>Study Code</th>
<th>Phase</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>STUDY 2015-168</td>
<td>Phase III</td>
<td>A Phase 3, Randomized, Controlled, Multi-Center, Open-Label Study to Compare Tivozanib Hydrochloride to Sorafenib in Subjects With Refractory Advanced Renal Cell Carcinoma</td>
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<tr>
<td>STUDY 2016-201</td>
<td>Phase III</td>
<td>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).</td>
</tr>
<tr>
<td>STUDY 2017-013</td>
<td>Phase I</td>
<td>A Phase 1, Multiple-Dose, Dose-Escalation Trial of PT2385 Tablets, a HIF-2a Inhibitor in Patients with Advanced Clear Cell Renal Cell Carcinoma</td>
</tr>
<tr>
<td>STUDY 2016-126</td>
<td>Phase II</td>
<td>Phase II Study of Atezolizumab + Bevacizumab in Patients with Advanced Non-Clear Cell Renal Cell Carcinoma</td>
</tr>
<tr>
<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>
</tr>
<tr>
<td>STUDY NEW 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 NEW 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>
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<tr>
<td>STUDY NEW 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>
</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 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>
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<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>
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</table>
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 2013-162**  
**Phase I**  
A Phase I, Open-label, Multiple-ascending Dose Trial to Investigate the Safety, Tolerability, Pharmacokinetics, Biological and Clinical Activity of MSB0010718C in Subjects with Metastatic or Locally Advanced Solid Tumors and Expansion to Selected Indications

**STUDY 2015-109**  
**Phase I**  
A Phase 1b, Open Label, Dose Escalation Study to Evaluate Safety, Pharmacokinetics And Pharmacodynamics of Axitinib (AG-013736) in Combination With Crizotinib (PF-02341066) in Patients With Advanced Solid Tumors

**PROSTATE**  
**STUDY 2013-108**  
NA  
Immune Evaluation Study of Sipuleucel-T in African American and Non African American Men with Castrate Resistant Prostate Cancer

**STUDY 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 1 Safety and Tolerability Study of ZEN003694 in Combination with Enzalutamide in Patients with Metastatic Castration-Resistant Prostate Cancer

**STUDY NEW 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 2016-028**  
**Phase I**  
A Phase 1 Safety and Tolerability Study of ZEN003694 in Patients with Metastatic Castration-Resistant Prostate Cancer

**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 2015-096
Phase I/II
A Phase 1/2 Open-label Study to Assess the Safety, Pharmacokinetics, and Antitumor Activity of Oral EPI-506 in Patients with Metastatic Castration-resistant Prostate Cancer

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 2013-162
Phase I
A Phase I, Open-label, Multiple-ascending Dose Trial to Investigate the Safety, Tolerability, Pharmacokinetics, Biological and Clinical Activity of MSB0010718C in Subjects with Metastatic or Locally Advanced Solid Tumors and Expansion to Selected Indications

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 NEW 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 NEW 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 2015-101  
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 2016-052  
Phase III  
A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of Ramucirumab plus Docetaxel Versus Placebo plus Docetaxel in Patients with Locally Advanced or Unresectable or Metastatic Urothelial Carcinoma Who Progressed on or After Platinum-Based Therapy

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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<table>
<thead>
<tr>
<th>Study ID</th>
<th>Type</th>
<th>Description</th>
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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 NEW   | 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 2016-121 | Phase II  
A Phase 2, Single-Arm Study to Evaluate the Safety and Efficacy of Niraparib in Patients with Advanced, Relapsed, High-Grade Serous Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Who Have Received Three or Four Previous Chemotherapy Regimens |
| STUDY NEW   | 2017-064 | 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   | 2017-029 | 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 NEW   | 2017-023 | Phase I/II  
PISARRO: p53 Suppressor Activation in Recurrent High Grade Serous Ovarian Cancer, a Phase I/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 NRG-GY003**  
Phase II  
Phase II Randomized Trial of Nivolumab with or without Ipilimumab in Patients with Persistent or Recurrent Epithelial Ovarian, Primary Peritoneal or Fallopian Tube 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 NEW 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 2016-121**  
Phase II  
A Phase 2, Open-Label, Single-Arm Study to Evaluate the Safety and Efficacy of Niraparib in Patients with Advanced, Relapsed, High-Grade Serous Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Who Have Received Three or Four Previous Chemotherapy Regimens

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

STAGES I/II/III
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 2016-174
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 NEW 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
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

Phase II 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

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

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

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

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

Molecular Analysis for Therapy Choice (MATCH)

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

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

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

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
# 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 E1A11
- **Phase III**
- Randomized Phase III Trial of Bortezomib, Lenalidomide and Dexamethasone (VRd) Versus Carfilzomib, Lenalidomide and Dexamethasone (CRd) Followed by Limited or Indefinite Duration Lenalidomide Maintenance in Patients with Newly Diagnosed Symptomatic Multiple Myeloma (ENDURANCE)

### 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 2010-106
- **Phase III**
- A Randomized Phase III Study Comparing Conventional Dose Treatment Using a Combination of Lenalidomide, Bortezomb 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 2015-022
Phase I
A Phase Ib Study of the Safety and Pharmacokinetics of Atezolizumab (ANTIPD-L1 ANTIBODY) Alone or in Combination with an Immunomodulatory Drug and/or Daratumumab in Patients with Multiple Myeloma (Relapsed and Post- Autologous Stem Cell Transplantation)

STUDY 2015-036
Phase II
A Phase II Study of Ixazomib, Lenalidomide, & Dexamethasone for Consolidation Therapy Post Autologous Stem Cell Transplantation followed by Maintenance Ixazomib or Lenalidomide for Multiple Myeloma

AMYLOIDOSIS or LIGHT CHAIN DEPOSITION DISEASE
STUDY 2012-086
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 2016-060
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

STUDY 2015-054
Phase I
A Phase 1, First-in-Human, Open-Label, Dose Escalation Study of JNJ-64052781, a Humanized CD19 x CD3 Dual-Affinity Re-Targeting (DART®) Protein in Subjects with Relapsed or Refractory B-cell Malignancies

Acute Myeloid Leukemia (AML)
STUDY 2014-031
Phase III
A Phase 3 Open-Label Randomized Study of Quizartinib (AC220) Monotherapy Versus Salvage Chemotherapy In Subjects with FLT3-ITD Positive Acute Myeloid Leukemia (AML) Refractory to or Relapsed After First-Line Treatment With or Without Hematopoietic Stem Cell Transplantation(HSCT) Consolidation

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

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<th>Title</th>
<th>Phase</th>
<th>Study Details</th>
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<tbody>
<tr>
<td>STUDY 2016-103</td>
<td>Phase II Study of CX-01 Combined With Standard Induction Therapy for Newly Diagnosed Acute Myeloid Leukemia</td>
<td>Phase II</td>
<td>A Randomized, Phase II Study of CX-01 Combined With Standard Induction Therapy for Newly Diagnosed Acute Myeloid Leukemia</td>
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<tr>
<td>STUDY 2016-103</td>
<td>Phase I</td>
<td></td>
<td>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</td>
</tr>
<tr>
<td><strong>Chronic Lymphocytic Leukemia (CLL)</strong></td>
<td>STUDY NEW 2015-054</td>
<td>Phase I</td>
<td>A Phase 1, First-in-Human, Open-Label, Dose Escalation Study of JNJ- 64052781, a Humanized CD19 x CD3 Dual-Affinity Re-Targeting (DART®) Protein in Subjects with Relapsed or Refractory B-cell Malignancies</td>
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<tr>
<td><strong>Chronic Myeloid Leukemia (CML)</strong></td>
<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>
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<tr>
<td><strong>LYMPHOMA</strong></td>
<td><strong>Hodgkin's</strong></td>
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<td>STUDY 2016-033</td>
<td>Phase II</td>
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<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>
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<td>STUDY 2015-126</td>
<td>Phase I/II</td>
<td></td>
<td>A Study Evaluating Brentuximab Vedotin in Combination with the PD-1 Inhibitor Nivolumab in Patients with Relapsed or Refractory Hodgkin Lymphoma after Failure of Frontline Therapy</td>
</tr>
<tr>
<td>STUDY 016-058</td>
<td>Phase III</td>
<td></td>
<td>A Phase III, Randomized, Open-label, Clinical Trial to Compare Pembrolizumab with Brentuximab Vedotin in Subjects with Relapsed or Refractory Classical Hodgkin Lymphoma</td>
</tr>
<tr>
<td><strong>Non-Hodgkin's</strong></td>
<td><strong>Aggressive (Mantle Cell, Large B-Cell Lymphoma)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STUDY 2015-054</td>
<td>Phase I</td>
<td></td>
<td>A Phase 1, First-in-Human, Open-Label, Dose Escalation Study of JNJ-64052781, a Humanized CD19 x CD3 Dual-Affinity Re-Targeting (DART®) Protein in Subjects with Relapsed or Refractory B-cell Malignancies</td>
</tr>
<tr>
<td>STUDY NEW 2017-025</td>
<td>Phase III</td>
<td></td>
<td>Phase 3 Study of Ibrutinib in Combination with Venetoclax in Subjects with Mantle Cell Lymphoma</td>
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<tr>
<td>STUDY 2013-178</td>
<td>Phase I/II</td>
<td></td>
<td>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</td>
</tr>
<tr>
<td>STUDY 2017-007</td>
<td>Phase I</td>
<td></td>
<td>A Multi-Center, Open label, Dose Escalation, Phase I/Ib Study to Evaluate the Safety and Efficacy of RP4010, a Calcium Release</td>
</tr>
</tbody>
</table>
### Activated Calcium (CRAC) Channel Inhibitor, in Patients with Relapsed or Refractory Non-Hodgkin Lymphoma

**STUDY 2015-125**  
**Phase II**  
Randomized, Open Label, Phase 2 Study of Rituximab and Bendamustine with or without Brentuximab V downtin for Relapsed or Refractory CD30-Positive Diffuse 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 2016-147**  
**Phase II**  
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)

**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 Or Diffuse Large B-Cell Lymphoma

### T cell

**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 2016-139**  
**Phase I**  
A Phase I/b, 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

**STUDY 2016-125**  
**Phase I/II**  
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

**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 2017-008**  
**Phase I**  
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

### MYELODYSPLASTIC SYNDROME (MDS)

**STUDY 2014-037**  
**Phase I**  
A Phase 1 Study to Evaluate the Safety and Tolerability of MEDI4736 in Subjects with Myelodysplastic Syndrome after Treatment with Hypomethylating Agents

**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 2016-054
Phase III
A Phase 3, Double-blind, Randomized Study to Compare the Efficacy and Safety of Luspatercept (ACE-536) Versus Placebo for the Treatment of Anemia Due to IPSS-R Very Low, Low, or Intermediate Risk Myelodysplastic Syndromes in Subjects with Ring Sideroblasts Who Require Red Blood Cell Transfusions (The "MEDALIST" Trial)

OTHER
STUDY 2016-024
Phase I
Phase Ib Trial of Pembrolizumab (MK-3475) in Combination with Dinaciclib (MK-7965) in Subjects with Hematologic Malignancies (KEYNOTE-155)

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 2016-148
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.

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

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 NEW 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 NEW 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 2017-053
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 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 Pharmcodynamic 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
<table>
<thead>
<tr>
<th>Study Number</th>
<th>Phase</th>
<th>Title</th>
</tr>
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<tbody>
<tr>
<td>STUDY 2015-086</td>
<td>Phase I</td>
<td>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</td>
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<tr>
<td>STUDY 2015-117</td>
<td>Phase III</td>
<td>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)</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>
</tr>
<tr>
<td>STUDY NEW 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>
</tr>
<tr>
<td>STUDY NEW 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 2016-149</td>
<td>Phase I/II</td>
<td>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</td>
</tr>
<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 EAY131</td>
<td>Phase II</td>
<td>Molecular Analysis for Therapy Choice (MATCH)</td>
</tr>
</tbody>
</table>

**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](mailto:Phase1NewPt@karmanos.org).
All patients will need to go through an initial new patient screening consultation to determine if they are eligible for one of our Phase 1 studies and to ensure that it is the best treatment option available for them.

**ALL SOLID TUMORS**

**STUDY 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 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 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 2014-116
Pilot
Molecular Profiling of Tumors From Cancer Patients Who Are Exceptional Responders

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 I Study of ALKS 4230 in Subjects with Advanced Solid Tumors

STUDY 2015-109
Phase I
A Phase 1b, Open Label, Dose Escalation Study to Evaluate Safety, Pharmacokinetics And Pharmacodynamics of Axitinib (AG-013736) in Combination With Crizotinib (PF-02341066) in Patients 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 2013-162
Phase I
A Phase I, Open-label, Multiple-ascending Dose Trial to Investigate the Safety, Tolerability, Pharmacokinetics, Biological and Clinical Activity of MSB0010718C in Subjects with Metastatic or Locally Advanced Solid Tumors and Expansion to Selected Indications

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 (Varlitumab) 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 NEW 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 2017-053**  
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 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 2015-109**  
Phase I  
A Phase 1b, Open Label, Dose Escalation Study to Evaluate Safety, Pharmacokinetics And Pharmacodynamics of Axitinib (AG-013736) in Combination With Crizotinib (PF-02341066) in Patients With Advanced Solid Tumors

**STUDY 2015-096**  
Phase I/II  
A Phase 1/2 Open-label Study to Assess the Safety, Pharmacokinetics, and Antitumor Activity of Oral EPI-506 in Patients with Metastatic Castration-resistant Prostate 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
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

<table>
<thead>
<tr>
<th>Study Name</th>
<th>Phase</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>ADJUVANT STUDY 2015-080</td>
<td>Phase III</td>
<td>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-IIIA Non-Small Cell Lung Cancer</td>
</tr>
<tr>
<td>STUDY NEW 2017-053</td>
<td>Phase I/II</td>
<td>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</td>
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<tr>
<td>STAGE I/II STUDY E4512</td>
<td>Phase III</td>
<td>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</td>
</tr>
<tr>
<td>STUDY NEW 2017-053</td>
<td>Phase I/II</td>
<td>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</td>
</tr>
<tr>
<td>STUDY 2016-110</td>
<td>Phase II</td>
<td>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</td>
</tr>
<tr>
<td>STUDY A081105</td>
<td>Phase III</td>
<td>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)</td>
</tr>
<tr>
<td>STAGE III A/B STUDY 2015-103</td>
<td>Phase I</td>
<td>A Phase 1b Open-Label Study of PEGylated Recombinant Human Hyaluronidase (PEGPH20) Combined with Pembrolizumab in Subjects with Selected Hyaluronan-High Solid Tumors</td>
</tr>
<tr>
<td>STUDY S1206</td>
<td>Phase I/I</td>
<td>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</td>
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</table>
STUDY NEW 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 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 NEW 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 2016-034
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 2016-092
Phase I
An Open-Label, Phase 1/1b, Single-Agent Study of RXDX-105 in Patients With Phase I Advanced Solid Tumors

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
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 NEW 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 NEW 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 2016-172
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 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 2017-029**  
**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