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.

Volume 5, Issue 9

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

Bone Marrow Clinical Trials

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

BONE MARROW TRANSPLANT
STUDY BMTCN1101
Phase III
A Multi-Center, Phase III, Randomized Trial of Reduced Intensity (RIC) Conditioning and Transplantation of Double Unrelated Umbilical Cord Blood (dUCB) versus HLA-Haploidentical Related Bone Marrow (Haplo) for Patients with Hematologic Malignancies.

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 NEW 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 NEW 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 NEW 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 2010-051**
NA
Retrospective Chart and Literature Review of Allogeneic Hematopoietic Stem Cell (HSC) Transplant with a Preparative Regimen of Either Busulfan/Fludarabine or Busulfan/Fludarabine/Total Body Irradiation in Patients Diagnosed with Acute Myelogenous Leukemia and Myelodysplastic Syndrome.

**STUDY 2011-204**
Phase I/II
Phase I/II Study of Dasatinib in Recipients of Allogeneic Stem Cell Transplantation for Hematologic Malignancies.

**STUDY BMTCN1102**
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 2014-029**
Phase II
A Phase 2A Study of ALXN1007 in Subjects with Newly Diagnosed Acute Graft-Versus-Host Disease Involving the Lower Gastrointestinal Tract

**STUDY 2014-063**
Phase II
Non-Comparative , Multi-Cohort, Single Arm, Open-Label, Phase 2 Study of Nivolumab (BMS-96558) in Classical Hodgkin Lymphoma (cHL) Subjects

**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 2016-049**
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...
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

STUDY 2014-139
Phase III
A Study of Neratinib Plus Capecitabine Versus Lapatinib Plus Capecitabine in Patients With HER2+ Metastatic Breast Cancer Who Have Received Two or More Prior HER2-Directed Regimens in the Metastatic Setting (NALA)

STUDY B-55
Phase III
B-55/BIG 6-13: A Randomised, Double-Blind, Parallel Group, Placebo-Controlled Multi-Centre Phase III Study to Assess the Efficacy and Safety of Olaparib Versus Placebo as Adjuvant Treatment in Patients with Germline BRCA1/2 Mutations and High Risk HER2 Negative Primary Breast Cancer Who Have Completed Definitive Local Treatment and Neoadjuvant or Adjuvant Chemotherapy

STUDY E2112
Phase III
A Randomized Phase III Trial of Endocrine Therapy plus Entinostat/Placebo in Patients with Hormone Receptor-Positive Advanced Breast Cancer

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

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.
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 B-54-I
Phase III
Phase III Study Evaluating Palbociclib (PD-0332991), a Cyclin-Dependent Kinase (CDK) 4/6 Inhibitor in Patients with Hormone-Receptor-positive, HER2-Normal Primary Breast Cancer with High Relapse Risk after Neoadjuvant Chemotherapy (PENELOPE B)

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 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 2015-085
Phase I/II
Phase 1/2a Study of Double-Immune Suppression Blockade by Combining a CSF1R Inhibitor (PLX3397) with an Anti-PD-1 Antibody (Pembrolizumab) to Treat Advanced Melanoma and Other 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
OTHERS

STUDY NEW 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 NEW 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)

Gastrointestinal Clinical Trials

For more information on Gastrointestinal 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.

ESOPHAGUS

STUDY 2016-001
Phase I
A Phase 1 Study to Assess Safety, Pharmacokinetics, and Pharmacodynamics of PLX73086 as a Single Agent in Subjects with Advanced Solid Tumors and in Subjects with Locally Advanced or Refractory Tenosynovial Giant Cell Tumor (TGCT)

STUDY 2015-153
Phase III
A Phase III Randomized Open-label Study of Single Agent Pembrolizumab vs Physicians' Choice of Single Agent Docetaxel, Paclitaxel, or Irinotecan in Subjects with Advanced/Metastatic Adenocarcinoma and Squamous Cell Carcinoma of the Esophagus that have Progressed after First-Line Standard Therapy

STUDY 2015-138
Phase I
A Phase 1 Study of Alisertib (MLN8237) in Combination with mFOLFOX in Gastrointestinal Tumors

STUDY NEW 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 2015-085**  
Phase I/II  
Phase 1/2a Study of Double-Immune Suppression Blockade by Combining a CSF1R Inhibitor (PLX3397) with an Anti-PD-1 Antibody (Pembrolizumab) to Treat Advanced Melanoma and Other Solid Tumors

**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 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 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 2016-001**  
Phase I  
A Phase 1 Study to Assess Safety, Pharmacokinetics, and Pharmacodynamics of PLX73086 as a Single Agent in Subjects with Advanced Solid Tumors and in Subjects with Locally Advanced or Refractory Tenosynovial Giant Cell Tumor (TGCT)

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

**STUDY 2015-092**  
Phase III  
A Randomized, Active-Controlled, Partially Blinded, Biomarker Select, Phase III Clinical Trial of Pembrolizumab as Monotherapy and in Combination with Cisplatin+5-Fluorouracil versus Placebo+Cisplatin+5-Fluorouracil as First Line Treatment in Subjects with Advanced Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma

**STUDY NEW 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 2015-138**  
Phase I  
A Phase 1 Study of Alisertib (MLN8237) in Combination with mFOLFOX in Gastrointestinal Tumors

**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**
<table>
<thead>
<tr>
<th>Study ID</th>
<th>Study Title</th>
<th>Phase</th>
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<tr>
<td>STUDY 2015-085</td>
<td>Phase I/II Study of Double-Immune Suppression Blockade by Combining a CSF1R Inhibitor (PLX3397) with an Anti-PD-1 Antibody (Pembrolizumab) to Treat Advanced Melanoma and Other Solid Tumors</td>
<td>I/II</td>
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<tr>
<td>STUDY S1313</td>
<td>A Phase I/II Randomized Study of Modified FOLFIRINOX + Pegylated Recombinant Human Hyaluronidase (PEGPH20) versus Modified FOLFIRINOX Alone in Patients with Good Performance Status Metastatic Pancreatic Adenocarcinoma</td>
<td>I/II</td>
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<tr>
<td>STUDY NEW 2013-133</td>
<td>A Phase Ib/II Study of the Selective Inhibitor of Nuclear Export (SINE) Selinexor (KPT-330), Gemcitabine and nab-Paclitaxel in Patients with Metastatic Pancreatic Cancer</td>
<td>I/II</td>
</tr>
<tr>
<td>STUDY 2016-011</td>
<td>A Phase III, 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</td>
<td>III</td>
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<tr>
<td>Neuroendocrine</td>
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<td>Phase II</td>
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<tr>
<td>STUDY EA2142</td>
<td>Randomized Phase II Study of Cisplatin and Etoposide versus Temozolomide and Capecitabine in Patients with Advanced G3 Non-Small Cell Gastroenteropancreatic Neuroendocrine Carcinomas</td>
<td>II</td>
</tr>
<tr>
<td>STUDY NEW 2013-133</td>
<td>A Phase Ib/II Study of the Selective Inhibitor of Nuclear Export (SINE) Selinexor (KPT-330), Gemcitabine and nab-Paclitaxel in Patients with Metastatic Pancreatic Cancer</td>
<td>I/II</td>
</tr>
<tr>
<td>STUDY NEW 2016-025</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>
<td>I/II</td>
</tr>
<tr>
<td>STUDY NEW 2016-116</td>
<td>A Phase 2 Study of Cediranib in Combination with Olaparib in Advanced Solid Tumors</td>
<td>II</td>
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<tr>
<td>STUDY RTOG0848</td>
<td>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</td>
<td>III</td>
</tr>
<tr>
<td>STUDY 2016-001</td>
<td>A Phase 1 Study to Assess Safety, Pharmacokinetics, and Pharmacodynamics of PLX73086 as a Single Agent in Subjects with Advanced Solid Tumors and in Subjects with Locally Advanced or Refractory Tenosynovial Giant Cell Tumor (TGCT)</td>
<td>I</td>
</tr>
<tr>
<td>HCC Metastatic</td>
<td>STUDY 2015-086</td>
<td></td>
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</tbody>
</table>
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 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 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 2016-079
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 2015-085
Phase I/II
Phase 1/2a Study of Double-Immune Suppression Blockade by Combining a CSF1R Inhibitor (PLX3397) with an Anti-PD-1 Antibody (Pembrolizumab) to Treat Advanced Melanoma and Other Solid Tumors

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 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 NEW 2016-063
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 2016-092
Phase I
An Open-Label, Phase 1/1b, Single-Agent Study of RXDX-105 in Patients With Advanced Solid Tumors

STUDY E7208
Phase II
A Randomized Phase II Study of Irinotecan and Cetuximab with or without the Anti-Angiogenic Antibody, Ramucirumab (IMC-1121B), in Advanced, K-ras Wildtype Colorectal Cancer Following Progression on Bevacizumab-Containing Chemotherapy

STUDY 2016-001
Phase I
A Phase 1 Study to Assess Safety, Pharmacokinetics, and Pharmacodynamics of PLX73086 as a Single Agent in Subjects with Advanced Solid Tumors and in Subjects with Locally Advanced or Refractory Tenosynovial Giant Cell Tumor (TGCT)

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

STUDY 2015-085
Phase I/II
Phase 1/2a Study of Double-Immune Suppression Blockade by Combining a CSF1R Inhibitor (PLX3397) with an Anti-PD-1 Antibody (Pembrolizumab) to Treat Advanced Melanoma and Other Solid Tumors

STUDY NEW 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 2015-138
Phase I
A Phase 1 Study of Alisertib (MLN8237) in Combination with mFOLFOX in Gastrointestinal Tumors

RECTUM
STUDY NEW 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 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 2015-138
Phase I
A Phase 1 Study of Alisertib (MLN8237) in Combination with mFOLFOX in Gastrointestinal Tumors

ANAL
**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

**SARCOMA (INCLUDING GIST)**  
**Metastatic**  
**STUDY 2015-085**  
**Phase I/II**  
Phase 1/2a Study of Double-Immune Suppression Blockade by Combining a CSF1R Inhibitor (PLX3397) with an Anti-PD-1 Antibody (Pembrolizumab) to Treat Advanced Melanoma and Other Solid Tumors

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

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**STUDY 2016-037**  
**Phase I**  
A Phase 1 Trial of X4P-001 as Single Agent and in Combination with Axitnib in Patients with Advanced Renal Cell Carcinoma

**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 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 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 2014-010**  
**Phase I**  
A Phase I 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 2015-156**  
**Phase I**  
A Phase I 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 2013-083**  
**Phase II**  
Randomized Phase II Screening Trial of Enzalutamide/MDV-3100 and LHRH Analogue vs Combined Androgen Deprivation (LHRH Analogue + Bicalutamide) in Metastatic Hormone Sensitive Prostate Cancer

**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 Tumorassociated Macrophage Inhibitor, in Men with Unfavorable Risk Prostate Cancer Treated with Radiation and Androgen Deprivation Therapy

**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 2015-059**  
**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 2016-028**  
**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 2015-143
Phase I/II
Phase 1/2, Open-label, Uncontrolled, Multiple-Dose Escalation, Cohort Expansion and Extension Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of ASN001 in Subjects with Metastatic Progressive Castrate Resistant Prostate Cancer

STUDY 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 2015-042
Phase II
A Phase 2, Open-Label, Single-Arm Study of 18F-Sodium Fluoride PET/CT Bone Imaging in Enzalutamide-Treated Chemotherapy-Naïve Patients With Bone-Metastatic Castration-Resistant Prostate Cancer

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 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 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 2016-052  
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 2015-159  
Phase I  
A Phase 1 Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Preliminary Clinical Activity of MEDI0562 in Adult Subjects with Selected 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 2013-104  
Phase I  
A Phase 1 Study of the Safety and Pharmacokinetics of Escalating Doses of AGS15E Given as Monotherapy in Subjects with Metastatic Urothelial Cancer

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 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

Gynecologic Clinical Trials

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

CERVIX
STUDY GOG-0274  
Phase III  
A Phase III Trial of Adjuvant Chemotherapy Following Chemoradiation AsPrimary Treatment for Locally Advanced Cervical Cancer Compared to Chemoradiation Alone: The Outback Trial

STUDY NRG-GY006  
Phase II  
Randomized Phase II Trial of Radiation Therapy and Cisplatin Alone or in Combination with Intravenous Triapine in Women with Newly Diagnosed Bulky Stage IB2, Stage II, IIIB, orIVA Cancer of the Uterine Cervix or Stage II-IVA Vaginal Cancer

STUDY 2015-159  
Phase I  
A Phase 1 Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Preliminary Clinical Activity of MEDI0562 in Adult Subjects with Selected Advanced Solid Tumors

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 (Varilimumab) Administered in Combination with Anti-PD-1 (Nivolumab) in Advanced Refractory Solid Tumors

STUDY 2012-041  
Phase I  
A Phase 1, First-in-Human Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of IMGN853 in Adults with Ovarian Cancer and other FOLR1-Positive Solid Tumors

STUDY 2015-146  
Phase I  
A Pivotal Pharmacokinetic Bioequivalence Study Comparing Generic to Reference Liposome-Encapsulated Doxorubicin Hydrochloride in Subjects with Epithelial Ovarian Carcinoma Who Have Failed Platinum-Based Chemotherapy.

STUDY NEW 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 2015-154  
Phase I  
A First-in-Human Phase 1, Dose Escalation, Safety and Pharmacokinetic Study of PF-06647263 in Adult Patients with Advanced Solid Tumors

STUDY NRG-GY005  
Phase II/III  
Randomized Phase II/III Study of the Combination of Cediranib and Olaparib Compared to Cediranib Alone or Olaparib Alone or Standard of Care Chemotherapy in Women with Recurrent Platinum-Resistant or -Refractory Ovarian, Fallopian Tube or Primary Peritoneal Cancer

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

STUDY 2015-085  
Phase I/Ii  
Phase 1/2a Study of Double-Immune Suppression Blockade by Combining a CSF1R Inhibitor (PLX3397) with an Anti-PD-1 Antibody (Pembrolizumab) to Treat Advanced Melanoma and Other Solid Tumors
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 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 NRG-GY006
Phase II
Randomized Phase II Trial of Radiation Therapy and Cisplatin Alone or in Combination with Intravenous Triapine in Women with Newly Diagnosed Bulky Stage IB2, Stage II, IIIB, orIVA Cancer of the Uterine Cervix or Stage II-IVA Vaginal Cancer

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

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Head & Neck Clinical Trials

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

STAGES I/II/III
STUDY 2015-031
Phase III
A Phase 3 Clinical Trial of Pembrolizumab (MK-3475) in First Line Treatment of Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma
STAGES I - IV

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

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 2016-001
Phase I
A Phase 1 Study to Assess Safety, Pharmacokinetics, and Pharmacodynamics of PLX73086 as a Single Agent in Subjects with Advanced Solid Tumors and in Subjects with Locally Advanced or Refractory Tenosynovial Giant Cell Tumor (TGCT)

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 2016-017
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 2015-085
Phase I/II
Phase 1/2a Study of Double-Immune Suppression Blockade by Combining a CSF1R Inhibitor (PLX3397) with an Anti-PD-1 Antibody (Pembrolizumab) to Treat Advanced Melanoma and Other Solid Tumors

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 (Varilimumab) Administered in Combination with Anti-PD-1 (Nivolumab) in Advanced Refractory Solid Tumors

STUDY 2015-159
Phase I
A Phase 1 Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Preliminary Clinical Activity of MEDI0562 in Adult Subjects with Selected Advanced 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 NEW 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

### Hematology Clinical Trials

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#### MULTIPLE MYELOMA

**STUDY 2015-094**  
**Phase II**  
Phase II Trial of Combination of Elotuzumab and Lenalidomide, and Dexamethasone in High-Risk Smoldering 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 NEW 2016-008**  
**Phase II**  
A Phase II Study of Pembrolizumab Monotherapy in Third-line Previously Treated Subjects with Advanced/Metastatic Adenocarcinoma or Squamous Cell Carcinoma of the Esophagus or Advanced/Metastatic Siewert Type I Adenocarcinoma of the Esophagogastric Junction (KEYNOTE-180)

**STUDY NEW 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

**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 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 2015-147**  
**Phase I/II**  
An Open-Label Phase I/IIa Study of the Safety and Efficacy of MelphalanFlufenamide (Melflufen) and Dexamethasone Combination for Patients with Relapsed and/or Relapsed-Refractory Multiple Myeloma

**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 E3A06
Phase III
Randomized Phase III Trial of Lenalidomide Versus Observation Alone in Patients with Asymptomatic High-Risk Smoldering Multiple Myeloma

STUDY 2015-148
Phase III
A Phase III Study of Pomalidomide and Low Dose Dexamethasone with or without Pembrolizumab (MK3475) in Refractory or Relapsed and Refractory Multiple Myeloma

STUDY 2015-036
Phase II
A Phase II Study of IRD (Ixzomib, Lenalidomide, & Dexamethasone) for Consolidation Therapy Post Autologous Stem Cell Transplantation followed by Maintenance Ixzomib 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 2015-007
Phase III
A Phase 3, Randomized, Multicenter, Double-Blind, Placebo-Controlled, 2-Arm, Efficacy and Safety Study of NEOD001 Plus Standard of Care vs. Placebo Plus Standard of Care in Subjects with Light Chain (AL) Amyloidosis

STUDY 2016-006
Phase II
A Phase 2b, Randomized, Double-blind, Placebo-controlled Study of NEOD001 in Previously Treated Subjects with Light Chain (AL) Amyloidosis who have Persistent Cardiac Dysfunction

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 S1318
Phase II
A Phase II Study of Blinatumomab (NSC-765986) and POMP (Prednisone, Vincristine, Methotrexate, 6-Mercaptopurine) for Patients >/= 65 Years of Age with Newly Diagnosed Philadelphia Chromosome Negative (Ph-) Acute Lymphoblastic Leukemia (ALL) and of Dasatinib (NSC-732517) ,Prednisone and Blinatumomab for Patients >/= 65 Years of Age with Newly Diagnosed Philadelphia-Chromosome Positive (Ph+) ALL

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 Transplant(HSCT) Consolidation

STUDY 2015-052
Phase I
A Phase 1b Dose-escalation Study of SGN-CD33A in Combination with Standard-of-Care for Patients with Newly Diagnosed Acute Myeloid Leukemia (AML)

STUDY 2015-070
Phase II
A Randomized Phase 2 Study of DACOGEN® (Decitabine) Plus JNJ-56022473 (Anti-CD123) Versus DACOGEN (Decitabine) Alone in Patients with AML who are not Candidates for Intensive Chemotherapy

**STUDY NEW 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 NEW 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 Lymphocytic Leukemia (CLL)**
**STUDY 2013-140**
Phase I
A Phase IB, Open-Label Study Evaluating The Safety and Pharmacokinetics of Venetoclus (GDC-0199 [ABT-199]) in Combination with Bendamustine/Rituximab (BR) or Bendamustine+Obinutuzumab (BG) in Patients with Relapsed Refractory or Untreated Chronic Lymphocytic 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 2015-126**
Phase I/II
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

**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

**Non-Hodgkin’s**
**Aggressive (Mantle Cell, Large B-Cell Lymphoma)**
**STUDY 2016-057**
Phase II
Open-Label, Phase 2 Study to Evaluate the Efficacy and Safety of CUDC-907 With and Without Rituximab in Patients With Relapsed/Refractory MYC-Altered Diffuse Large B-Cell Lymphoma

**STUDY 2014-133**
Phase III
Phase 3 Randomized, Double-Blind, Placebo Controlled, Multicenter Study to Compare the Efficacy and Safety of Lenalidomide (CC-5013) Plus R-CHOP Chemotherapy (R2-CHOP) Versus Placebo Plus R-CHOP Chemotherapy in Subjects with Previously Untreated Activated B-cell Type Diffuse Large B-cell Lymphoma

**STUDY 2014-109**
Phase I
A Phase 1/2, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB050465 and INCB039110 in Subjects With Previously Treated B-Cell Malignancies
<table>
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<tr>
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<th>Phase</th>
<th>Title</th>
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<tbody>
<tr>
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<td>I/II</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 2015-125</td>
<td>II</td>
<td>Randomized, Open Label, Phase 2 Study of Rituximab and Bendamustine with or without Brentuximab Vedeotin for Relapsed or Refractory CD30-Positive Diffuse Large B-Cell Lymphoma</td>
</tr>
<tr>
<td>STUDY 2013-047</td>
<td>I</td>
<td>A Phase 1 Multiple Ascending Dose Study of DS-3032B, an Oral MDM2 Inhibitor, in Subjects with Advanced Solid Tumors or Lymphomas</td>
</tr>
<tr>
<td>STUDY 2015-150</td>
<td>I/II</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>
</tr>
<tr>
<td>STUDY 2014-037</td>
<td>I</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>
</tr>
<tr>
<td>MYELODYSPLASTIC SYNDROME (MDS) STUDY 2014-037</td>
<td>I</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>
</tr>
<tr>
<td>STUDY 2016-054</td>
<td>III</td>
<td>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 &quot;MEDALIST&quot; Trial)</td>
</tr>
<tr>
<td>STUDY NEW 2016-035</td>
<td>I</td>
<td>A Phase 1/1b, Multicenter, Open-label, Dose-Escalation Study of FT-2102 as a Single Agent and in Combination with Azacitidine in Patients with Acute Myeloid Leukemia or Myelodysplastic Syndrome with an IDH1 Mutation</td>
</tr>
<tr>
<td>STUDY 2015-151</td>
<td>I/II</td>
<td>A Phase 1/2 Study of Vadastuximab Talirine (SGN-CD33A) in Combination with Azacitidine in Patients with Previously Untreated International Prognostic Scoring System</td>
</tr>
<tr>
<td>OTHER STUDY 2013-113</td>
<td>II</td>
<td>A Multicenter Phase 2 Study of the Bruton's Tyrosine Kinase Inhibitor PCI 32765 (Ibrutinib) for Treatment of Relapsed Hairy Cell Leukemia</td>
</tr>
<tr>
<td>STUDY 2016-024</td>
<td>I</td>
<td>Phase Ib Trial of Pembrolizumab (MK-3475) in Combination with Dinaciclib (MK-7965) in Subjects with Hematologic Malignancies</td>
</tr>
</tbody>
</table>
**Immunotherapy Clinical Trials**

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

**IMMUNOTHERAPY STUDY 2015-100**  
Phase I/II  
Phase Ib/II Treatment of Advanced Pancreatic Cancer with anti-CD3 x anti-EGFR-Bispecific Antibody Armed Activated T-Cells (BATs) in Combination with Low Dose IL-2 and GM-CSF.

**STUDY 2010-056**  
Phase II  
A Phase II Study of Anti-CD3 x Anti-HER2/neu (Her2Bi) Armed Activated T Cells (ATC) after Neoadjuvant Chemotherapy in Patients with HER2/neu (0-2+) Negative Stage II-III Breast Cancers

**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 2015-085**  
Phase I/II  
Phase 1/2a Study of Double-Immune Suppression Blockade by Combining a CSF1R Inhibitor (PLX3397) with an Anti-PD-1 Antibody (Pembrolizumab) to Treat Advanced Melanoma and Other Solid Tumors

**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 BRAF V600 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 BRAF V600E/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

STUDY 2013-030
Phase I/II
A Phase Ib/II, Multicenter, Open Label, Study of LEE011 in Combination with MEK162 in Adult Patients with NRAS Mutant Melanoma

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 2015-156
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 2016-055
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)
### Neuro-Oncology Clinical Trials

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

### Phase I Clinical Trials

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

**ALL SOLID TUMORS**

**STUDY 2014-027**

**Phase I**

An Open-Label Phase I Dose-Escalation Study to Characterize the Safety, Tolerability, Pharmacokinetics, and Maximum Tolerated Dose of Oral BAY 1161909 in Combination with Weekly Intravenous Paclitaxel given in an Intermittent Dosing Schedule in Subjects with Advanced Malignancies

**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 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 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 NEW 2015-005**

**Phase I**

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

**STUDY 2007-014**

**Phase I**

A Phase I Dose-Escalation Study of Oral ABT-888 (NSC #737664) Plus Intravenous Irinotecan (CPT-11, NSC#616348) Administered in Patients with Advanced Solid Tumors NCI 7977

**STUDY 2016-102**

**Phase I**

An Open-Label Phase 1 Study to Determine the Effect of Lenvatinib (E7080) on the Pharmacokinetics of Midazolam, a CYP3A4 Substrate, in Subjects 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 2015-085
Phase I/II
Phase 1/2a Study of Double-Immune Suppression Blockade by Combining a CSF1R Inhibitor (PLX3397) with an Anti-PD-1 Antibody (Pembrolizumab) to Treat Advanced Melanoma and Other 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 1 Study of ALKS 4230 in Subjects with Advanced Solid Tumors

STUDY 2014-137
Phase I/II
A Phase I/II, Multicenter, Open-label Safety, Pharmacokinetic and Preliminary Efficacy Study of Wild-type Sparing EGFR Inhibitor, AC0010MA, in Adult Patients with Previously Treated EGFRmut and Acquired T790M Mutation Non-Small Cell Lung Cancer (NSCLC)

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

STUDY 2013-112
Phase I
A Two-Part, Phase I, Multicenter, Open-Label Study Of Ro6870810/Ten-010 Given Subcutaneously; Part A: A Dose-Escalation Study In Patients With Advanced Solid Tumors Part B: An Expansion Cohort In Patients With Selected Malignancies With Advanced Solid Tumors Part B: An Expansion Cohort In Patients With Selected Malignancies

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 (Varilimumab) 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 2015-159
Phase I
A Phase 1 Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Preliminary Clinical Activity of MEDI0562 in Adult Subjects with Selected Advanced Solid Tumors

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 2012-041
Phase I
A Phase 1, First-in-Human Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of IMGN853 in Adults with Ovarian Cancer and other FOLR1-Positive 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 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 2015-143
Phase I/II
Phase 1/2, Open-label, Uncontrolled, Multiple-Dose Escalation, Cohort Expansion and Extension Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of ASN001 in Subjects with Metastatic Progressive Castrate Resistant Prostate Cancer

STUDY 2014-143
Phase I/II
Phase I/II Study of Varlilumab (CDX-1127) in Combination with Sunitinib in Patients with Metastatic Clear Cell Renal Cell Carcinoma

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 2013-030
Phase I/II
A Phase Ib/Ii, Multicenter, Open Label, Study of LEE011 in Combination with MEK162 in Adult Patients with NRAS Mutant Melanoma

STUDY 2015-138
Phase I
A Phase 1 Study of Alisertib (MLN8237) in Combination with mFOLFOX in Gastrointestinal Tumors

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 2016-001
Phase I
A Phase 1 Study to Assess Safety, Pharmacokinetics, and Pharmacodynamics of PLX73086 as a Single Agent in Subjects with Advanced Solid Tumors and in Subjects with Locally Advanced or Refractory Tenosynovial Giant Cell Tumor (TGCT)

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 2015-073
Phase I
A Phase I, Multi-Center, Open Label, Drug-Drug Interaction Study to Assess the Effect of Ceritinib on the Pharmacokinetics of Warfarin
and Midazolam Administered as a Two-Drug Cocktail in Patients with ALK-Positive Advanced Tumors Including Non-Small Cell Lung Cancer (NSCLC)

**STUDY 2016-016**
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 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 form.](javascript:openReferralForm())

**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-IIIA Non-Small Cell Lung Cancer

**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 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 2015-073
Phase I
A Phase I, Multi-Center, Open Label, Drug-Drug Interaction Study to Assess the Effect of Ceritinib on the Pharmacokinetics of Warfarin and Midazolam Administered as a Two-Drug Cocktail in Patients with ALK-Positive Advanced Tumors Including Non-Small Cell Lung Cancer (NSCLC)

STUDY 2015-103
Phase I
A Phase I, Multi-Center, Open Label, Drug-Drug Interaction Study to Assess the Effect of Ceritinib on the Pharmacokinetics of Warfarin and Midazolam Administered as a Two-Drug Cocktail in Patients with ALK-Positive Advanced Tumors Including Non-Small Cell Lung Cancer (NSCLC)

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 1400
Phase II/III
A Biomarker-Driven Master Protocol for Previously Treated Squamous Cell Lung Cancer (Lung-MAP)

STUDY 2013-021
Phase I
Phase I Study of Thoracic Radiotherapy and Concurrent Chemotherapy with Soy Isoflavones in Stage III NSCLC (Non-Small Cell Lung Cancer) Patients

STAGE IV
ALK
STUDY 2015-062
Phase II
A Phase II, Multi-Center, Open-Label, Five-Arm Study to Evaluate the Efficacy and Safety of Oral Ceritinib Treatment for Patients with ALK-positive Non-Small Cell Lung Cancer (NSCLC) Metastatic to the Brain and/or to Leptomeninges

STUDY 2015-073
Phase I
A Phase I, Multi-Center, Open Label, Drug-Drug Interaction Study to Assess the Effect of Ceritinib on the Pharmacokinetics of Warfarin and Midazolam Administered as a Two-Drug Cocktail in Patients with ALK-Positive Advanced Tumors Including Non-Small Cell Lung Cancer (NSCLC)

STUDY 2016-018
Phase I
A Phase Ib Study of the Safety and Pharmacology of Atezolizumab (MPDL3280A) Administered with Erlotinib or Alectinib in Patients with Advanced Non-Small Cell Lung Cancer

STUDY 2016-100
Phase II
An Open Label, Multicenter, Single Arm Expanded Access Study of Brigatinib (AP26113) for Patients with Anaplastic Lymphoma Kinase Positive (ALK+) Nonsmall Cell Lung Cancer (NSCLC)

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

**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 2014-106**  
**Phase III**  
JUNIPER: A Randomized Phase 3 Study of Abemaciclib plus Best Supportive Care versus Erlotinib plus Best Supportive Care in Patients with Stage IV NSCLC with a Detectable KRAS Mutation Who Have Progressed After Platinum-Based Chemotherapy

**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 2015-026**  
**Phase II**  
A Phase II, Open-label Study of Ponatinib, a Multi-Targeted Oral Tyrosine Kinase Inhibitor, in Advanced Non-Small-Cell Lung Cancer Harboring RET Translocations

**STUDY NEW 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 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 2016-017**  
**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 2015-171**  
Phase I/II  
A Phase 1b Open-label Study to Evaluate the Safety and Tolerability of MEDI4736 in Combination with Tremelimumab in Subjects with Advanced Non-small Cell Lung Cancer

**STUDY 2009-139**  
Phase I  
A 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 2015-131**  
Phase II  
A Phase II 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 2015-158**  
Phase III  
A Randomized, Double-Blind, Phase III Study of Platinum+ Pemetrexed Chemotherapy with or without Pembrolizumab (MK-3475) in First Line Metastatic Non-squamous Non-small Cell Lung Cancer Subjects (KEYNOTE-189)

**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 2012-041**  
Phase I  
A Phase I, First-in-Human Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of IMGN853 in Adults with Ovarian Cancer and other FOLR1-Positive Solid Tumors

**STUDY 2015-085**  
Phase I/II  
A Phase 1/2a Study of Double-Immune Suppression Blockade by Combining a CSF1R Inhibitor (PLX3397) with an Anti-PD-1 Antibody (Pembrolizumab) to Treat Advanced Melanoma and Other Solid Tumors

**STUDY 2015-019**  
Phase III  
A Phase III, Open-Label, Multicenter, Randomized Study Evaluating the Efficacy and Safety of MPDL3280A (ANTI-PD-L1 Antibody) in Combination with Carboplatin + Paclitaxel or MPDL3280A in Combination with Carboplatin+ NABPaclitaxel versus Carboplatin+ NABPaclitaxel in Chemotherapy-Naive Patients with Stage IV Squamous Non-Small Cell Lung Cancer

**STUDY 2015-112**  
Phase I/II  
A Phase Ib/II, Open-label, Multicenter Trial with Oral cMET Inhibitor INC280 Alone and in Combination with Erlotinib versus Platinum/Pemetrexed in Adult Patients with EGFR Mutated, cMET-Amplified, Locally Advanced/Metastatic Nonsmall Cell Lung Cancer (NSCLC) with Acquired RRResistance to Prior EGFR Tyrosine Kinase Inhibitor (EGFR TKI)

**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  
A 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 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

STUDY 2015-085
Phase I/II
Phase 1/2a Study of Double-Immune Suppression Blockade by Combining a CSF1R Inhibitor (PLX3397) with an Anti-PD-1 Antibody (Pembrolizumab) to Treat Advanced Melanoma and Other Solid Tumors

SCLC EXTENSIVE
STUDY 2015-140
Phase II
An Open-label, Single-Arm, Phase 2 Study Evaluating the Efficacy, Safety and Pharmacokinetics of Rovalpituzumab Tesirine (SC16LD6.5) for Third-line and Later Treatment of Subjects with Relapsed or Refractory Delta-Like Protein 3-Expressing Small Cell Lung Cancer (TRINITY)

STUDY NEW 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

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

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

STUDY NEW 2016-116
Phase II
A Phase 2 Study of Cediranib in Combination with Olaparib in 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 NEW 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 2014-150
NA
Preoperative CT-Guided Pulmonary Nodule Marking

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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