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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<td>Genitourinary</td>
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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 2015-114**

Phase I

A Randomized, Parallel-Cohort Phase 1 Study of INCB039110 in Combination With Corticosteroids for the Treatment of Grades II to IV Acute Graft-Versus-Host Disease

**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 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 2011-086
NA
A Multicenter Access and Distribution Protocol for Unlicensed Cryopreserved Cord Blood Units (CBUs) for Transplantation in Pediatric and Adult Patients with Hematologic Malignancies and Other Indications.

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

STUDY BMTCTN1101
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 2013-064
Phase II
A Phase II, Randomized Trial of Standard of Care, With or Without Midostaurin to Prevent Relapse Following Allogeneic Hematopoietic Stem Cell Transplantation in Patients With FLT3-ITD Mutated Acute Myeloid Leukemia.

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

STUDY NEW 2014-063
Phase II

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

STUDY 2012-076
Phase III
A Phase III, Randomised, Observer-Blind, Placebo-Controlled, Multicenter, Clinical Trial to Assess the Prophylactic Efficacy, Safety, and Immunogenicity of GSK Biologicals' Herpes Zoster gE/AS01B Candidate Vaccine When Administered Intramuscularly on a Two-Dose Schedule to Adult Autologous Hematopoietic Stem Cell Transplant (HCT) Recipients

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 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

**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)

**NEOADJUVANT**  
**STUDY NEW 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 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

**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)

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

STUDY 2015-046
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

OTHERS
STUDY 2013-118
Phase I
A Phase 1, Open-label, Dose-Escalation Study to Evaluate the Safety and Tolerability of SGN-LIV1A in Patients with LIV-1-positive Metastatic Breast Cancer.

STUDY Z11102
Phase II
Impact of Breast Conservation Surgery on Surgical Outcomes and Cosmesis in Patients with Multiple Ipsilateral Breast Cancers (MIBC)

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

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

GASTRIC AND GASTROESOPHAGEAL JUNCTION

Metastatic
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
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<tr>
<td>STUDY 2016-001</td>
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<td>STUDY 2013-162</td>
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<td>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</td>
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<tr>
<td>STUDY NEW 2016-003</td>
<td>Phase I/II</td>
<td>A Phase 1b/2 Study of Ibrutinib Combination Therapy in Selected Advanced Gastrointestinal and Genitourinary Tumors</td>
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<td>STUDY 2015-056</td>
<td>Phase III</td>
<td>A Phase III, Randomized, Open-label Clinical Trial of Pembrolizumab (MK-3475) versus Paclitaxel in Subjects with Advanced Gastric or Gastroesophageal Junction Adenocarcinoma who Progressed after First-line Therapy with Platinum and Fluoropyrimidine</td>
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<tr>
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<td>STUDY 2015-092</td>
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<td>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</td>
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<td><strong>PANCREAS</strong></td>
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<tr>
<td>STUDY S1313</td>
<td>Phase I/II</td>
<td>A Phase 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>
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<td>STUDY 2014-110</td>
<td>Phase I/II</td>
<td>A Phase I/II, Two-Part, Multicenter Study to Evaluate the Safety and Efficacy of M402 in Combination with nab-Paclitaxel and Gemcitabine in Patients with Metastatic Pancreatic Cancer</td>
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<td>STUDY 2016-001</td>
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<td>STUDY 2014-114</td>
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<td>Nab-Paclitaxel (Abraxane) plus Gemcitabine in Subjects with Locally Advanced Pancreatic Cancer (LAPC): An International Open-</td>
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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

STUDY 2013-133
Phase I/II
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

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

COLON
Adjuvant
STUDY S0820
Phase III
A Double Blind, Placebo-Controlled Trial of Efornithine and Sulindac to Prevent Recurrence of High Risk Adenomas and Second Primary Colorectal Cancers in Patients with Stage 0-III Colon or Rectal Cancer, Phase III - Preventing Adenomas of the Colon with Efornithine and Sulindac (PACES)

Metastatic (Includes Rectal)
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 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 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 2016-001
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 NEW 2016-003
Phase I/II
A Phase 1b/2 Study of Ibrutinib Combination Therapy in Selected Advanced Gastrointestinal and Genitourinary Tumors

STUDY 2015-110
Phase I/II
A Phase I/II, Dose-escalation and Cohort Expansion Study of the Safety, Tolerability and Efficacy of Anti-CD27 antibody (Varilimumab) Administered in Combination with Anti-PD-1 (Nivolumab) in Advanced Refractory Solid Tumors
STUDY 2015-138
Phase I
A Phase 1 Study of Alisertib (MLN8237) in Combination with mFOLFOX in Gastrointestinal Tumors

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

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

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Genitourinary Clinical Trials

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RENA L
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 S0931
Phase III
EVEREST: EVErolimus for Renal Cancer Ensuing Surgical Therapy, A Phase III Study

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 2009-130
Phase I
A Phase I, Open-Label, Multi-Center, Dose Escalation Study of Oral BGJ398, a Pan FDF-R Kinase Inhibitor, in Adult Patients with Advanced Solid Malignancies

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 2014-121
Phase I
A Phase 1 Trial of SGN-CD70A in Patients with CD70-positive Malignancies

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
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<tr>
<td>STUDY 2015-109</td>
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<td>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</td>
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<tr>
<td>PROSTATE</td>
<td>STUDY 2015-143</td>
<td>Phase I/II, 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</td>
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<td>STUDY A031201</td>
<td>Phase II</td>
<td>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</td>
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<tr>
<td>STUDY 2015-049</td>
<td>Phase I</td>
<td>Phase I, Open-Label Trial to Evaluate the Safety and Immunogenicity of INO-5150 Alone or in Combination with INO-9012 in Men with Biochemically Relapsed (PSA) Prostate Cancer</td>
</tr>
<tr>
<td>STUDY 2015-042</td>
<td>Phase I</td>
<td>A Phase I, Open-label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ascending Doses 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, with Expansion to Assess the Pharmacodynamic Activity of AZD8186</td>
</tr>
<tr>
<td>STUDY NEW 2015-059</td>
<td>Phase II</td>
<td>A Phase 1b/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</td>
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<tr>
<td>STUDY 2015-050</td>
<td>Phase II</td>
<td>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.</td>
</tr>
<tr>
<td>STUDY 2015-033</td>
<td>Phase III</td>
<td>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</td>
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<tr>
<td>STUDY 2015-057</td>
<td>Phase I</td>
<td>A Phase I, Open-label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ascending Doses 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, with Expansion to Assess the Pharmacodynamic Activity of AZD8186</td>
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<tr>
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<tr>
<td>STUDY 2013-083</td>
<td>Phase II</td>
<td>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</td>
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<tr>
<td>STUDY 2013-036</td>
<td>Phase II</td>
<td>A Phase II Randomized 3-arm Study of Abiraterone Acetate Alone, Abiraterone Acetate plus Degarelix, a GnRH Antagonist, and Degarelix Alone for Patients with Prostate Cancer with a Rising PSA or a Rising PSA and Nodal Disease Following Definitive Radical Prostatectomy</td>
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<tr>
<td>STUDY 2013-108</td>
<td>NA</td>
<td>Immune Evaluation Study of Sipuleucel-T in African American and Non African American Men with Castrate Resistant Prostate Cancer</td>
</tr>
<tr>
<td>STUDY 2014-078</td>
<td>Phase III</td>
<td>A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase III Study of ARN-509 in Men with Non-Metastatic (M0) Castration-Resistant Prostate Cancer SPARTAN (Selective Prostate AR Targeting with ARN-509)</td>
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<tr>
<td>STUDY 2014-075</td>
<td>Phase I</td>
<td>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</td>
</tr>
<tr>
<td>STUDY 2015-029</td>
<td>Phase II</td>
<td>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</td>
</tr>
<tr>
<td>STUDY 2015-051</td>
<td>Phase III</td>
<td>A Phase 3, Randomized, Open Label, Multicenter, Controlled Study of Galeterone Compared to Enzalutamide in Men Expressing Androgen Receptor Splice Variant-7 mRNA (AR-V7) Metastatic (M1) Castrate Resistant Prostate Cancer(CRPC)</td>
</tr>
<tr>
<td>STUDY 2015-002</td>
<td>Phase II</td>
<td>A Phase II Open-label, Parallel Group Study of Abiraterone Acetate in African American and Caucasian Men with Metastatic Castrate-resistant Prostate Cancer</td>
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<tr>
<td>STUDY 2013-104</td>
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<td>A Phase 1 Study of the Safety and Pharmacokinetics of Escalating Doses of AGS15E Given as Monotherapy in Subjects with Metastatic Urothelial Cancer</td>
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<tr>
<td>STUDY 2015-084</td>
<td>Phase III</td>
<td>A Phase III, Open-Label, Multicenter, Randomized Study of MPDL3280A (ANTIPD-L1 Antibody) versus Observation as Adjuvant Therapy in Patients with PDL1-Positive, High-Risk Muscle-Invasive Bladder Cancer After Cystectomy</td>
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<tr>
<td>STUDY 2015-119</td>
<td>Phase III</td>
<td>A Phase III, Randomized, Open-label, Controlled, Multi-Center, Global Study of First-Line MEDI4736 Monotherapy and MEDI4736 in Combination with Tremelimumab Versus Standard of Care Chemotherapy in Patients with Unresectable Stage IV Urothelial Bladder</td>
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<td>Study</td>
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<tr>
<td>STUDY NEW 2015-159</td>
<td>Phase I</td>
<td>A Phase I Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Preliminary Clinical Activity of MEDI0562 in Adult Subjects with Selected Advanced Solid Tumors</td>
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<tr>
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<tr>
<td>STUDY NEW 2016-003</td>
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<td>A Phase 1b/2 Study of Ibrutinib Combination Therapy in Selected Advanced Gastrointestinal and Genitourinary Tumors</td>
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<tr>
<td>STUDY 2013-120</td>
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<td>STUDY 2013-129</td>
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<tr>
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<td>Phase II</td>
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</table>

**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](#).

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<th>CERVIX</th>
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<tr>
<td>STUDY NEW 2015-159</td>
<td>Phase I</td>
<td>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</td>
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</table>
**STUDY NEW NRG-GY002**

**Phase II**
A Phase II Evaluation of Nivolumab, a Fully Human Antibody against PD-1, in Phase II the Treatment of Persistent or Recurrent Cervical Cancer

**OVARY**

**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

**STUDY 2015-118**

**Phase II**
A Phase 2 Proof-of-Concept Study of ACP-196 Alone and in Combination with Pembrolizumab in Subjects with Recurrent Ovarian Cancer

**STUDY NEW 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 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 NEW GOG-3005**

**Phase III**
A Phase 3 Placebo-Controlled Study of Carboplatin/Paclitaxel With or Without Concurrent and Continuation Maintenance Veliparib (PARP inhibitor) in Subjects with Previously Untreated Stages III or IV High-Grade Serous Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

**STUDY 2013-076**

**Phase III**
A Randomized, Open-Label Study Comparing the Combination of YONDELIS® and DOXIL®/CAELYX® With DOXIL®/CAELYX® Monotherapy for the Treatment of Advanced-Relapsed Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Cancer

**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 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
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 GOG-0277
Phase III
A Phase III Randomized Trial Of Gemcitabine (NSC# 613327) Plus Docetaxel (NSC# 628503) Followed By Doxorubicin (NSC# 123127) versus Observation For Uterus-Limited, High Grade Uterine Leiomyosarcoma

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, or IVA Cancer of the Uterine Cervix or Stage II-IVA Vaginal Cancer

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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

STUDY 2015-081
Phase II

STAGES I - IV
STUDY 2014-130
Phase I
A Phase 1 Study to Evaluate the Safety, Tolerability, and Efficacy of MEDI4736 in Combination with Tremelimumab in Subjects with Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck

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 2013-042
Phase I
A Multicenter, Open Label, Phase 1 First in Human Dose Escalation Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Intravenous MP-3549.1 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

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 NEW 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

Hematology Clinical Trials
For more information on Hematology 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.

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 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 S1211
Phase I/II
A Randomized Phase I/II Study of Optimal Induction Therapy of Bortezomib, Dexamethasone and Lenalidomide with or without Elotuzumab (NSC-764479) for Newly Diagnosed High Risk Multiple Myeloma (HRMM)

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 2014-011
Phase I
A Phase 1, Multicenter, Open-Label,Dose-Escalation Combination Study of Pomalidomide, Marizomib, And Low-dose Dexamethasone(PMD) in Subjects with Relapsed and Refractory Multiple Myeloma
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 MPDL3280A (ANTIPD-L1 ANTIBODY) Alone or in Combination with Lenalidomide in Patients with Multiple Myeloma (Relapsed and Post-Autologous Stem Cell Transplantation)

STUDY 2014-090
Phase I
A Phase I Study of the Combination of a Selective Inhibitor of Nuclear Export (SINE), Selinexor with Carfilzomib and Dexamethasone in Patients with Relapsed or Relapsed/Refractory Multiple Myeloma.

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

STUDY 2015-021
Phase II
A Phase 2b, Open-Label, Single-Arm Study of Selinexor (KPT-330) plus Dexamethasone in Patients with Multiple Myeloma Exposed to Bortezomib, Carfilzomib, Lenalidomide and Pomalidomide and Refractory to an IMiD and a Proteasome Inhibitor

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 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)

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

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

Acute Myeloid Leukemia (AML)
STUDY 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

Chronic Lymphocytic Leukemia (CLL)
STUDY 2015-009
Phase III
A Pivotal Multicenter Trial of Moxetumomab Pasudotox in Relapsed/Refractory Hairy Cell Leukemia

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

STUDY E1912
Phase III
A Randomized Phase III Study of Ibrutinib (PCI-32765)-based Therapy vs Standard Fludarabine, Cyclophosphamide, and Rituximab (FCR) Chemoimmunotherapy in Untreated Younger Patients with Chronic Lymphocytic Leukemia (CLL)

Chronic Myeloid Leukemia (CML)
STUDY NEW 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

Non-Hodgkin’s
Aggressive (Mantle Cell, Large B-Cell Lymphoma)
STUDY E1411
Phase II
Intergroup Randomized Phase II Four Arm Study In Patients With Previously Untreated Mantle Cell Lymphoma Of Therapy With: Arm A = Rituximab+Bendamustine Followed By Rituximab Consolidation (RB ‾ R); Arm B =Rituximab + Bendamustine + Bortezomib Followed By Rituximab Consolidation(RBV ‾ R), Arm C = Rituximab + Bendamustine Followed By Lenalidomide + Rituximab Consolidation (RB ‾ LR) or Arm D = Rituximab + Bendamustine + Bortezomib Followed By Lenalidomide + Rituximab Consolidation (RBV ‾ LR)

STUDY 2013-178
Phase I/II
A Multicenter Open-Label, Randomized Phase 1b/2, Study of the Bruton's Tyrosine Kinase (BTK) Inhibitor, Ibrutinib, in Combination with Lenalidomide, with and without Rituximab in Subjects with Relapsed or Refractory Diffuse Large B-Cell Lymphoma
STUDY 2014-134
Phase I/II
A Phase Ib/II Study of Evaluating the Safety, Tolerability and Anti-Tumor Activity of Polatuzumab Vedotin (DCDS4501A) in Combination with Rituximab or Obinutuzumab, Cyclophosphamide, Doxorubicin and Prednisone in Patients with B-Cell Non-Hodgkin's Lymphoma

STUDY E1412
Phase II
Randomized Phase II Open Label Study of Lenalidomide R-CHOP (R2CHOP) vs RCHOP (Rituximab, Cyclophosphamide, Doxorubicin, Vincristine and Prednisone) in Patients with Newly Diagnosed Diffuse Large B Cell Lymphoma

STUDY 2015-150
Phase II
A Phase I/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

STUDY 2014-109
Phase I
A Phase 1, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB050465 Monotherapy and in Combination with INCB039110 in Subjects With Previously Treated B-Cell Malignancies

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 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

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 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

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 E2905
Phase III
Randomized Phase III Trial Comparing the Frequency of Major Erythroid Response (MER) to Treatment with Lenalidomide (Revlimid®) Alone and in Combination with Epoetin Alfa (Procrit®) in Subjects with Low- or Intermediate-1 Risk MDS and Symptomatic Anemia

OTHER
STUDY 2013-113
Phase II
A Multicenter Phase 2 Study of the Bruton's Tyrosine Kinase Inhibitor PCI 32765 (Ibrutinib) for Treatment of Relapsed Hairy Cell Leukemia

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 2015-004
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 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 2013-184
Phase II
Stand Up to Cancer Consortium Genomics-Enabled Medicine for Melanoma (G.E.M.M.): Using Molecularly-Guided Therapy for Patients with BRAF wild-type (BRAFwt) Metastatic Melanoma

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 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 2009-139
Phase I
A 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 2013-047
Phase I
A Phase 1 Multiple Ascending Dose Study of DS-3032B, an Oral MDM2 Inhibitor, in Subjects with Advanced Solid Tumors or Lymphomas

STUDY NEW 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

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

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 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 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 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 2013-112
Phase I
A Two Part, Phase 1, Multicenter, Open-label Study of 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

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 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 2009-130
Phase I
A Phase I, Open-Label, Multi-Center, Dose Escalation Study of Oral BGJ398, a Pan FDF-R Kinase Inhibitor, in Adult Patients with Advanced Solid 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 2014-116
Pilot
Molecular Profiling of Tumors From Cancer Patients Who Are Exceptional Responders

STUDY 2013-042
Phase I
A Multicenter, Open Label, Phase 1 First in Human Dose Escalation Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Intravenous MP-3549.1 in Subjects with Advanced 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 2015-005
Phase I
A Phase 1A Dose-Escalation Study of OBP-801 in Patients with Advanced Solid Tumors.

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, UPCLI# 10-115)
<table>
<thead>
<tr>
<th>Study No.</th>
<th>Phase</th>
<th>Description</th>
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<tr>
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<td>Phase I</td>
<td>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</td>
</tr>
<tr>
<td>STUDY 2015-034</td>
<td>Phase I/II</td>
<td>A Phase 1/2a Study to Assess the Safety, Pharmacokinetics, and Pharmacodynamics of PLX8394 in Patients with Advanced, Unresectable Solid Tumors</td>
</tr>
<tr>
<td>STUDY 2013-119</td>
<td>Phase I</td>
<td>A Phase I, First-in-Human, Dose Escalation Trial of MSC2363318A, a Dual p70S6K/Akt Inhibitor, in Subjects with Advanced Malignancies</td>
</tr>
<tr>
<td>STUDY 2015-071</td>
<td>Phase I</td>
<td>A Phase Ib, Open-Label, Multi-Centre Study to Assess the Safety, Tolerability, Pharmacokinetics, and Anti-tumour Activity of AZD1775 Monotherapy in Patients with Advanced Solid Tumours</td>
</tr>
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<td>STUDY 2009-139</td>
<td>Phase I</td>
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<td>STUDY 2014-134</td>
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<td>A Phase 1/2a Study to Assess the Safety, Pharmacokinetics, and Pharmacodynamics of PLX8394 in Patients with Advanced, Unresectable Solid Tumors</td>
</tr>
<tr>
<td>STUDY 2015-143</td>
<td>Phase I</td>
<td>A Phase 1 Study of Alisertib (MLN8237) in Combination with mFOLFOX in Gastrointestinal Tumors</td>
</tr>
<tr>
<td>STUDY 2013-120</td>
<td>Phase I</td>
<td>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</td>
</tr>
<tr>
<td>STUDY 2013-046</td>
<td>Phase I</td>
<td>A Phase I, Multicenter, Open-Label, Two-Part, Dose-escalation Study of RAD1901 in Postmenopausal Women with Advanced Estrogen Receptor Positive and HER2-Negative Breast Cancer</td>
</tr>
<tr>
<td>STUDY 2013-047</td>
<td>Phase 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>
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<tr>
<td>STUDY 2013-030</td>
<td>Phase I/II</td>
<td>A Phase Ib/II, Multicenter, Open Label, Study of LEE011 in Combination with MEK162 in Adult Patients with NRAS Mutant Melanoma</td>
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<td>STUDY 2015-138</td>
<td>Phase I</td>
<td>A Phase 1 Study of Alisertib (MLN8237) in Combination with mFOLFOX in Gastrointestinal Tumors</td>
</tr>
<tr>
<td>STUDY 2015-143</td>
<td>Phase I/II</td>
<td></td>
</tr>
<tr>
<td>Study ID</td>
<td>Phase</td>
<td>Description</td>
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</tr>
<tr>
<td>STUDY 2013-129</td>
<td>Phase 1</td>
<td>A Phase 1/2 Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of ASN001 in Subjects with Metastatic Progressive Castrate Resistant Prostate Cancer</td>
</tr>
<tr>
<td>STUDY 2015-047</td>
<td>Phase I</td>
<td>A Phase 1 Open-Label, Dose-Finding Study Evaluating Safety and Pharmacokinetics of FPA144 in Patients with Advanced Solid Tumors</td>
</tr>
<tr>
<td>STUDY 2013-119</td>
<td>Phase I</td>
<td>A Phase I, First-in-Human, Dose Escalation Trial of MSC2363318A, a Dual p70S6K/Akt Inhibitor, in Subjects with Advanced Malignancies</td>
</tr>
<tr>
<td>STUDY 2016-001</td>
<td>Phase I</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>
</tr>
<tr>
<td>STUDY 2015-096</td>
<td>Phase I/II</td>
<td>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</td>
</tr>
<tr>
<td>STUDY 2015-003</td>
<td>Phase I/II</td>
<td>A Phase 1b/Adaptive Phase 2 Study of Docetaxel With or Without MLN1117 in Patients With Locally Advanced or Metastatic Non-small Cell Lung Cancer</td>
</tr>
<tr>
<td>STUDY 2015-073</td>
<td>Phase I</td>
<td>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)</td>
</tr>
<tr>
<td>STUDY NEW 2015-159</td>
<td>Phase I</td>
<td>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</td>
</tr>
<tr>
<td>STUDY 2013-042</td>
<td>Phase I</td>
<td>A Multicenter, Open Label, Phase 1 First in Human Dose Escalation Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Intravenous MP-3549.1 in Subjects with Advanced Solid Tumors</td>
</tr>
<tr>
<td>STUDY 2015-110</td>
<td>Phase I/II</td>
<td>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</td>
</tr>
<tr>
<td>STUDY 2013-162</td>
<td>Phase I</td>
<td>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</td>
</tr>
<tr>
<td>STUDY 2015-109</td>
<td>Phase I</td>
<td>A Phase 1b, Open Label, Dose Escalation Study to Evaluate Safety, Pharmacokinetics And Pharmacodynamics of Axitinib (AG-</td>
</tr>
</tbody>
</table>
013736) in Combination With Crizotinib (PF-02341066) in Patients With Advanced Solid Tumors

**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 2013-118**  
**Phase I**  
A Phase I, Open-label, Dose-Escalation Study to Evaluate the Safety and Tolerability of SGN-LIV1A in Patients with LIV-1-positive Metastatic Breast Cancer.

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

**STUDY 2009-130**  
**Phase I**  
A Phase I, Open-Label, Multi-Center, Dose Escalation Study of Oral BGYJ398, a Pan FDF-R Kinase Inhibitor, in Adult Patients with Advanced Solid Malignancies

**STUDY 2013-184**  
**Phase II**  
Stand Up to Cancer Consortium Genomics-Enabled Medicine for Melanoma (G.E.M.M.): Using Molecularly-Guided Therapy for Patients with BRAF wild-type (BRAFwt) Metastatic Melanoma

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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.

**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

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**MAINTENANCE**
STUDY 2013-177
Pilot
A Pilot Trial of Platinum, Gemcitabine, or Pemetrexed Single- or Multi-Agent Therapy with Serial Tumor Specimen Collection in Patients with Advanced 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 2015-003
Phase I/II
A Phase 1b/Adaptive Phase 2 Study of Docetaxel With or Without MLN1117 in Patients With Locally Advanced or Metastatic Non-small Cell Lung Cancer

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 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 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 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 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 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 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 Nonsmall Cell Lung Cancer

**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 2015-112**  
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 Resistance to Prior EGFR Tyrosine Kinase Inhibitor (EGFR TKI)

**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 2015-085**  
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 2015-003**  
Phase I/II  
A Phase 1b/Adaptive Phase 2 Study of Docetaxel With or Without MLN1117 in Patients With Locally Advanced or Metastatic Non-small
Cell Lung Cancer

**STUDY 2014-115**
*Phase II*
A 3-Arm Phase 2 Double-Blind Randomized Study of Carboplatin, Pemetrexed Plus Placebo versus Carboplatin, Pemetrexed plus 1 or 2 Truncated Courses of Demcizumab in Subjects with Non-Squamous Non-Small Cell Lung 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 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 2015-019**
*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+ NAB-Paclitaxel in Chemotherapy-Naive Patients with Stage IV Squamous Non-Small Cell Lung Cancer

**STUDY 2013-177**
*Pilot*
A Pilot Trial of Platinum, Gemcitabine, or Pemetrexed Single- or Multi-Agent Therapy with Serial Tumor Specimen Collection in Patients with Advanced Non-Small-Cell Lung Cancer

**RECURRENT**

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

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

**STUDY 2013-177**
*Pilot*
A Pilot Trial of Platinum, Gemcitabine, or Pemetrexed Single- or Multi-Agent Therapy with Serial Tumor Specimen Collection in Patients with Advanced Non-Small-Cell Lung Cancer

**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 2014-111
Phase II
Phase II study of MK-3475 as Maintenance Therapy in Extensive Stage Small Cell Lung Cancer (SCLC) Patients

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 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