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.

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 2015-098
Phase I
A Phase 1 Dose Escalation and Cohort Expansion Study of the Safety, Tolerability, and Efficacy of Anti-LAG-3 (BMS-986016) in Relapsed or Refractory Chronic Lymphocytic Leukemia and Lymphomas

STUDY 2015-115
Phase II
A Phase 2 Multicenter Study Evaluating the Efficacy of KTE-C19 in Subjects with Relapsed/Refractory Mantle Cell Lymphoma (r/r MCL)

STUDY 2016-109
Phase II
A Multi-Center, Phase II Trial of HLA-Mismatched Unrelated Donor Bone Marrow Transplantation with Post-Transplantation...
Cyclophosphamide for Patients with Hematologic Malignancies (Protocol Number 15-MMUD).

STUDY 2014-103
Phase I/II
A Phase 1-2 Multi-Center Study Evaluating the Safety and Efficacy of KTE-C19 in Subjects with Refractory Aggressive Non-Hodgkin Lymphoma (NHL)

STUDY BMTCTN1302
Phase II
Multicenter Phase II, Double-blind Placebo Controlled Trial of Maintenance Ixazomib After Allogeneic Hematopoietic Stem Cell Transplantation for High Risk Multiple Myeloma.

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

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

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

Breast Clinical Trials

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

ADJUVANT
STUDY S1207
Phase III
Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients with High-Risk, Hormone Receptor-Positive and HER2/neu Negative Breast Cancer - e3 Breast Cancer Study - evaluating Everolimus with Endocrine Therapy.

STUDY NRG-BR003
Phase III
A Randomized Phase III Trial of Adjuvant Therapy Comparing Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel with or without Carboplatin for Node-Positive or High-Risk Node-Negative Triple-Negative Invasive Breast Cancer

STUDY A011202
Phase III
A Randomized Phase III Trial Comparing Axillary Lymph Node Dissection to Axillary Radiation in Breast Cancer Patients (cT1-3 N1) Who Have Positive Sentinel Lymph Node Disease After Neoadjuvant Chemotherapy

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

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

**STUDY RTOG1304**  
**Phase III**  
NSABP B-51 RTOG1304: A Randomized Phase III Clinical Trial Evaluating Post Mastectomy Chest Wall and Regional Nodal XRT and Post-Lumpectomy Regional Nodal XRT in Patients with Positive Axillary Nodes Before Neoadjuvant Chemotherapy Who Convert to Pathologically Negative Axillary Nodes After Neoadjuvant Chemotherapy.

**STUDY EA1131**  
**Phase III**  
A Randomized Phase III Post-Operative Trial of Platinum Based Chemotherapy Vs. Capecitabine in Patients with Residual Triple-Negative Basal-Like Breast Cancer following Neo-adjuvant Chemotherapy

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

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

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

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

**STUDY 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**
*TITL**E
A Phase Ib, Open-Label, Two-Arm Study Evaluating the Safety and Pharmacokinetics of Atezolizumab (Anti-PD-L1 Antibody) in Combination with Trastuzumab Emtansine or with Trastuzumab and Pertuzumab in Patients with HER2-Positive Breast Cancer

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

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

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

**STUDY 2015-085**
*Phase III*
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 I, Open-Label, Two-Arm Study Evaluating the Safety and Pharmacokinetics of Atezolizumab (Anti-PD-L1 Antibody) in Combination with Trastuzumab Emtansine or with Trastuzumab and Pertuzumab in Patients with HER2-Positive Breast Cancer

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

**STUDY 2016-055**
*Phase I*
A Phase 1/1b, Open-Label, Multicenter, Repeat-Dose, Dose-Selection Study of CPI-444 as Single Agent and in Combination with Atezolizumab in Patients with Selected Incurable Cancers

**STUDY 2016-123**
*Phase III*
A Randomized, Double-Blind, Phase III Study of Pembrolizumab (MK-3475) plus Chemotherapy vs Placebo plus Chemotherapy for Previously Untreated Locally Recurrent Inoperable or Metastatic Triple Negative Breast Cancer - (KEYNOTE-355)
STUDY 2016-189
Phase I
A Phase 1, Multicenter, Open-Label, Dose-Escalation Study of SGN-2FF in Patients with Advanced Solid Tumors

STUDY 2015-157
Phase I/II
Phase 1/2 Clinical Study of Niraparib in Combination with Pembrolizumab in Patients with Advanced or Metastatic Triple-Negative Breast Cancer and in Patients with Recurrent Ovarian Cancer

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

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

STUDY 2016-025
Phase III
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 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 I Open-Label, Dose-Finding Study Evaluating Safety and Pharmacokinetics of FPA144 in Patients with Advanced Solid Tumors

**STUDY 2016-038**

Phase III

A Phase 3 Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of GS-5745 Combined with mFOLFOX6 as First Line Treatment in Patients with Advanced Gastric or Gastroesophageal Junction Adenocarcinoma

**STUDY 2015-103**

Phase I

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

**STUDY 2016-050**

Phase I

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

**STUDY 2015-156**

Phase I

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

**STUDY 2016-001**

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 2016-025**

Phase III

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
Phase I
A Phase I Study of Alisertib (MLN8237) in Combination with mFOLFOX in Gastrointestinal Tumors

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

Metastatic

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

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

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

Neuroendocrine

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

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

Phase II
A Phase 2 Study of Cediranib in Combination with Olaparib in Advanced Solid Tumors

HCC

Metastatic

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
<table>
<thead>
<tr>
<th>Study Number</th>
<th>Phase</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>STUDY 2015-086</td>
<td>Phase I</td>
<td>A First-in-Human Study of Repeat Dosing with REGN2810, a Monoclonal, Fully Human Antibody to Programmed Death-1 (PD-1), as Single Therapy and in Combination with Other Anti-Cancer Therapies, in Patients with Advanced Malignancies</td>
</tr>
<tr>
<td>STUDY 2016-064</td>
<td>Phase III</td>
<td>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)</td>
</tr>
<tr>
<td>STUDY NEW 2016-039</td>
<td>Phase I/II</td>
<td>A Phase Ib/II Clinical Study of BBI608 in Combination with Sorafenib or BBI503 in Combination with Sorafenib in Adults with Hepatocellular Carcinoma</td>
</tr>
<tr>
<td>STUDY 2016-079</td>
<td>Phase I</td>
<td>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</td>
</tr>
</tbody>
</table>

**Biliary/Gall Bladder**

| Metastatic |
| STUDY 2015-085 | Phase I/II | Phase 1/2a Study of Double-Immunosuppression Blockade by Combining a CSF1R Inhibitor (PLX3397) with an Anti-PD-1 Antibody (Pembrolizumab) to Treat Advanced Melanoma and Other Solid Tumors |
| STUDY 2016-186 | Phase II | A Phase 2, Open-Label, Single-Arm, Multicenter Study to Evaluate the Efficacy and Safety of INCB054828 in Subjects With Advanced/Metastatic or Surgically Unresectable Cholangiocarcinoma Including FGFR2 Translocations Who Failed Previous Therapy |
| STUDY NEW 2014-081 | Phase II | A Phase II Multicenter, Single Arm Study of Oral BGJ398 in Adult Patients with Advanced or Metastatic Cholangiocarcinoma with FGFR2 Gene Fusions or other FGFR Genetic Alterations who Failed or Are Intolerant to Platinum-Based Chemotherapy |
| STUDY 2016-041 | Phase II | Randomized, Double-Blind, Phase 2 Study of Ramucirumab or Merestinib or Placebo plus Cisplatin and Gemcitabine as First-Line Treatment in Patients with Advanced or Metastatic Biliary Tract Cancer |

**Metastatic (Includes Rectal)**

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

<p>| 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 | |</p>
<table>
<thead>
<tr>
<th>Study ID</th>
<th>Title</th>
<th>Phase(s)</th>
</tr>
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<tbody>
<tr>
<td>STUDY 2015-131</td>
<td>A Phase 1/1b, Open-Label, Multicenter, Repeat-Dose, Dose-Selection Study of CPI-444 as Single Agent and in Combination with Atezolizumab in Patients with Selected Incurable Cancers</td>
<td>Phase II</td>
</tr>
<tr>
<td></td>
<td></td>
<td>An Open-Label, Multicenter, Global Phase 2 Basket Study of Entrectinib for the Treatment of Patients with Locally Advanced or Metastatic Solid Tumors that Harbor NTRK1/2/3, ROS1, or ALK Gene Rearrangements</td>
</tr>
<tr>
<td>STUDY 2016-050</td>
<td>A Phase 1 Dose Escalation and Cohort Expansion Study of ERY974, an Anti-Glypican 3 (GPC3)/CD3 Bispecific Antibody, in Patients with Advanced Solid Tumors.</td>
<td>Phase I</td>
</tr>
<tr>
<td>STUDY 2015-110</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>
<td>Phase I/II</td>
</tr>
<tr>
<td>STUDY 2016-157</td>
<td>Phase I Clinical Trial of VX-970 in Combination with the Topoisomerase I Inhibitor Irinotecan in Patients with Advanced Solid Tumors</td>
<td>Phase I</td>
</tr>
<tr>
<td>STUDY 2016-063</td>
<td>A Phase III Study of Pembrolizumab (MK-3475) vs. Chemotherapy in Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Stage IV Colorectal Carcinoma (KEYNOTE-177)</td>
<td>Phase I</td>
</tr>
<tr>
<td>STUDY 2016-092</td>
<td>An Open-Label, Phase 1/1b, Single-Agent Study of RXDX-105 in Patients With Advanced Solid Tumors</td>
<td>Phase I</td>
</tr>
<tr>
<td>STUDY E7208</td>
<td>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</td>
<td>Phase II</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>Phase I</td>
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<tr>
<td>STUDY 2016-003</td>
<td>A Phase 1b/2 Study of Ibrutinib Combination Therapy in Selected Advanced Gastrointestinal And Genitourinary Tumors</td>
<td>Phase I/II</td>
</tr>
<tr>
<td>STUDY 2015-085</td>
<td>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</td>
<td>Phase I/II</td>
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<tr>
<td>STUDY 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>Phase I/II</td>
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</table>
STUDY 2015-138
Phase I
A Phase 1 Study of Alisertib (MLN8237) in Combination with mFOLFOX in Gastrointestinal Tumors

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

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

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

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

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

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

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

SARCOMA (INCLUDING GIST)
Metastatic
STUDY 2015-085
Phase III/I
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
### Genitourinary Clinical Trials

For more information on Genitourinary 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.

**RENAIIL**

**STUDY S1500**

**Phase II**

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

**STUDY 2016-037**

**Phase I**

A Phase 1 Study of ALKS 4230 in Subjects with Advanced Solid Tumors

**STUDY 2016-078**

**Phase I/II**

A Phase 1/2 Trial of X4P-001 as Single Agent and in Combination with Avitinib 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 NEW 2016-201**

**Phase III**

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

**STUDY 2016-050**

**Phase I**

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

**STUDY 2016-157**

**Phase I**

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

**STUDY 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 Ib, Open Label, Dose Escalation Study to Evaluate Safety, Pharmacokinetics And Pharmacodynamics of Axitinib (AG-013736) in Combination With Crizotinib (PF-02341066) in Patients With Advanced Solid Tumors

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

STUDY 2014-075
Phase I
Targeting the Prostatic Tumor Microenvironment with PLX3397, a Tumorassociated Macrophage Inhibitor, in Men with Unfavorable Risk Prostate Cancer Treated with Radiation and Androgen Deprivation Therapy

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

STUDY 2015-059
Phase III
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 NEW 2015-167
Phase II
A Randomized Phase 2 Trial of Ascorbic Acid in Combination with Docetaxel in Men with Metastatic Prostate Cancer

STUDY 2016-142
Phase II
A Phase 2 Efficacy and Safety Study of Niraparib in Men with Metastatic Castration-Resistant Prostate Cancer and DNA-Repair Anomalies

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

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

STUDY 2015-033
<table>
<thead>
<tr>
<th><strong>Phase III</strong></th>
<th>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</th>
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<td><strong>STUDY 2015-086</strong></td>
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<td><strong>STUDY 2015-057</strong></td>
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</tr>
<tr>
<td>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</td>
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<tr>
<td><strong>STUDY 2015-096</strong></td>
<td><strong>Phase III</strong></td>
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<tr>
<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>
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<tr>
<td><strong>STUDY 2015-050</strong></td>
<td><strong>Phase II</strong></td>
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<tr>
<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>
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<tr>
<td><strong>BLADDER</strong></td>
<td><strong>STUDY 2016-055</strong></td>
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<tr>
<td><strong>Phase I</strong></td>
<td>A Phase I/1b, Open-Label, Multicenter, Repeat-Dose, Dose-Selection Study of CPI-444 as Single Agent and in Combination with Atezolizumab in Patients with Selected Incurable Cancers</td>
</tr>
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<td><strong>STUDY 2016-050</strong></td>
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<tr>
<td>A Phase 1 Dose Escalation and Cohort Expansion Study of ERY974, an Anti-Glypican 3 (GPC3)/CD3 Bispecific Antibody, in Patients with Advanced Solid Tumors.</td>
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<tr>
<td><strong>STUDY 2015-084</strong></td>
<td><strong>Phase III</strong></td>
</tr>
<tr>
<td>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</td>
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<tr>
<td><strong>STUDY 2016-003</strong></td>
<td><strong>Phase III</strong></td>
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<tr>
<td>A Phase 1b/2 Study of Ibrutinib Combination Therapy in Selected Advanced Gastrointestinal And Genitourinary Tumors</td>
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<td><strong>STUDY S1314</strong></td>
<td><strong>Phase II</strong></td>
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<tr>
<td>A Randomized Phase II Study of Co-Expression Extrapolation (COXEN) with Neoadjuvant Chemotherapy for Localized, Muscle-Invasive Bladder Cancer</td>
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<td><strong>STUDY 2015-101</strong></td>
<td><strong>Phase III</strong></td>
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<tr>
<td>A Study of Intravesical Bacillus Calmette-Guerin (BCG) in Combination with ALT-803 in patients with BCG-naïve Non-Muscle Invasive Bladder Cancer</td>
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</table>
STUDY 2016-175
Phase II
A Randomized Phase 2 Trial of Cisplatin/Gemcitabine with or without VX-970 in Metastatic Urothelial Carcinoma

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

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

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

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

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

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

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

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

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 As Primary Treatment for Locally Advanced Cervical Cancer Compared to Chemoradiation Alone: The Outback Trial
OVARY
STUDY 2015-110
Phase I/II
A Phase III, 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 2015-157
Phase I/II
Phase 1/2 Clinical Study of Niraparib in Combination with Pembrolizumab in Patients with Advanced or Metastatic Triple-Negative Breast Cancer and in Patients with Recurrent Ovarian Cancer

STUDY 2016-121
Phase II
A Phase 2, Open-Label, Single-Arm Study to Evaluate the Safety and Efficacy of Niraparib in Patients with Advanced, Relapsed, High-Grade Serous Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Who Have Received Three or Four Previous Chemotherapy Regimens

STUDY 2016-025
Phase III
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 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 2016-037
Phase I
A Phase 1 Study of ALKS 4230 in Subjects with Advanced Solid Tumors

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

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

STUDY 2015-066
Phase III
A Phase III, Open Label, Randomised, Controlled, Multi-centre Study to assess the efficacy and safety of Olaparib Monotherapy versus Physician’s Choice Single Agent Chemotherapy in the Treatment of Platinum Sensitive Relapsed Ovarian Cancer in Patients carrying germline BRCA1/2 Mutations
**UTERUS**
**STUDY GOG-0238**
Phase II
A Randomized Trial of Pelvic Irradiation with or without Concurrent Weekly Cisplatin in Patients with Pelvic-Only Recurrence of Carcinoma of the Uterine Corpus

**STUDY NEW NRG-GY008**
Phase II
A Phase II Evaluation of Copanlisib (BAY 80-6946) (Ind #130822), A Selective Inhibitor of PI3KCA, in Patients with Persistent or Recurrent Endometrial Carcinoma Harboring PIK3CA Hotspot Mutations

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

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

**OTHER**
**STUDY 2016-121**
Phase II
A Phase 2, Open-Label, Single-Arm Study to Evaluate the Safety and Efficacy of Niraparib in Patients with Advanced, Relapsed, High-Grade Serous Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Who Have Received Three or Four Previous Chemotherapy Regimens

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

**STUDY NEW 2016-165**
**TITLE**
A Randomized Double-Blind Phase 3 Study of Avelumab in Combination with Standard of Care Chemoradiotherapy (Cisplatin Plus Definitive Radiation Therapy) Versus Standard of Care Chemoradiotherapy in the Front-Line Treatment of Patients with Locally Advanced Squamous Cell Carcinoma of the Head and Neck
<table>
<thead>
<tr>
<th>Study title</th>
<th>Phase</th>
<th>Study description</th>
</tr>
</thead>
<tbody>
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<td></td>
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<td>Phase I Safety, Pharmacokinetic and Pharmacodynamic Study of PF-02341066, A C-Met/HGFR Selective Tyrosine Kinase Inhibitor, Administered Orally to Patients with Advanced Cancer</td>
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<td><strong>STUDY 2016-149</strong></td>
<td></td>
<td><strong>STUDY 2016-017</strong></td>
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<tr>
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<td></td>
<td>A Phase 1B/2 Open-Label Study to Evaluate Safety, Clinical Activity, Pharmacokinetics and Pharmacodynamics of Avelumab* (MSB0010718C) in Combination with Other Cancer Immunotherapies in Patients with Advanced Malignancies</td>
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<td></td>
<td><strong>OTHER</strong></td>
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**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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**Hematology Clinical Trials**

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**MULTIPLE MYELOMA**

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

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

**STUDY 2012-122**
**Phase I/II**
Multicenter, Open-label, Single-arm, Phase 1b/2 Study of the Safety and Efficacy of Combination Treatment with Pomalidomide, Dexamethasone, and Carfilzomib (PdC) in Subjects with Relapsed and Relapsed/Refractory Multiple Myeloma

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

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

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

**STUDY 2016-086**
**Phase I**
A Phase 1b/2a Multicenter, Open-label, Dose-escalation Study to Determine the Maximum Tolerated Dose, Assess the Safety and Tolerability, Pharmacokinetics and Preliminary Efficacy of CC-220 Monotherapy and in Combination with Dexamethasone in Subjects with Relapsed and Refractory Multiple Myeloma

**STUDY 2010-106**
**Phase III**
A Randomized Phase III Study Comparing Conventional Dose Treatment Using a Combination of Lenalidomide, 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 2015-022**
**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 (Ixazomib, Lenalidomide, & Dexamethasone) for Consolidation Therapy Post Autologous Stem Cell Transplantation followed by Maintenance Ixazomib or Lenalidomide for Multiple Myeloma

**AMYLOIDOSIS or LIGHT CHAIN DEPOSITION DISEASE**

**STUDY 2012-086**
**Phase III**
A Phase 3, Randomized, Controlled, Open-Label, Multicenter, Safety and Efficacy Study of Dexamethasone Plus MLN9708 or Physicians Choice of Treatment Administered to Patients With Relapsed or Refractory Systemic Light Chain (AL) Amyloidosis

**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

**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 Retargeting (DART®) Protein in Subjects with Relapsed or Refractory B-cell Malignancies

**Acute Myeloid Leukemia (AML)**

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

**STUDY 2016-035**
**Phase I**
A Phase 1/1b, Multicenter, Open-label, Dose-Escalation Study of FT-2102 as a Single Agent and in Combination with Azacitidine in Patients with Acute Myeloid Leukemia or Myelodysplastic Syndrome with an IDH1 Mutation

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

STUDY 2016-103
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 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 NEW 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

Chronic Myeloid Leukemia (CML)
STUDY 2015-128
Phase II
A Randomized, Open-label, Phase 2 Trial of Ponatinib in Patients with Resistant Chronic Phase Chronic Myeloid Leukemia to Characterize the Efficacy and Safety of a Range of Doses

LYMPHOMA
Hodgkin's
STUDY 2016-033
Phase II
A Phase II Multicenter Single Arm Study to Evaluate the Efficacy and Safety of Single Agent Bruton's Tyrosine Kinase Inhibitor, Ibrutinib, in Patients with Relapsed Refractory Hodgkin's Lymphoma

STUDY NEW 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 NEW 2016-058
Phase III
A Phase III, Randomized, Open-label, Clinical Trial to Compare Pembrolizumab with Brentuximab Vedotin in Subjects with Relapsed or Refractory Classical Hodgkin Lymphoma

Non-Hodgkin's
Aggressive (Mantle Cell, Large B-Cell Lymphoma)
STUDY 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

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 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 2015-125

Phase II
Randomized, Open-Label, Phase 2 Study of Rituximab and Bendamustine with or without Brentuximab Vedotin for Relapsed or Refractory CD30-Positive Diffuse Large B-Cell Lymphoma

STUDY 2013-047

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

STUDY 2015-150

Phase I/II
A Phase Ib/II Study Evaluating The Safety And Efficacy Of Obinutuzumab In Combination With Polatuzumab Vedotin And Lenalidomide In Patients With Relapsed Or Refractory Follicular Or Diffuse Large B-Cell Lymphoma

T cell
STUDY 2009-139

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

STUDY 2016-139

Phase I
A Phase I/II, Dose Escalation Study to Evaluate Safety and Efficacy of RP6530, a dual PI3K δ/γ inhibitor, in Patients with Relapsed or Refractory T-cell Lymphoma

MYELODYSPLASTIC SYNDROME (MDS)
STUDY 2014-037

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

STUDY 2016-035

Phase I
A Phase 1/1b, Multicenter, Open-label, Dose-Escalation Study of FT-2102 as a Single Agent and in Combination with Azacitidine in Patients with Acute Myeloid Leukemia or Myelodysplastic Syndrome with an IDH1 Mutation

STUDY 2016-054

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

**STUDY 2015-151**
**Phase I/II**
A Phase 1/2 Study of Vadastuximab Talirine (SGN-CD33A) in Combination with Azacitidine in Patients with Previously Untreated International Prognostic Scoring System

**OTHER**

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

**STUDY 2013-113**
*Phase II*
A Multicenter Phase 2 Study of the Bruton's Tyrosine Kinase Inhibitor PCI32765 (Ibrutinib) for Treatment of Relapsed Hairy Cell Leukemia

**STUDY 2016-148**
*Phase I/II*
A Phase 1-2 Dose-Escalation and Cohort-Expansion Study of Oral eFT508 in Subjects with Hematological Malignancies

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

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**Immunotherapy Clinical Trials**

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

**RETURN TO TOP**

**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 BRAFV600 Mutant Melanoma

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

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

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

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

STUDY 2016-017
Phase I/II
A Phase 1B/2 Open-Label Study to Evaluate Safety, Clinical Activity, Pharmacokinetics and Pharmacodynamics of Avelumab* (MSB0010718C) in Combination with Other Cancer Immunotherapies in Patients with Advanced Malignancies

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

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

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

**STUDY 2016-149**  
**Phase I/II**  
A Phase 1b/2, Open-label, Multicenter, Dose-escalation and Expansion Trial of Intratumoral SD-101 in Combination With Pembrolizumab in Patients With Metastatic Melanoma or Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma

**STUDY 2016-055**  
**Phase I**  
A Phase 1/1b, Open-Label, Multicenter, Repeat-Dose, Dose-Selection Study of CPI-444 as Single Agent and in Combination With Atezolizumab in Patients with Selected Incurable Cancers

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

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**Neuro-Oncology Clinical Trials**

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

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**Phase I Clinical Trials**

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

**ALL SOLID TUMORS**

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

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

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

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

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

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

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

STUDY 2015-156
Phase I
A Phase 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 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-Immunosuppression 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 I Study of ALKS 4230 in Subjects with Advanced Solid Tumors

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

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

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

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

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

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

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

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

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

STUDY 2016-055
Phase I
A Phase 1/1b, Open-Label, Multicenter, Repeat-Dose, Dose-Selection Study of CPI-444 as Single Agent and in Combination with Atezolizumab in Patients with Selected Incurable Cancers

STUDY 2015-157
Phase I/II
Phase 1/2 Clinical Study of Niraparib in Combination with Pembrolizumab in Patients with Advanced or Metastatic Triple-Negative Breast Cancer and in Patients with Recurrent Ovarian Cancer

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

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

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

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

**STUDY 2015-138**  
**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 III**  
A Phase II/III Multicenter Study of the Combination of AZD2014 and Palbociclib on a Background of Hormonal Therapy in Patients with Locally Advanced/Metastatic Estrogen Receptor Positive Breast Cancer Comprising a Safety, Pharmacokinetic and Preliminary Efficacy Evaluation followed by a Randomized, Double-Blind, Placebo-controlled, Parallel Group Extension (PASTOR)

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

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

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

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

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

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

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

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

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

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

STAGE IV
ALK
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 2016-100
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 2014-071
Phase I/II
Phase 1/2 Study of PF-06463922 (An ALK/ROS1 Tyrosine Kinase Inhibitor) in Patients with Advanced Non-Small Cell Lung Cancer Harboring Specific Molecular Alterations

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

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

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

**Other Genetic Marker**

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

**STUDY 2014-002**  
Phase II  
A Study to Assess the Ability to Initiate Therapy in Advanced Non-Small Cell Lung Cancer (NSCLC) Patients Based on Genomic Analyses of Tumor Specimens.

**STUDY 2015-0103**  
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 2016-034**  
Phase I  
A Phase 1b Study of Abemaciclib in Combination with Pembrolizumab for Patients with Stage IV Non-Small Cell Lung Cancer or Hormone Receptor Positive, HER2 Negative Breast Cancer

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

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

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

**STUDY 2015-131**  
Phase II  
An Open-Label, Multicenter, Global Phase 2 Basket Study of Entrectinib for the Treatment of Patients with Locally Advanced or Metastatic Solid Tumors that Harbor NTRK1/2/3, ROS1, or ALK Gene Rearrangements
STUDY 2016-055  
Phase I  
A Phase 1/1b, Open-Label, Multicenter, Repeat-Dose, Dose-Selection Study of CPI-444 as Single Agent and in Combination with Atezolizumab in Patients with Selected Incurable Cancers

STUDY 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 2015-085  
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

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 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)

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

STUDY S1403
Phase II/III
A Randomized Phase II/III Trial of Afatinib plus Cetuximab versus Afatinib Alone in Treatment-Naive Patients with Advanced, EGFR Mutation Positive Non-Small Cell Lung Cancer (NSCLC) (B1200.124)

STUDY 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 2016-025
Phase II/III
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

RETURN TO TOP