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.

### Bone Marrow Transplant

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### Bone Marrow Clinical Trials

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

**BONE MARROW TRANSPLANT**

**STUDY BMTCN1101**

Phase III

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

**STUDY 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

**STUDY 2011-204**

Phase I/II

Phase I/II Study of Dasatinib in Recipients of Allogeneic Stem Cell Transplantation for Hematologic Malignancies
STUDY 2012-140
Phase III
A Phase 3b Multi-Center, Double-Blind, Randomized, Placebo Controlled Study to Demonstrate the Safety and Efficacy of Fidaxomicin for Prophylaxis against Clostridium difficile Associated Diarrhea in Adults Undergoing Hematopoietic Stem Cell Transplantation (HSCT)

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

STUDY E2906
Phase III
Phase III Randomized Trial of Clofarabine as Induction and Post-Remission Therapy vs. Standard Daunorubicin & Cytarabine Induction and Intermediate Dose Cytarabine Post-Remission Therapy, Followed by Decitabine Maintenance vs. Observation in Newly-Diagnosed Acute Myeloid Leukemia in Older Adults (Age≥ 60 Years)

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 2013-064
Phase II
A Phase II, Randomized Comparative 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.

IMMUNOTHERAPY
STUDY 2011-025
Phase I
Treatment of Advanced Colorectal or Pancreatic Cancer with anti-CD3 x anti-Erbilux® Armed Activated T Cells (Phase Ib)

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 B-47
Phase III
A Randomized Phase III Trial of Adjuvant Therapy Comparing Chemotherapy Alone (Six Cycles of Docetaxel Plus Cyclophosphamide or Four Cycles of Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel) to Chemotherapy Plus Trastuzumab in Women with Node-Positive or High-Risk Node-Negative HER2-Low Invasive Breast Cancer

STUDY 2011-026
Phase II
Phase II Placebo-Controlled Trial of Lisinopril and Coreg CR® to Reduce Cardiotoxicity in Patients with Breast Cancer Receiving (Neo)Adjuvant Chemotherapy with Trastuzumab (Herceptin®)
STUDY NEW S1202
Phase III
A Randomized Placebo-Controlled Phase III Study of Duloxetine for Treatment of Aromatase Inhibitor-Associated Musculoskeletal Symptoms in Women with Early Stage Breast Cancer

STUDY 2013-085
Phase III
A Randomized, Multicenter, Open-Label Phase III Study to Evaluate the Efficacy and Safety of Trastuzumab Emtansine versus Trastuzumab as Adjuvant Therapy for Patients with HER2-Positive Primary Breast Cancer Who Have Residual Tumor Present Pathologically in the Breast or Axillary Lymph Nodes Following Preoperative Therapy

STUDY 2013-165
Phase III
A Randomized, Multicenter, Open-Label Phase III Trial Comparing Trastuzumab Plus Pertuzumab Plus a Taxane Following Anthracyclines versus Trastuzumab Emtansine Plus Pertuzumab Following Anthracyclines as Adjuvant Therapy in Patients with Operable Her2-Positive Primary Breast Cancer

ADJUVANT HORMONAL
STUDY S1007
Phase III
A Phase III, Randomized Clinical Trial of Standard Adjuvant Endocrine Therapy +/- Chemotherapy in Patients with 1-3 Positive Nodes, Hormone Receptor-Positive and HER2-Negative Breast Cancer with Recurrence Score RS) of 25 or Less

NEOADJUVANT
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

STUDY A011104
Phase III
Effect of Preoperative Breast MRI on Surgical Outcomes, Costs and Quality of Life of Women with Breast Cancer

ADVANCED (Stage IV) CHEMOTHERAPY
STUDY 2009-085
Phase II
A Phase II Study of anti-CD3 x anti-HER2/neu Armed Activated T Cells for Patients with HER2/neu (0, 1+ or 2+) Metastatic Breast Cancer

STUDY 2013-168
Phase III
A Randomized Double-Blind, Placebo-Controlled Study of LEE011 in Combination with Letrozole for the Treatment of Postmenopausal Women with Hormone Receptor Positive, HER2-negative, Advanced Breast Cancer who Received no Prior Therapy for Advanced Disease

OTHERS
STUDY E2108
Phase III
A Randomized Phase III Trial of the Value of Early Local Therapy for the Intact Primary Tumor in Patients with Metastatic Breast Cancer
# 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](#).

## GASTRIC AND GASTROESOPHAGEAL JUNCTION

**Metastatic**

**STUDY 2013-035**  
Phase II  
An Open-Labeled, Multicenter Phase II Study of Cabazitaxel in Refractory Metastatic Gastric or Gastroesophageal Adenocarcinoma

**STUDY 2012-128**  
Phase I  
A Phase I Study of the Safety, Pharmacokinetics and Pharmacodynamics of Escalating Doses of the Selective Inhibitor of Nuclear Export (SINE) KPT-330 in Patients with Advanced or Metastatic Solid Tumor Malignancies

## PANCREAS

**Adenocarcinoma**  
**(Adjuvant)**

**STUDY 2014-021**  
Phase III  
A Phase III, Multicenter, Open-label, Randomized Study of nab-Paclitaxel Plus Gemcitabine Versus Gemcitabine Alone as Adjuvant Therapy in Subjects With Surgically Resected Pancreatic Adenocarcinoma

**(Metastatic)**

**STUDY 2011-116**  
Pilot  
Prevention of Nausea and Vomiting Secondary to FOLFIRINOX Chemotherapy Pilot in GI Cancer Patients

## Neuroendocrine

**STUDY E2211**  
Phase II  
A Randomized Phase II Study of Temozolomide or Temozolomide and Capecitabine in Patients with Advanced Pancreatic Neuroendocrine Tumors

**STUDY RTOG0848**  
Phase III  
A Phase III Trial Evaluating Both Erlotinib and Chemoradiation as Adjuvant Treatment for Patients with Resected Head of Pancreas Adenocarcinoma

**STUDY 2012-128**  
Phase I  
A Phase I Study of the Safety, Pharmacokinetics and Pharmacodynamics of Escalating Doses of the Selective Inhibitor of Nuclear Export (SINE) KPT-330 in Patients with Advanced or Metastatic Solid Tumor Malignancies

**STUDY 2011-141**  
Phase I  
Percutaneous Cryoablation for the Palliation of Abdominal Pain Associated with Pancreatic Cancer

**STUDY 2011-025**  
Phase I  
Treatment of Advanced Colorectal or Pancreatic Cancer with anti-CD3 x anti-Erbilux® Armed Activated T Cells(Phase Ib)

## HCC

**STUDY 2013-026**
**Phase III**
A Randomized, Double Blind, Placebo-Controlled, Multicenter Phase III Study of Regorafenib in Patients with Hepatocellular Carcinoma (HCC) after Sorafenib

**STUDY 2013-065**
**Phase III**
A Randomized, Double-Blind, Multi-Center Phase 3 Study of ADI-PEG 20 Plus Best Supportive Care (BSC) Versus Placebo Plus BSC in Subjects With Advanced Hepatocellular Carcinoma (HCC) Who Have Failed Prior Systemic Therapy

**STUDY 2011-145**
**Phase III**
A Phase III Clinical Trial of Intrararterial TheraSphere in the Treatment of Patients with Unresectable Hepatocellular Carcinoma (HCC)

**BILIARY/GALL BLADDER**
**STUDY S1310**
**Phase II**
Randomized Phase II Trial of Single Agent MEK Inhibitor Trametinib (GSK1120212) vs 5-Fluorouracil or Capecitabine in Refractory Advanced Biliary Cancer

**COLON**
**Adjuvant**
**STUDY C80702**
**Phase III**
A Phase III trial of 6 versus 12 Treatments of Adjuvant FOLFOX Plus CELECOXIB or PLACEBO for Patients with Resected Stage III Colon Cancer

**STUDY S0820**
**Phase III**
A Double Blind Placebo-Controlled Trial of Eflornithine and Sulindac to Prevent Recurrence of High Risk Adenomas and Second Primary Colorectal Cancers in Patients with Stage 0-III Colon Cancer, Phase III

**Metastatic (Includes Rectal)**
**STUDY 2011-144**
**Phase III**
A Phase III Clinical Trial Evaluating TheraSphere in Patients with Metastatic Colorectal Carcinoma of the Liver who have Failed First Line Chemotherapy

**STUDY 2011-025**
**Phase I**
Treatment of Advanced Colorectal or Pancreatic Cancer with anti-CD3 x anti- Erbitux® Armed Activated T Cells (Phase Ib)

**STUDY 2013-018**
**Phase II**
STEAM (Sequencing Triplet with Avastin and Maintenance): FOLFOXIRI/Bevacizumab Regimens (Concurrent and Sequential) vs. FOLFOX/Bevacizumab in First-Line Metastatic Colorectal Cancer

**STUDY 2011-116**
**Pilot**
Prevention of Nausea and Vomiting Secondary to FOLFIRINOX Chemotherapy Pilot in GI Cancer Patients

**STUDY 2012-128**
**Phase I**
A Phase I Study of the Safety, Pharmacokinetics and Pharmacodynamics of Escalating Doses of the Selective Inhibitor of Nuclear Export (SINE) KPT-330 in Patients with Advanced or Metastatic Solid Tumor Malignancies
RECTUM
STUDY N1048
Phase II/III
N1048 (PROSPECT**): A Phase II/III Trial of Neoadjuvant FOLFOX with Selective Use of Combined Modality Chemoradiation versus Preoperative Combined Modality Chemoradiation for Locally Advanced Rectal Cancer Patients Undergoing Low Anterior Resection with Total Mesorectal Excision

SUPPORTIVE CARE
STUDY 2011-116
Pilot
Prevention of Nausea and Vomiting Secondary to FOLFIRINOX Chemotherapy Pilot in GI Cancer Patients

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.

RENNAL
STUDY 2013-189
Phase III
A Phase 3, Randomized, Controlled Study of Cabozantinib (XL184) vs Everolimus in Subjects with Metastatic Renal Cell Carcinoma that has Progressed after Prior VEGFR Tyrosine Kinase Inhibitor Therapy

STUDY 2012-132
Phase III
An International Phase 3 Randomized Trial of Autologous Dendritic Cell Immunotherapy (AGS-003) Plus Standard Treatment of Advanced Renal Cell Carcinoma (ADAPT)

STUDY 2012-095
Phase I
A Phase I, Open Label, Multi-center Study to Assess the Safety, Pharmacokinetics and Effectiveness of AGS-16C3F Monotherapy in Subjects with Renal Cell Carcinoma of Clear Cell or Papillary Histology

STUDY NEW S0931
Phase III
EVEREST: EVErolimus for Renal Cancer Ensuing Surgical Therapy, A Phase III Study

STUDY NEW 2014-043
Phase II
A Phase II Trial to Evaluate the Efficacy of AZD6094 (HMPL-504) in Patients with Papillary Renal Cell Carcinoma (PRCC)

STUDY 2013-033
Phase II
A Randomized Phase II Study of AMG-386 with or without Continued Anti-VEGF Therapy in Patients with Renal Cell Carcinoma Progressed on Bevacizumab, Sunitinib, Sorafenib or Pazopanib.

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

PROSTATE
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<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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<td><strong>STUDY 2013-036</strong></td>
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<td><strong>Phase II</strong></td>
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<tr>
<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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<td><strong>STUDY 2013-082</strong></td>
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<td>A Randomized, Placebo Controlled, Multicenter Phase 2 Study of Etodolac and Propranolol in Patients with Clinically Progressive Prostate Cancer.</td>
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<td>A Three Arm Randomized, Open-Label Phase II Study of Radium-223 Dichloride 50 kBq/kg versus 80 kBq/kg, and versus 50 kBq/kg in an Extended Dosing Schedule in Subjects with Castration-Resistant Prostate Cancer Metastatic to the Bone</td>
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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 that Express Nectin-4

STUDY 2013-104
Phase I
A Phase 1 Study of the Safety and Pharmacokinetics of Escalating Doses of AGS15E Given as Monotherapy in Subjects with Metastatic Urothelial Cancer

STUDY 2014-042
Phase II
A Phase II, Multicenter, Single-Arm Study of MPDL3280A in Patients with Locally Advanced or Metastatic Urothelial Bladder Cancer

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 2013-160
Phase III
A Multicenter, Randomized, Double-Blind, Placebo-Controlled Phase 3 Study of Rucaparib as Switch Maintenance Following Platinum-Based Chemotherapy in Patients with Platinum-Sensitive, High-Grade Serous or Endometrioid Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Cancer

STUDY 2013-084
Phase III
The MILO Study (MEK Inhibitor in Low-grade Serous Ovarian Cancer): A Multinational, Randomized, Open-label Phase 3 Study of MEK162 vs. Physicians Choice Chemotherapy in Patients with Recurrent or Persistent Lowgrade Serous Carcinomas of the Ovary, Fallopian Tube or Primary Peritoneum

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 GOG-0225
NA
Can Diet and Physical Activity Modulate Ovarian, Fallopian Tube and Primary Peritoneal Cancer Progression-Free Survival?

STUDY GOG-0213
Phase III
A Phase III Randomized Controlled Clinical Trial of Carboplatin and Paclitaxel Alone or in Combination with Bevacizumab (NSC #704865, IND #7921) Followed by Bevacizumab and Secondary Cytoreductive Surgery in Platinum-Sensitive, Recurrent Ovarian, Peritoneal Primary and Fallopian Tube Cancer. NCI-Supplied Agents: (NSC #704865, IND #7921)
UTERUS
STUDY GOG-0277
Phase III
A Phase III Randomized Trial Of Gemcitabine (NSC# 613327) Plus Docetaxel (NSC# 628503) Followed By Doxorubicin (NSC# 123127) V. Observation For Uterus-Limited, High Grade Uterine Leiomyosarcoma

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-0286B
Phase II/III
A Randomized Phase II/III Study Of Paclitaxel/Carboplatin/Metformin (NSC#91485) Versus Paclitaxel/Carboplatin/Placebo as Initial Therapy for Measurable Stage III or IVA, Stage IVB, or Recurrent Endometrial Cancer

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

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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 RTOG0920
Phase III
A Phase III Study of Postoperative Radiation Therapy (IMRT) +/- Cetuximab for Locally-Advanced Resected Head and Neck Cancer.

STUDY 2012-131
Phase II
A Randomized Phase II Trial of ARQ 197 (Tivantinib)/Cetuximab versus Cetuximab in Patients with Recurrent/Metastatic Head and Neck Cancer

STUDY 2013-138
Phase II
A Randomized, Double-Blind, Placebo-Controlled Study of Chemotherapy Plus Cetuximab in Combination with VTX-2337 in Patients with Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck

STUDY 2013-139
Phase II
A Phase 2, Double-Blind, Randomized, Placebo-Controlled, Dose-Escalating, Multicenter Study of SGX942 for the Attenuation of Oral Mucositis in Patients Being Treated With Concomitant Chemoradiation for the Treatment of Squamous Cell Carcinoma of the Head and Neck

ANY STAGE
STUDY 2013-016
Phase I/II
Phase I/II trial of Cediranib Alone or Cediranib and Lenalidomide in Iodine 131-refractory Differentiated Thyroid Cancer
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 2012-070
Phase I
A Phase I Study of ARRY-520 and Bortezomib Plus Dexamethasone in Patients with Relapsed/Refractory Multiple Myeloma

STUDY 2013-125
Phase I
An Open-Label, Single Arm, Phase 1 Study of the Pharmacokinetics and Safety of Carfilzomib in Subjects with Relapsed Multiple Myeloma and End-stage Renal Disease

STUDY E3A06
Phase III
Randomized Phase III Trial of Lenalidomide Versus Observation Alone in Patients with Asymptomatic High-Risk Smoldering 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 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 2013-037
Phase I/II
Phase 1b/2, Multicenter, Open-label Study of Oprozomib and Dexamethasone in Patients with Relapsed and/or Refractory Multiple Myeloma

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 or Refractory Multiple Myeloma

STUDY 2013-131
Phase II
A Multicenter, Randomized, Open-label, Phase 2 Study of Carfilzomib With or Without ARRY-520 in Patients With Advanced 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 1211
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)
AMYLOIDOSIS OR LIGHT CHAIN DEPOSITION DISEASE
STUDY 2013-124
Phase I
A Phase I, Open Label, Dose Escalation Study of Intravenous Administration of Single Agent NEOD001 in Subjects with Light Chain (AL) Amyloidosis

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 2012-097
Phase II
Phase II Study of the Combination of Bendamustine and Dexamethasone in Patients with Relapsed AL Amyloidosis

STUDY NEW 2011-155
Phase I
Phase I Study of Pomalidomide, Bortezomib, and Dexamethasone (PVD) as First-Line Treatment of AL Amyloidosis or Light Chain Deposition Disease

LEUKEMIA
Acute Lymphoblastic Leukemia (ALL)
STUDY 2012-052
Phase III
An Open-label, Randomized Phase 3 Study of Inotuzumab Ozogamicin Compared to a Defined Investigator's Choice in Adult Patients with Relapsed or Refractory CD22-Positive Acute Lymphoblastic Leukemia (ALL)

STUDY 2011-170
Phase III
A Phase 3, Multicenter, Randomized Study To Evaluate The Substitution of Marqibo® (Vincristine Sulfate Liposomes Injection, VSLI) for Standard Vincristine Sulfate Injection (VSI) in the Induction, Intensification, and Maintenance Phases of Combination Chemotherapy in the Treatment of Malignant Hematology Leukemia Subjects > or = 60 Years old with Newly Diagnosed Acute Lymphoblastic Leukemia (ALL)

STUDY E1910
Phase III
A Phase III Randomized Trial of Blinatumomab for Newly Diagnosed BCR-ABL-negative B lineage Acute Lymphoblastic Leukemia in Adults

Acute Myeloid Leukemia (AML)
STUDY S1203
Phase III
A Randomized Phase III Study of Standard Cytarabine plus Daunorubicin (7+3) Therapy or Idarubicin with High Dose Cytarabine (IA) versus IA with Vorinostat (IA+V) in Younger Patients with Previously Untreated Acute Myeloid Leukemia (AML)

STUDY 2014-031
Phase III
A Phase III 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 (H SCT) Consolidation

Chronic Lymphocytic Leukemia (CLL)
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)

**STUDY NEW A041202**  
Phase III  
A Randomized Phase III Study Of Bendamustine Plus Rituximab Versus Ibrutinib Plus Rituximab Versus Ibrutinib Alone In Untreated Older Patients (greater than equal to 65 YEARS OF AGE) with Chronic Lymphocytic Leukemia (CLL)

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

**Chronic Myeloid Leukemia (CML)**  
**STUDY 2013-066**  
Phase II  
An Open Label, Multi-Center Imatinib Roll-Over Protocol for Patients who have Completed a Previous Novartis Sponsored Imatinib Study and are Judged by the Investigator to Benefit from Continued Imatinib Treatment

**LYMPHOMA**  
**Hodgkin’s**  
**STUDY 2012-121**  
Phase III  
A Randomized, Open-label, Phase 3 Trial of A+AVD Versus ABVD as Frontline Therapy in Patients With Advanced Classical Hodgkin Lymphoma

**STUDY 2014-044**  
Phase I  
A Multi-center Phase I/Ib Study Evaluating the Efficacy and Safety of Brentuximab Vedotin in Combination with TGR-1202, a Novel PI3K Delta Inhibitor, in Patients with Hodgkins Lymphoma (HL).

**Non-Hodgkin's**  
**Aggressive (Mantle Cell, Large B-Cell Lymphoma)**  
**STUDY E1411**  
Phase II  
Intergroup Randomized Phase II Four Arm Study In Patients >= 60 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 (RBB -R), Arm C = Rituximab + Bendamustine Followed By Lenalidomide + Rituximab Consolidation (RB - LR) or Arm D = Rituximab + Bendamustine + Bortezomib Followed By Lenalidomide + Rituximab Consolidation (RBB - LR)

**STUDY 2013-034**  
Phase III  
A Randomized, Double-blind, Placebo-controlled Phase 3 Study of the Bruton’s Tyrosine Kinase (BTK) Inhibitor, PCI-32765 (Ibrutinib), in Combination with Bendamustine and Rituximab (BR) in Subjects With Newly Diagnosed Mantle Cell Lymphoma

**STUDY 2013-178**  
Phase III  
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

**Indolent**  
**STUDY 2012-151**  
Phase III  
A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GS-1101 (CAL-101) in Combination with Rituximab for Previously Treated Indolent Non-Hodgkin Lymphomas
T Cell
STUDY 2012-043
Phase III
A Phase 3, Randomized, Two-Arm, Open-Label, Multicenter, International Trial of Alisertib (MLN8237) or Investigator’s Choice (Selected Single Agent) in Patients With Relapsed or Refractory Peripheral T-Cell Lymphoma

MYELODYSPLASTIC SYNDROME (MDS)
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

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

OTHER
STUDY 2013-050
Phase II
A Phase 2, Open-Label Study Evaluating the Efficacy, Safety, Tolerability, and Pharmacodynamics of GS-9973 in Subjects with Relapsed or Refractory Hematologic Malignancies

STUDY 2013-179
Phase III
APOLLO: A Phase 3 Multicenter, Multinational, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of ALN-TTR02 in Transthyretin (TTR)-Mediated Polyneuropathy (Familial Amyloidotic Polyneuropathy-FAP)

STUDY 2013-113
Phase II
A Multicenter Phase 2 Study of the Bruton's Tyrosine Kinase Inhibitor PCI-32765 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.

For study descriptions and eligibility requirements on these trials please visit the Karmanos website.

STUDY 2009-085
Phase II Therapeutic
A Phase II Study of anti-CD3 x anti-HER2/neu Armed Activated T Cells for Patients with HER2/neu (0, 1+ or 2+) Metastatic Breast Cancers.

STUDY 2010-056
Phase II Therapeutic
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

STUDY 2011-025
Phase I Therapeutic
Treatment of Advanced Colorectal or Pancreatic Cancer with anti-CD3 x anti- Erbitux® Armed Activated T Cells (Phase Ib)
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 2012-105
Phase III
A Phase III, Randomized, Double-Blind, Placebo-Controlled Study of Vemurafenib (RO5185426) Adjuvant Therapy in Patients with Surgically Resected, Cutaneous BRAF-Mutant Melanoma at High Risk for Recurrence

ADVANCED
STUDY E2607
Phase II
A Phase II Trial of Dasatinib in KIT-Positive Patients with Unresectable Locally Advanced or Stage IV Mucosal, Acral and Vulvovaginal Melanomas

STUDY 2013-039
Phase III
The NEMO Trial (NRAS melanoma and MEK inhibitor): A Randomized Phase III, Open Label, Multicenter, Two-Arm Study Comparing the Efficacy of MEK162 versus Dacarbazine in Patients with Advanced Unresectable or Metastatic NRAS Mutation-Positive Melanoma

STUDY NEW 2014-068
Phase II
Expanded Access of MK-3475 in Metastatic Melanoma Patients with Limited to No Treatment Options

STUDY 2013-095
Phase II
Open-Label, Randomized, Multi-Center Study comparing the Sequence of High Dose Aldesleukin (Interleukin-2) and Ipilimumab (Yervoy) in Patients with Metastatic Melanoma

STUDY 2012-055
NA
A Multi-Center Study of High Dose Aldesleukin (Interleukin-2) + Vemurafenib Therapy in Patients with BRAFV600 Mutation Positive Metastatic Melanoma

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

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

The Karmanos Phase 1 Program is one of 14 National Cancer Institute funded Phase 1 Clinical Pharmacology Programs in North America. In hope of finding new and better ways to help cancer patients, Karmanos’ Phase 1 Program has many clinical trials underway. Due to the specific requirements for patient eligibility, we are unable to post all of our open Phase 1 Clinical Trials in this newsletter. If you would like more information on our open Phase 1 Clinical Trials or to refer a patient, please call 313-576-8765 or email phase1@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 this is the best treatment option available for them.

### 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](#).

**MAINTENANCE STUDY 2013-177**

**Pilot**

A Pilot Trial of Docetaxel, Gemcitabine, or Pemetrexed Single Agent Therapy with Serial Tumor Specimen Collection in Patients with Advanced Non-Small-Cell Lung Cancer

**STAGE III A/B**

**STUDY 2014-014**

**Phase II**

A Randomized, Double-Blind Phase 2 Study of Ruxolitinib or Placebo in Combination With Pemetrexed/Cisplatin and Pemetrexed Maintenance for Initial Treatment of Subjects With Nonsquamous Non-Small Cell Lung Cancer That Is Stage IIIB With Pleural/Pericardial Effusion, Stage IV, or Recurrent

**STUDY NEW 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

**STUDY NEW 2014-051**

**Phase II**

A Randomized, Phase II Study of INCB039110 or placebo in Combination with Docetaxel in Subjects with Previously Treated Stage IIIb, IV, or Recurrent Non-Small Cell Lung Cancer.

**STAGE IV**

**ALK**

**STUDY 2012-143**
Phase I/II
A Study of HSP90 Inhibitor AT13387 Alone and in Combination with Crizotinib in the Treatment of Non-small Cell Lung Cancer (NSCLC)

EGFR
STUDY 2013-170
Phase I/II
A Phase I/II Study of MK-3475 (SCH900475) in Combination with Chemotherapy or Immunotherapy in Patients with Locally Advanced or Metastatic Non-Small Cell Lung Carcinoma

Other Genetic Marker
STUDY 2013-158
Phase I
Multi-arm, Non-randomized, Open-Label Phase IB Study to Evaluate GSK3052230 in Combination with Paclitaxel and Carboplatin, or Docetaxel or as Single Agent in Subjects with Solid Malignancies and Deregulated FGF Pathway Signaling

STUDY 2014-014
Phase II
A Randomized, Double-Blind Phase 2 Study of Ruxolitinib or Placebo in Combination With Pemetrexed/Cisplatin and Pemetrexed Maintenance for Initial Treatment of Subjects With Nonsquamous Non-Small Cell Lung Cancer That Is Stage IIIB With Pleural/Pericardial Effusion, Stage IV, or Recurrent

STUDY NEW 2014-051
Phase II
A Randomized, Phase II Study of INCB039110 or placebo in Combination with Docetaxel in Subjects with Previously Treated Stage IIIb, IV, or Recurrent Non-Small Cell Lung Cancer.

STUDY 2013-170
Phase I/III
A Phase I/II Study of MK-3475 (SCH900475) in Combination with Chemotherapy or Immunotherapy in Patients with Locally Advanced or Metastatic Non-Small Cell Lung Carcinoma

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

RECURRENT
EGFR
STUDY 2011-199
Phase I/II
A Phase 1/2, Open-Label, Safety, Pharmacokinetic and Preliminary Efficacy Study of Oral CO-1686 in Patients with Previously Treated Mutant EGFR Non-Small Cell Lung Cancer (NSCLC)

Other Genetic Marker
STUDY 2014-014
Phase II
A Randomized, Double-Blind Phase 2 Study of Ruxolitinib or Placebo in Combination With Pemetrexed/Cisplatin and Pemetrexed Maintenance for Initial Treatment of Subjects With Nonsquamous Non-Small Cell Lung Cancer That Is Stage IIIB With Pleural/Pericardial Effusion, Stage IV, or Recurrent
STUDY 2014-012
Phase III
A Phase III, Open-Label, Multicenter, Randomized Study to Investigate the Efficacy and Safety of MPDL3280A (ANTI-PD-L1 ANTIBODY) Compared with Docetaxel in Patients with Non-Small Cell Lung Cancer After Failure with Platinum-Containing Chemotherapy

STUDY NEW 2014-051
Phase II
A Randomized, Phase II Study of INCB039110 or placebo in Combination with Docetaxel in Subjects with Previously Treated Stage IIIb, IV, or Recurrent Non-Small Cell Lung Cancer.

STUDY 2012-003
Phase II
A Phase II, Double-Blind, Placebo-Controlled, Randomized Study Evaluating the Safety and Efficacy of Carboplatin/Paclitaxel and Carboplatin/Paclitaxel/Bevacizumab with and without GDC-0941 in Patients with Previously Untreated Advanced or Recurrent Non-Small Cell Lung Cancer

STUDY 2013-170
Phase III
A Phase I/II Study of MK-3475 (SCH900475) in Combination with Chemotherapy or Immunotherapy in Patients with Locally Advanced or Metastatic Non-Small Cell Lung Carcinoma

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

SCLC EXTENSIVE
STUDY 2013-127
Phase III
A Phase 1b/2 Study of OMP-59R5 in Combination with Etoposide and Cisplatin in Subjects with Untreated Extensive Stage Small Cell Lung Cancer

STUDY 2014-025
Phase II
A Randomized, Double-blind, Placebo-controlled, Phase 2 Clinical Trial of Alisertib (MLN8237) in Combination With Paclitaxel Versus Placebo in Combination With Paclitaxel as Second Line Therapy for Small Cell Lung Cancer (SCLC)

MESOTHELIOMA
STUDY S0905
Phase III
A Phase I/Randomized Phase II Study of Cediranib (NSC #732208) versus Placebo in Combination with Cisplatin and Pemetrexed in Chemo-naive Patients with Malignant Pleural Mesothelioma

STUDY 2013-158
Phase I
Multi-arm, Non-randomized, Open-Label Phase I Study to Evaluate GSK3052230 in Combination with Paclitaxel and Carboplatin, or Docetaxel or as Single Agent in Subjects with Solid Malignancies and Deregulated FGF Pathway Signaling

OTHER
STUDY 2013-111
Phase I
A Phase 1 Study to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of JNJ-42756493, a pan-Fibroblast Growth Factor Receptor (FGFR) Tyrosine Kinase Inhibitor, in Subjects With Advanced or Refractory Solid Tumors or Lymphoma