Karmanos offers clinical trials for many different forms of cancer. Below are the most current clinical trials open to new participants as of this publication’s issue date. If you have any questions regarding these clinical trials, please contact 313-576-9790.

To view the current issue online, please click here.

Get access to our clinical trials on your iPhone®, iPad® or Android™ mobile devices with the FREE KCI Trials App.

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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 BMTCTN1101
Phase III
A Multi-Center, Phase III, Randomized Trial of Reduced Intensity (RIC) Conditioning and Transplantation of Double Unrelated Umbilical Cord Blood (dUCB) versus HLA-Haploidentical Related Bone Marrow (Haplo) for Patients with Hematologic Malignancies

STUDY 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 I/II
Phase I/II Study of Dasatinib in Recipients of Autologous Stem Cell Transplantation for 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

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.

STUDY 2014-063
Phase II

STUDY BMTCTN1203
Phase II
A Multi-Center Phase II Trial Randomizing Novel Approaches for Graft-versus-Host Disease Prevention Compared to Contemporary Controls.

STUDY BMTCTN1204
Phase II
Reduced-Intensity Conditioning for Children and Adults with Hemophagocytic Syndromes or Selected Primary Immune Deficiencies (RICH).

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

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

STUDY 2013-171
Phase I/II
Treatment of Neuroblastoma and GD2-Positive Tumors with Activated T Cells Armed with OKT3 X Humanized 3F8 Bispecific Antibodies (GD2Bi): A Phase I/II Study

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-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 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 NEW 2014-083
Phase II
A Phase II, Single Arm Study of the Use of Steroid-based Mouthwash to Prevent Stomatitis in Postmenopausal Women with Advanced or Metastatic Hormone Receptor Positive Breast Cancer Being Treated with Everolimus Plus Exemestane.

STUDY 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

STUDY 2014-055
Phase II
A Randomized Double-Blind, Phase 2 study of Ruxolitinib or Placebo in Combination with Capecitabine in Subjects with Advanced or Metastatic HER2 Negative Breast Cancer

STUDY 2014-047
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 Chemotherapy in the Treatment of Metastatic Breast Cancer Patients with Germline BRCA1/2 Mutations

STUDY A011202
Phase III
A Randomized Phase III Trial Evaluating The Role Of Axillary Lymph Node Dissection In Breast Cancer Patients (cT1-3 N1) Who Have Positive Sentinel Lymph Node Disease After Neoadjuvant Chemotherapy

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

**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

**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

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**Gastrointestinal Clinical Trials**

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

**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 2014-032
Phase III
A Randomized, Double-Blind, Phase 3 Study of the JAK1/2 Inhibitor, Ruxolitinib or Placebo in Combination With Capecitabine in Subjects With Advanced or Metastatic Adenocarcinoma of the Pancreas Who Have Failed or Are Intolerant to First-Line Chemotherapy (The JANUS 1 Study)

STUDY NEW S1313
Phase I/II
A Phase IB/II Randomized Study of Modified FOLFIRINOX + Pegylated Recombinant Human Hyaluronidase (PEGPH20) versus Modified FOLFIRINOX Alone in Patients with Good Performance Status Metastatic Pancreatic Adenocarcinoma

STUDY NEW 2014-110
Phase I/II
A Phase I/II, Two-Part, Multicenter Study to Evaluate the Safety and Efficacy of M402 in Combination with nab-Paclitaxel and Capecitabine in Patients with Metastatic Pancreatic Cancer

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 2013-133
Phase I/II
A Phase Ib/II Study of the Selective Inhibitor of Nuclear Export (SINE) KPT-330, Gemcitabine and nab-Paclitaxel in Patients with Metastatic Pancreatic Cancer

STUDY 2011-025
Phase I
Treatment of Advanced Colorectal or Pancreatic Cancer with anti-CD3 x anti-Erbitux® 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 Intraarterial 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

STUDY 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

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 Efomithine and Sulindac to Prevent Recurrence of High Risk Adenomas and Second Primary Colorectal Cancers in Patients with Stage 0-III Colon Cancer, Phase III - Preventing Adenomas of the Colon with Efomithine and Sulindac (PACES)

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 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 withSelective Use of Combined Modality Chemoradiation versus PreoperativeCombined Modality Chemoradiation for Locally Advanced Rectal CancerPatients Undergoing Low Anterior Resection with Total Mesorectal Excision

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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.
RENAL
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 S0931
Phase III
EVEREST: EVRolimus for Renal Cancer Ensuing Surgical Therapy, A Phase III Study

STUDY 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 Pharmacokinetics of Escalating Doses of ASG-22CE Given as Monotherapy in Subjects with Metastatic Urothelial Cancer that Express Nectin-4

STUDY 2014-052
Phase II
A Phase II, Randomized Study of MPDL3280A Administered as Monotherapy or in Combination with Bevacizumab versus Sunitinib in Patients with Untreated Advanced Renal Cell Carcinoma

PROSTATE
STUDY 2013-032
Phase II
Phase II Trial of an Aurora Kinase A Inhibitor MLN8237 in Patients with Metastatic Castrate Resistant and Neuroendocrine Prostate Cancer

STUDY 2012-026
Phase II
Prostate Cancer: A Randomized Dose-Finding Study of the Effects of Two Doses of MPX Capsules on Rising Prostate-Specific Antigen Levels in Men Following Initial Therapy for Prostate Cancer

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

STUDY 2013-175
Phase I/II
An Open Label Phase I/II Study of Cabazitaxel with or without Carboplatin in Phase I/II Patients with Metastatic Castration-Resistant Prostate Cancer

STUDY 2013-166
Phase II
A Randomized Open-Label Phase Ila Study Evaluating Quantified Bone Scan Response Following Treatment with Radium-223 Dichloride Alone or in Combination with Abiraterone Acetate or Enzalutamide in Subjects with Castration-Resistant Prostate Cancer (CRPC) who have Bone Metastases

STUDY 2014-078
Phase III
A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase III Study of ARN-509 in Men with Non-Metastatic (M0) Castration-Resistant Prostate Cancer SPARTAN (Selective Prostate AR Targeting with ARN-509)
**STUDY 2010-150**  
**Phase I**  
A Phase I, Open-Label Study of the Safety and Pharmacokinetics of Escalating Doses of DSTP3086S in Patients with Metastatic Castration-Resistant Prostate Cancer

**STUDY NEW 2013-083**  
**Phase II**  
Randomized Phase II Screening Trial of Enzalutamide/MDV-3100 and LHRH Analogue vs Combined Androgen Depreivation (LHRH Analogue + Bicalutamide) in Metastatic Hormone Sensitive Prostate Cancer

**STUDY NEW 2011-185**  
**Pilot**  
Pilot Trial of Oral Cabozantinib/XL184 in Metastatic Castrate Resistant Prostate Cancer to Explore the Changes in Bone and Tumor Imaging Related Pathways

**BLADDER**  
**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 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

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**Gynecologic Clinical Trials**

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**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 Low grade 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

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

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

STUDY NEW 2014-069
Phase II
A Phase II Study of Sodium Cridanimod in Conjunction with Progestin Therapy in Patients with Progesterone Receptor Negative Recurrent or Persistent Endometrial Carcinoma

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 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 2014-092
Phase II
A Phase 2, Open-label Study of the Safety and Efficacy of the Selective Inhibitor of Nuclear Export (SINE) Selinexor (KPT-330) in Patients with Advanced Squamous Cell Carcinoma of Head and Neck, Lung, or Esophagus

STUDY 2013-185
Phase III
A Randomised, Double-blind, Placebo-Controlled, Phase III Study to Evaluate the Efficacy and Safety of Afatinib (BIBW 2992) as Adjuvant Therapy after Chemo-Radiotherapy in Primary Unresected Patients with Stage III, IVa, or IVb Loco-regionally Advanced Head and Neck Squamous Cell Carcinoma

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 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 NEW 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 2013-125
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 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 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 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 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 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 (HSCT) 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 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 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 2014-087  
Phase I  
A Phase 1 Study of the Safety, Tolerability, Pharmacokinetics and Immunoregulatory Activity of Urelumab (BMS-663513) in Subjects with Advanced and/or Metastatic Solid Tumors and Relapsed/Refractory B-cell Non-Hodgkin's Lymphoma (B-NHL)

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

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

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

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

STUDY 2013-095
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 2013-184
Phase II
Stand Up to Cancer Consortium Genomics-Enabled Medicine for Melanoma (G.E.M.M.): Using Molecularly-Guided Therapy for Patients with BRAF wild-type (BRAFwt) Metastatic Melanoma

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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

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 Stage IV, or Recurrent

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

STUDY 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 S1400
Phase II/III
Phase II/III Biomarker-Driven Master Protocol for Second Line Therapy of Squamous Cell Lung Cancer (Screening Step)

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)
STUDY 2014-050
Phase III
Randomized, Multicenter, Phase III, Open-Label Study of Alectinib versus Crizotinib in Treatment-Naive Anaplastic Lymphoma Kinase-Positive Advanced Non-Small Cell Lung Cancer

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

STUDY NEW 2014-102
Phase II
TIGER 1: A Randomized, Open-Label, Phase II Study of CO-1686 or Erlotinib as First-Line Treatment of Patients with EGFR-Mutant Advanced Non-Small Cell Lung Cancer (NSCLC)

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 S1400
Phase II/III
Phase II/III Biomarker-Driven Master Protocol for Second Line Therapy of Squamous Cell Lung Cancer (Screening Step)

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, Stage IV, or Recurrent

STUDY 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/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

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
ALK
STUDY NEW S1300
Phase II
A Randomized, Phase II Trial of Crizotinib Plus Pemetrexed Versus Pemetrexed Monotherapy in ALK-Positive Non-Squamous NSCLC
Patients Who Have Progressed Systemically After Previous Clinical Benefit from Crizotinib Monotherapy

**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 NEW 2014-082**  
Phase II  
A Phase II, Multicenter, Single-Arm Study of Trastuzumab Emtansine in Patients with HER2 IHC-Positive, Locally Advanced or Metastatic Non-Small Cell Lung Cancer Who Have Received at Least One Prior Chemotherapy Regimen

**STUDY NEW 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 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, Stage IV, or Recurrent

**STUDY 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 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 I/II  
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 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

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