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

To view the current issue online, please [click here](#).

**Volume 5, Issue 1**

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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](mailto:newpt@karmanos.org) or fill out this [online referral form](#).

**BONE MARROW TRANSPLANT**

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

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

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

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

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

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.

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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 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 2015-067
Phase III
A Phase III, Multicenter, Randomized, Placebo-Controlled Study of MPDL3280A (ANTI-PD-L1 ANTIBODY) in Combination with NAB-Paclitaxel Compared with Placebo with NAB-Paclitaxel for Patients with Previously Untreated Metastatic Triple-Negative Breast Cancer

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

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

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

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.

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

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

STUDY B-52
Phase III
A Randomized Phase III Trial Evaluating Pathologic Complete Response Rates in Patients with Hormone Receptor-Positive, HER2-Positive, Large Operable and Locally Advanced Breast Cancer Treated with Neoadjuvant Therapy of Docetaxel, Carboplatin, Trastuzumab, and Pertuzumab (TCHP) With or Without Estrogen Deprivation

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

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

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

Metastatic
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 NEW 2014-146
Phase II
A Phase II Clinical Trial of Pembrolizumab as Monotherapy and in Combination with Cisplatin + 5-Fluorouracil in Subjects with Recurrent or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma (KEYNOTE-059)

STUDY 2015-056
Phase III
A Phase III, Randomized, Open-label Clinical Trial of Pembrolizumab (MK-3475) versus Paclitaxel in Subjects with Advanced Gastric or Gastroesophageal Junction Adenocarcinoma who Progressed after First-line Therapy with Platinum and Fluopyrimidine

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

PANCREAS

Adenocarcinoma
Adjuvant
STUDY 2014-021
Phase III
A Phase 3, 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 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 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 Gemcitabine in Patients with Metastatic Pancreatic Cancer

STUDY 2014-138
Phase III
An International, Multi-Center, Double-Blind, Randomized, Phase III Trial of 90Y-Clivatuzumab Tetraxetan plus Low-Dose Gemcitabine Versus Placebo plus Low-Dose Gemcitabine in Patients with Metastatic (Stage IV) Pancreatic Adenocarcinoma Who Received at Least Two Prior Treatments (PANCRT-1)

STUDY 2014-114
Phase II
Nab-Paclitaxel (Abraxane) plus Gemcitabine in Subjects with Locally Advanced Pancreatic Cancer (LAPC): An International Open-Label, Multicenter Phase 2 Study (LAPACT)

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

**STUDY 2013-133**
Phase 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 RTOG0848**
Phase III
A Phase II-R and a Phase III Trial Evaluating Both Erlotinib (PH II-R) and Chemoradiation (PH III) as Adjuvant Treatment for Patients with Resected Head of Pancreas Adenocarcinoma

**BILIARY/GALL BLADDER**

**Metastatic**
**STUDY**
**2014-081**
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 2015-060**
Phase II
A Phase 2 Study to Determine the Efficacy and Safety of BIND-014 (docetaxel nanoparticles for injectable suspension) in Patients with Urothelial Carcinoma, Cholangiocarcinoma, Cervical Cancer, and Squamous Cell Carcinoma of the Head and Neck

**COLO**

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

**RENA**

**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

**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.

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

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

PROSTATE
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 2015-033
Phase III
A Randomized, Double Blind, Multicenter, Parallel-Group, Phase III Study to Evaluate Efficacy and Safety of DCVAC/PCa Versus Placebo in Men with Metastatic Castration Resistant Prostate Cancer Eligible for 1st Line Chemotherapy

STUDY 2013-036
Phase II
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

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

STUDY A031201
Phase III
Phase III Trial of Enzalutamide (NSC # 766085) versus Enzalutamide, Abiraterone and Prednisone for Castration Resistant Metastatic Prostate Cancer

STUDY 2015-057
Phase I
A Phase I, Open-label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ascending Doses of AZD8186 in Patients with Advanced Castration-resistant Prostate Cancer (CRPC), Squamous Non-Small Cell Lung Cancer (sqNSCLC), Triple Negative Breast Cancer (TNBC) and Patients with Known PTEN-deficient/mutated or PIK3CB mutated/amplified Advanced Solid Malignancies, with Expansion to Assess the Pharmacodynamic Activity of AZD8186

STUDY 2015-050
Phase II
A Single-arm, Phase 2 Study to Evaluate the Safety and Efficacy of VT-464 in Patients with Castration-Resistant Prostate Cancer Progressing on Enzalutamide or Abiraterone.

STUDY 2015-096
Phase I/II
A Phase 1/2 Open-label Study to Assess the Safety, Pharmacokinetics, and Antitumor Activity of Oral EPI-506 in Patients with Metastatic Castration-resistant Prostate Cancer

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

STUDY 2015-049
Phase I
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<td>Phase I</td>
<td>Open-Label Trial to Evaluate the Safety and Immunogenicity of INO-5150 Alone or in Combination with INO-9012 in Men with Biochemically Relapsed (PSA) Prostate Cancer</td>
</tr>
<tr>
<td>STUDY 2015-002</td>
<td><strong>Phase II</strong> A Phase II Open-label, Parallel Group Study of Abiraterone Acetate in African American and Caucasian Men with Metastatic Castrate-resistant Prostate Cancer</td>
</tr>
<tr>
<td>STUDY 2015-051</td>
<td><strong>Phase III</strong> A Phase 3, Randomized, Open Label, Multicenter, Controlled Study of Galeterone Compared to Enzalutamide in Men Expressing Androgen Receptor Splice Variant-7 mRNA (AR-V7) Metastatic (M1) Castrate Resistant Prostate Cancer(CRPC)</td>
</tr>
<tr>
<td>STUDY 2015-029</td>
<td><strong>Phase II</strong> Phase II Randomized Placebo-Controlled Double-Blind Study of Salvage Radiation Therapy (SRT) Plus Placebo Versus SRT Plus Enzalutamide in Men with High-Risk PSA-Recurrent Prostate Cancer after Radical Prostatectomy</td>
</tr>
<tr>
<td>STUDY 2014-075</td>
<td><strong>Phase I</strong> Targeting the Prostatic Tumor Microenvironment with PLX3397, a Tumorassociated Macrophage Inhibitor, in Men with Unfavorable Risk Prostate Cancer Treated with Radiation and Androgen Deprivation Therapy</td>
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<td>STUDY 2013-108</td>
<td>NA Immune Evaluation Study of Sipuleucel-T in African American and Non African American Men with Castrate Resistant Prostate Cancer</td>
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<td>BLADDER</td>
<td>Study 2015-072 A Multicenter, Non-Randomized, Phase II Study of Regorafenib for Advanced Urothelial Cancer Following Prior Chemotherapy</td>
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<tr>
<td>STUDY 2014-010</td>
<td><strong>Phase I</strong> 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</td>
</tr>
<tr>
<td>STUDY NEW 2015-084</td>
<td><strong>Phase III</strong> A Phase III, Open-Label, Multicenter, Randomized Study of MPDL3280A (ANTIPD-L1 Antibody) versus Observation as Adjuvant Therapy in Patients with PDL1-Positive, High-Risk Muscle-Invasive Bladder Cancer After Cystectomy</td>
</tr>
<tr>
<td>STUDY 2015-119</td>
<td><strong>Phase III</strong> A Phase III, Randomized, Open-label, Controlled, Multi-Center, Global Study of First-Line MEDI4736 Monotherapy and MEDI4736 in Combination with Tremelimumab Versus Standard of Care Chemotherapy in Patients with Unresectable Stage IV Urothelial Bladder Cancer</td>
</tr>
<tr>
<td>STUDY 2013-104</td>
<td><strong>Phase I</strong> A Phase 1 Study of the Safety and Pharmacokinetics of Escalating Doses of AGS15E Given as Monotherapy in Subjects with Metastatic Urothelial Cancer</td>
</tr>
<tr>
<td>OTHER</td>
<td>Study 2015-060 <strong>Phase II</strong> A Phase 2 Study to Determine the Efficacy and Safety of BIND-014 (docetaxel nanoparticles for injectable suspension) in Patients with Urothelial Carcinoma, Cholangiocarcinoma, Cervical Cancer, and Squamous Cell Carcinoma of the Head and Neck</td>
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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 2015-060**
*Phase II*
A Phase 2 Study to Determine the Efficacy and Safety of BIND-014 (docetaxel nanoparticles for injectable suspension) in Patients with Urothelial Carcinoma, Cholangiocarcinoma, Cervical Cancer, and Squamous Cell Carcinoma of the Head and Neck

**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 2013-076**
*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 NEW 2015-118**
*Phase II*
A Phase 2 Proof-of-Concept Study of ACP-196 Alone and in Combination with Pembrolizumab in Subjects with Recurrent Ovarian Cancer

**STUDY 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 2013-160**
*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 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 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-3007
Phase II
A Randomized Phase II Trial of Everolimus and Letrozole or Hormonal Therapy (Tamoxifen/Medroxyprogesterone Acetate) in Women with Advanced, Persistent, or Recurrent Endometrial Carcinoma

STUDY GOG-0238
Phase II
A Randomized Trial of Pelvic Irradiation with or without Concurrent Weekly Cisplatin in Patients with Pelvic-Only Recurrence of Carcinoma of the Uterine Corpus

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

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

STAGES I/II/III
STUDY 2015-074
Phase II
A Phase II, Multi-Center, Single-Arm, Global Study of MEDI4736 Monotherapy in Patients with Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck (SCCHN)

STUDY 2015-075
Phase II
A Phase II, Randomized, Open-Label, Multi-Center, Global Study of MEDI4736 Monotherapy, Tremelimumab Monotherapy, and MEDI4736 in Combination with Tremelimumab in Patients with Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck (SCCHN)

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

STUDY NEW 2015-081
Phase II
A Multicenter, Randomized, Placebo-controlled, Double-blinded Study of the Efficacy, Safety, and Pharmacokinetics of Cobiprostone for the Prevention of Severe Oral Mucositis in Subjects with Head and Neck Cancer (HNC) Receiving Concurrent Radiation and Chemotherapy (RT/CT)

STAGES I - IV
STUDY 2014-130
Phase I
A Phase 1 Study to Evaluate the Safety, Tolerability, and Efficacy of MEDI4736 in Combination with Tremelimumab in Subjects with Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck
OTHER
STUDY 2015-060
Phase II
A Phase 2 Study to Determine the Efficacy and Safety of BIND-014 (docetaxel nanoparticles for injectable suspension) in Patients with Urothelial Carcinoma, Cholangiocarcinoma, Cervical Cancer, and Squamous Cell Carcinoma of the Head and Neck

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 2012-122
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 2015-021
Phase II
A Phase 2b, Open-Label, Single-Arm Study of Selinexor (KPT-330) plus Low- Dose Dexamethasone in Patients with Multiple Myeloma Quad-refractory to Previous Therapies

STUDY 2015-094
Phase II
Phase II Trial of Combination of Elotuzumab and Lenalidomide +/- Dexamethasone in 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 2014-090
Phase I
A Phase I Study of the Combination of a Selective Inhibitor of Nuclear Export (SINE), Selinexor with Carfilzomib and Dexamethasone in Patients with Relapsed or Relapsed/Refractory Multiple Myeloma.

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

STUDY 2014-011
Phase I
A Phase 1, Multicenter, Open-Label,Dose-Escalation Combination Study of Pomalidomide, Marizomib, And Low-dose Dexamethasone(PMD) in Subjects with Relapsed and Refractory Multiple Myeloma

STUDY 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 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 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 2015-022
Phase I
A Phase Ib Study of the Safety and Pharmacokinetics of MPDL3280A (ANTIPD-L1 ANTIBODY) Alone or in Combination with Lenalidomide in Patients with Multiple Myeloma (Relapsed and Post-Autologous Stem Cell Transplantation)

STUDY 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

STUDY 2015-007
Phase III
A Phase 3, Randomized, Multicenter, Double-Blind, Placebo-Controlled, 2-Arm, Efficacy and Safety Study of NEOD001 Plus Standard of Care vs. Placebo Plus Standard of Care in Subjects with Light Chain (AL) Amyloidosis

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

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

STUDY 2015-070
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 2015-093
Phase II
Randomized Phase II Study to Assess the Role of Nivolumab as Single Agent to Eliminate Minimal Residual Disease and Maintain Remission in Acute Myelogenous Leukemia (AML) Patients After Chemotherapy
**Chronic Lymphocytic Leukemia (CLL)**

**STUDY 2015-009**  
Phase III  
A Pivotal Multicenter Trial of Moxetumomab Pasudotox in Relapsed/Refractory Hairy Cell Leukemia

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

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

**LYMPHOMA**

**Non-Hodgkin's**

**Aggressive (Mantle Cell, Large B-Cell Lymphoma)**

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

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

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

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

**STUDY 2013-178**  
Phase I/II  
A Multicenter Open-Label, Randomized Phase 1b/2, Study of the Bruton's Tyrosine Kinase (BTK) Inhibitor, Ibrutinib, in Combination with Lenalidomide, with and without Rituximab in Subjects with Relapsed or Refractory Diffuse Large B-Cell Lymphoma

**STUDY 2014-134**  
Phase II/II  
A Phase Ib/II Study of Evaluating the Safety, Tolerability and Anti-Tumor Activity of Polatuzumab Vedotin (DCDS4501A) in Combination with Rituximab or Obinutuzumab, Cyclophosphamide, Doxorubicin and Prednisone in Patients with B-Cell Non-Hodgkin's Lymphoma

**STUDY 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
MYELODYSPLASTIC SYNDROME (MDS)
STUDY 2014-037
Phase I
A Phase 1 Study to Evaluate the Safety and Tolerability of MEDI4736 in Subjects with Myelodysplastic Syndrome after Treatment with Hypomethylating Agents

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

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

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

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

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

Melanoma/Skin Clinical Trials
For more information on Melanoma/Skin Clinical Trials, contact the Karmanos Clinical Trials Office at 313-576-9790. To refer a patient for these clinical trials, contact the Karmanos Patient Concierge at 800-527-6266, email newpt@karmanos.org or fill out this online referral form.
ADVENTED STUDY 2013-184
Phase II
Stand Up to Cancer Consortium Genomics-Enabled Medicine for Melanoma (G.E.M.M.): Using Molecularly-Guided Therapy for Patients with BRAF wild-type (BRAFwt) Metastatic Melanoma

STUDY 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

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.
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

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

STAGE I/II
STUDY E4512
Phase III
A Phase III Double-Blind Trial for Surgically Resected Early Stage Non-Small Cell Lung Cancer: Crizotinib versus Placebo for Patients with Tumors Harboring the Anaplastic Lymphoma Kinase (ALK) Fusion Protein

STUDY A081105
Phase III
Randomized Double Blind Placebo Controlled Study of Erlotinib or Placebo in Patients with Completely Resected Epidermal Growth Factor Receptor (EGFR) Mutant Non-Small Cell Lung Cancer (NSCLC)

STAGE III A/B
STUDY 2015-103
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 S1400
Phase II/III
A Biomarker-Driven Master Protocol for Previously Treated Squamous Cell Lung Cancer (Lung-MAP)

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

STAGE IV
ALK
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 NEW 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
**Other Genetic Marker**

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

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

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

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

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

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

**STUDY 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 2014-115**
Phase II
A 3-Arm Phase 2 Double-Blind Randomized Study of Carboplatin, Pemetrexed Plus Placebo versus Carboplatin, Pemetrexed plus 1 or 2 Truncated Courses of Demcizumab in Subjects with Non-Squamous Non-Small Cell Lung Cancer

**STUDY 2015-061**
Phase II
A Phase 2 Proof-of-Concept Study of the Combination of ACP-196 and Pembrolizumab in Subjects with Advanced Non-small Cell Lung Carcinoma

**RECURRENT EGFR**
STUDY 2015-018  
Phase III  
TIGER-3: A Phase 3, Open-label, Multicenter, Randomized Study of Oral Rociletinib (CO-1686) Monotherapy Versus Single-agent Cytotoxic Chemotherapy in Patients with Mutant EGFR Non-small Cell Lung Cancer (NSCLC) after Failure of at Least 1 Previous EGFR-directed Tyrosine Kinase Inhibitor (TKI) and Platinum-doublet Chemotherapy

Other Genetic Marker  
STUDY 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 2015-061  
Phase II  
A Phase 2 Proof-of-Concept Study of the Combination of ACP-196 and Pembrolizumab in Subjects with Advanced Non-small Cell Lung Carcinoma

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

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

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

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

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
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