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**

**STUDY2015-115**  
Phase II  
A Phase 2 Multicenter Study Evaluating the Efficacy of KTE-C19 in Subjects with Relapsed/Refractory Mantle Cell Lymphoma (r/r MCL)

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

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

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

**STUDY NEW 2016-177**  
**Phase II**  
A Phase II, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study of the Safety and Efficacy of PRO 140 for Prophylaxis of Acute Graft-Versus-Host Disease in Patients With Acute Myeloid Leukemia (AML) or Myelodysplastic Syndromes (MDS) Undergoing Allogeneic Stem-Cell Transplantation

**STUDY NEW 2016-209**  
**Phase II**  
A Phase II Trial of CD24Fc for Prevention of Acute Graft-versus-Host Disease Following Myeloablative Allogeneic Hematopoietic Stem Cell Transplant

**STUDY NEW 2017-072**  
**Phase III**  
A Randomized, Double-Blind, Placebo-Controlled Phase 3 Study of Itacitinib or Placebo in Combination With Corticosteroids for the Treatment of First-Line Acute Graft-Versus-Host Disease

**STUDY A051301**  
**Phase III**  
A Randomized Double-Blind Phase III Study of Ibrutinib During and Following Autologous Stem Cell Transplantation Versus Placebo in Patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma of the Activated B-Cell Subtype

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

**STUDY 2016-032**  
**Phase II**  
A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Tolerability of Entospletinib, a Selective SYK Inhibitor, in Combination with Systemic Corticosteroids as First-Line Therapy in Subjects with Chronic Graft Versus Host Disease (cGVHD)

**STUDY 2016-194**  
**Phase III**  
A Randomized, Double-Blind Phase 3 Study of Ibrutinib in Combination With Corticosteroids versus Placebo in Combination With Corticosteroids in Subjects with New Onset Chronic Graft Versus Host Disease (cGVHD)

**STUDY 2016-049**  
**Phase I/II**  
A Phase 1 Non-randomized/2 Randomized Study of ProTmune (ex vivo Programmed Mobilized Peripheral Blood Cells) for Allogeneic Hematopoietic Cell Transplantation in Adult Patients with Hematologic Malignancies.

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

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

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

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

**ADJUVANT HORMONAL**

**STUDY 2016-016**
Phase I/II
A Phase I/II Multicenter Study of the Combination of AZD2014 and Palbociclib on a Background of Hormonal Therapy in Patients with Locally Advanced/Metastatic Estrogen Receptor Positive Breast Cancer Comprising a Safety, Pharmacokinetic and Preliminary Efficacy Evaluation followed by a Randomized, Double-Blind, Placebo-controlled, Parallel Group Extension (PASTOR)

**NEOADJUVANT**

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

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

**STUDY S1418**
Phase III
A Randomized, Phase III Trial to Evaluate the Efficacy and Safety of MK-3475 as Adjuvant Therapy for Triple Receptor-Negative Breast Cancer with > 1 cm Residual Invasive Cancer or Positive Lymph Nodes (>pN1mic) After Neoadjuvant Chemotherapy.

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

**ADVANCED (STAGE IV) CHEMOTHERAPY**

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

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

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

STUDY 2017-064
Phase I/II
A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of INCAGN01876 in Combination With Immune Therapies in Subjects With Advanced or Metastatic Malignancies

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

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

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

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

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

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

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

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

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

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

STUDY NEW A011401
Phase III
Randomized Phase III Trial Evaluating the Role of Weight Loss in Adjuvant Treatment of Overweight and Obese Women With Early Breast Cancer

STUDY 2017-029
Phase I
An Open-Label, Phase I Trial To Determine The Maximum-Tolerated Dose And Investigate Safety, Pharmacokinetics, And Efficacy Of BI 754091 In Patients With Advanced Solid Tumours

STUDY 2016-116
Phase II
A Phase 2 Study of Cediranib in Combination with Olaparib in Advanced Solid Tumors

STUDY 2016-152
Phase I
A Phase 1b Study to Evaluate TAK-659 in Combination With Nivolumab in Patients With Advanced Solid Tumors

STUDY 2016-018
Phase I
A Phase 1, First-in-Human, Multi-Part Study of RAD140 in Postmenopausal Women with Hormone Receptor Positive Breast Cancer

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

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

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

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

STUDY 2017-064
Phase I/II
A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of INCAGN01876 in Combination With Immune Therapies in
Subjects With Advanced or Metastatic Malignancies

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

**GASTRIC AND GASTROESOPHAGEAL JUNCTION**  
**Metastatic**  
**STUDY 2016-210**  
Phase I/II  
An Open-Label, Dose-Finding And Proof Of Concept Study Of The PD-L1 Probody Therapeutic, CX-072, As Monotherapy And In Combination With Yervoy (Ipilimumab) Or With Zelboraf (Vemurafenib) In Subjects With Advanced Or Recurrent Solid Tumors Or Lymphomas

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

**STUDY 2017-064**  
Phase I/II  
A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of INCAGN01876 in Combination With Immune Therapies in Subjects With Advanced or Metastatic Malignancies

**STUDY 2017-029**  
Phase I  
An Open-Label, Phase I Trial To Determine The Maximum-Tolerated Dose And Investigate Safety, Pharmacokinetics, And Efficacy Of BI 754091 In Patients With Advanced Solid Tumours

**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 2017-054**  
Phase III  
A Prospective, Randomized, Double-Blinded, Placebo-Controlled, Multinational, Multicenter, Parallel-Group, Phase III Study to Evaluate the Efficacy and Safety of Apatinib plus Best Supportive Care (BSC) Compared to Placebo plus BSC in Patients with Advanced or Metastatic Gastric Cancer (GC)

**STUDY NEW 2017-087**  
Phase I  
A Phase 1, Open-label, Dose-Escalation Study of SEA-CD40 in Adult Patients with Advanced Malignancies

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

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

**STUDY 2016-003**  
Phase I/II  
A Phase 1b/2 Study of Ibrutinib Combination Therapy in Selected Advanced Gastrointestinal And Genitourinary Tumors
STUDY 2016-025
Phase I/II
A Multi-Center Study of hTERT Immunotherapy Alone or in Combination with IL-12 DNA followed by Electroporation in Adults with Solid Tumors at High Risk of Relapse Post Definitive Surgery and Standard Therapy

PANCREAS

Adenocarcinoma
Borderline Resectable
STUDY A021501
Phase III
Preoperative Extended Chemotherapy vs. Chemotherapy Plus Hypofractionated Radiation Therapy for Borderline Resectable Adenocarcinoma of the Head of the Pancreas

Metastatic
STUDY S1513
Phase II
Randomized Phase II Study of 2nd Line FOLFIRI versus Modified FOLFIRI with PARP Inhibitor ABT-888 (Veliparib) (NSC-737664) in Metastatic Pancreatic Cancer

STUDY S1505
Phase II
A Randomized Phase II Study of Perioperative mFOLFIRINOX versus Gemcitabine/NAB-Paclitaxel as Therapy for Resectable Pancreatic Adenocarcinoma

STUDY 2016-011
Phase III
A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study of PEGylated Recombinant Human Hyaluronidase (PEGPH20) in Combination with nab-Paclitaxel Plus Gemcitabine Compared with Placebo Plus nab- Paclitaxel and Gemcitabine in Subjects with Hyaluronan-High Stage IV Previously Untreated Pancreatic Ductal Adenocarcinoma

Neuroendocrine
STUDY EA2142
Phase II
Randomized Phase II Study of Cisplatin and Etopeoside versus Temozolomide and Capecitabine in Patients with Advanced G3 Non-Small Cell Gastroenteropancreatic Neuroendocrine Carcinomas

STUDY EA2161
Phase II
A Phase II Study of MLN0128 (TAK-228) in Rapalog-Resistant Advanced Pancreatic Neuroendocrine Tumors (PNET)

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

STUDY 2017-069
Phase I/II
A Phase 1/2a Study of BMS-986205 Administered in Combination with Nivolumab anti-PD-1 Monoclonal Antibody) and in Combination with Both Nivolumab and Ipilimumab (anti-CTLA-4 Monoclonal Antibody) in Advanced Malignant Tumors

STUDY 2016-116
Phase II
A Phase 2 Study of Cediranib in Combination with Olaparib in Advanced Solid Tumors

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

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

STUDY 2017-064
Phase I/II
A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of INCAGN01876 in Combination With Immune Therapies in Subjects With Advanced or Metastatic Malignancies

STUDY 2017-034
Phase I
A Phase Ib Study Of PDR001 In Combination With Sorafenib In Patients With Advanced Hepatocellular Carcinoma (HCC)

STUDY 2016-039
Phase I/II
A Phase Ib/II Clinical Study of BBI608 in Combination with Sorafenib or BBI503 in Combination with Sorafenib in Adult Patients with Hepatocellular Carcinoma

STUDY 2016-079
Phase I
An Open-Label Multicenter Phase 1 Study to Evaluate the Safety, Pharmacokinetics and Pharmacodynamics of H3B-6527 in Subjects With Advanced Hepatocellular Carcinoma or Intrahepatic Cholangiocarcinoma

BILIARY/GALL BLADDER
Metastatic
STUDY 2016-186
Phase II
A Phase 2, Open-Label, Single-Arm, Multicenter Study to Evaluate the Efficacy and Safety of INCB054828 in Subjects With Advanced/Metastatic or Surgically Unresectable Cholangiocarcinoma Including FGFR2 Translocations Who Failed Previous Therapy

STUDY 2014-081
Phase II
A Phase II Multicenter, Single Arm Study of Oral BGI398 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

Metastatic (Includes Rectal)
2nd Line
STUDY 2016-055
Phase I
A Phase 1/1b, Open-Label, Multicenter, Repeat-Dose, Dose-Selection Study of CPI-444 as Single Agent and in Combination with Atezolizumab in Patients with Selected Incurable Cancers

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

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

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

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

**STUDY 2016-185**
**Phase I/II**
A Phase 1b/2 Trial of Hu5F9-G4 in Combination with Cetuximab in Patients with Solid Tumors and Advanced Colorectal Cancer

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

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

**STUDY 2016-003**
**Phase I/II**
A Phase 1b/2 Study of Ibrutinib Combination Therapy in Selected Advanced Gastrointestinal And Genitourinary Tumors

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

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

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

**STUDY NRG-GI002**
**Phase II**
A Phase II Clinical Trial Platform of Sensitization Utilizing Total Neoadjuvant Therapy (TNT) Phase II in Rectal Cancer

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

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

STUDY 2017-064
Phase I/II
A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of INCAGN01876 in Combination With Immune Therapies in Subjects With Advanced or Metastatic Malignancies

Genitourinary Clinical Trials

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RENA
STUDY S1500
Phase II
A Randomized, Phase II Efficacy Assessment of Multiple MET Kinase Inhibitors (Cabozantinib [NSC #761968], Crizotinib [NSC #749005], Savolitinib [NSC #785348], and Sunitinib [NSC #736511]) in Metastatic Papillary Renal Carcinoma (PAPMET)

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

STUDY 2016-003
Phase I/II
A Phase 1b/2 Study of Ibrutinib Combination Therapy in Selected Advanced Gastrointestinal And Genitourinary Tumors

STUDY 2015-168
Phase III
A Phase 3, Randomized, Controlled, Multi-Center, Open-Label Study to Compare Tivozanib Hydrochloride to Sorafenib in Subjects With Refractory Advanced Renal Cell Carcinoma

STUDY 2017-069
Phase I/II
A Phase 1/2a Study of BMS-986205 Administered in Combination with Nivolumab anti-PD-1 Monoclonal Antibody) and in Combination with Both Nivolumab and Iplimumab (anti-CTLA-4 Monoclonal Antibody) in Advanced Malignant Tumors

STUDY 2016-201
Phase III
A Multicenter, Open-label, Randomized, Phase 3 Trial to Compare the Efficacy and Safety of Lenvatinib in Combination with Everolimus or Pembrolizumab Versus Sunitinib Alone in First-Line Treatment of Subjects with Advanced Renal Cell Carcinoma (CLEAR).

STUDY 2016-126
Phase II
Phase II Study of Atezolizumab + Bevacizumab in Patients with Advanced Non-Clear Cell Renal Cell Carcinoma

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

STUDY 2017-036
Phase I
A Phase I Open-Label Pharmacokinetics and Safety Study of Talazoparib (MDV3800) in Patients With Advanced Solid Tumors and Normal or Varying Degrees of Renal Impairment

STUDY 2017-064
Phase I/II
A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of INCAGN01876 in Combination With Immune Therapies in Subjects With Advanced or Metastatic Malignancies

STUDY 2017-029
Phase I
An Open-Label, Phase I Trial To Determine The Maximum-Tolerated Dose And Investigate Safety, Pharmacokinetics, And Efficacy Of BI 754091 In Patients With Advanced Solid Tumors

STUDY EA8143
Phase III
A Phase 3 RandOmized Study Comparing PERioperative Nivolumab vs. Observation in Patients with Localized Renal Cell Carcinoma Undergoing Nephrectomy (PROSPER RCC)

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

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

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

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

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

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

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

STUDY 2015-059
Phase I/II
A Phase Ib/II, Multicentre, Open Label, Randomised Study of BI 836845 in Combination with Enzalutamide, versus Enzalutamide alone, in Metastatic Castration-Resistant Prostate Cancer (CRPC) Following Disease Progression on Docetaxel-Based Chemotherapy and Abiraterone

STUDY 2016-153
Phase I
<table>
<thead>
<tr>
<th>Study Code</th>
<th>Phase</th>
<th>Description</th>
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<tr>
<td>STUDY 2016-069</td>
<td>Phase II</td>
<td>Phase II Trial of Pembrolizumab (MK-3475) in Subjects with Metastatic Castration-Resistant Prostate Cancer (mCRPC) Previously Treated with Chemotherapy (KEYNOTE-199)</td>
</tr>
<tr>
<td>STUDY 2016-178</td>
<td>Phase I</td>
<td>A Phase 1, Dose-Finding and Signal-Seeking Study of the Safety and Efficacy of Intravenous CAVATAK(TM) (coxsackievirus A21, CVA21) Alone and in Combination with Pembrolizumab in Patients with Late Stage Solid Tumours (NSCLC, Castrate-Resistant Prostate Cancer, Melanoma and Bladder Cancer)</td>
</tr>
<tr>
<td>STUDY NEW 2016-066</td>
<td>Phase I/II</td>
<td>A Phase 1b/2 Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of GS-5829 as a Single Agent and In Combination With Enzalutamide in Subjects with Metastatic Castrate-Resistant Prostate Cancer</td>
</tr>
<tr>
<td>STUDY NEW 2016-184</td>
<td>Phase III</td>
<td>A Phase III, Multicenter, Randomized Study of Atezolizumab (Anti-Pd-L1 Antibody) in Combination with Enzalutamide Versus Enzalutamide Alone in Patients with Metastatic Castration-Resistant Prostate Cancer After Failure of an Androgen Synthesis Inhibitor and Failure of, Ineligibility for, or Refusal of a Taxane Regimen</td>
</tr>
<tr>
<td>STUDY 2017-015</td>
<td>Phase I</td>
<td>A Phase 1 Study of a Prostate-Specific Membrane Antigen Targeting-Tubulysin Conjugate EC1169 in Patients with Recurrent Metastatic, Castration-Resistant, Prostate Cancer (mCRPC)</td>
</tr>
<tr>
<td>STUDY 2017-051</td>
<td>Phase I</td>
<td>A Phase I Study of PCUR-101 in Combination with Androgen Suppression Therapy in the Treatment of Patients with Metastatic Castration-Resistant Prostate Cancer</td>
</tr>
<tr>
<td>STUDY 2015-167</td>
<td>Phase II</td>
<td>A Randomized Phase 2 Trial of Ascorbic Acid in Combination with Docetaxel in Men with Metastatic Prostate Cancer</td>
</tr>
<tr>
<td>STUDY 2017-046</td>
<td>Phase I</td>
<td>A Phase IB Open-Label, Dose Escalation and Expansion Study to Investigate the Safety, Pharmacokinetics, Pharmacodynamics and Clinical Activity of GSK525762 in Combination with Androgen Deprivation Therapy and Other Agents in Subjects with Castrate Resistant Prostate Cancer (CRPC)</td>
</tr>
<tr>
<td>STUDY 2015-029</td>
<td>Phase II</td>
<td>Phase II Randomized Placebo-Controlled Double-Blind Study of Salvage Radiation Therapy (SRT) Plus Placebo Versus SRT Plus Enzalutamide in Men with High-Risk PSA-Recurrent Prostate Cancer after Radical Prostatectomy</td>
</tr>
<tr>
<td>STUDY 2015-033</td>
<td>Phase III</td>
<td>A Randomized, Double Blind, Multicenter, Parallel-Group, Phase III Study to Evaluate Efficacy and Safety of DCVAC/PCa Versus Placebo in Men with Metastatic Castration Resistant Prostate Cancer Eligible for 1st Line Chemotherapy</td>
</tr>
<tr>
<td>STUDY 2015-057</td>
<td>Phase I</td>
<td>A Phase I, Open-label, Multicenter Study to Assess the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Preliminary Anti-tumor Activity of AZD8186 in Patients with Advanced Castration-resistant Prostate Cancer (CRPC), Squamous Non-Small Cell Lung Cancer (sqNSCLC), Triple Negative Breast Cancer (TNBC) and Patients with Known PTEN-deficient/mutated or PIK3CB Mutated/amplified Advanced Solid Malignancies, as Monotherapy and in Combination with Abiraterone Acetate or AZD2014</td>
</tr>
</tbody>
</table>
**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.

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

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

**STUDY 2017-029**  
**Phase I**  
An Open-Label, Phase I Trial To Determine The Maximum-Tolerated Dose And Investigate Safety, Pharmacokinetics, And Efficacy Of BI 754091 In Patients With Advanced Solid Tumours

**STUDY 2015-084**  
**Phase III**  
A Phase III, Open-Label, Multicenter, Randomized Study of Atezolizumab (Anti-PD-L1 Antibody) Versus Observation as Adjuvant Therapy in Patients With, High-Risk Muscle-Invasive Urothelial Carcinoma After Surgical Resection

**STUDY 2016-003**  
**Phase I/II**  
A Phase 1b/2 Study of Ibrutinib Combination Therapy in Selected Advanced Gastrointestinal And Genitourinary Tumors

**STUDY S1314**  
**Phase II**  
A Randomized Phase II Study of Co-Expression Extrapolation (COXEN) with Neoadjuvant Chemotherapy for Localized, Muscle-Invasive Bladder Cancer

**STUDY 2017-064**  
**Phase I/II**  
A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of INCAGN01876 in Combination With Immune Therapies in Subjects With Advanced or Metastatic Malignancies

**STUDY 2017-069**  
**Phase I/II**  
A Phase 1/2a Study of BMS-986205 Administered in Combination with Nivolumab anti-PD-1 Monoclonal Antibody) and in Combination with Both Nivolumab and Ipilimumab (anti-CTLA-4 Monoclonal Antibody) in Advanced Malignant Tumors

**STUDY 2016-178**  
**Phase I**  
A Phase 1, Dose-Finding and Signal-Seeking Study of the Safety and Efficacy of Intravenous CAVATAK(TM) (coxsackievirus A21, CVA21) Alone and in Combination with Pembrolizumab in Patients with Late Stage Solid Tumours (NSCLC, Castrate-Resistant Prostate Cancer, Melanoma and Bladder Cancer)

**STUDY 2015-101**  
**Phase I/II**  
A Study of Intravesical Bacillus Calmette-Guerin (BCG) in Combination with ALT-803 in patients with BCG-naïve Non-Muscle Invasive Bladder Cancer

**STUDY 2016-175**  
**Phase II**  
A Randomized Phase 2 Trial of Cisplatin/Gemcitabine with or without VX-970 in Metastatic Urothelial Carcinoma
STUDY 2016-157
Phase I
Phase I Clinical Trial of VX-970 in Combination with the Topoisomerase I Inhibitor Irinotecan in Patients with Advanced Solid Tumors

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

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

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

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

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

STUDY NEW 2017-076
Phase I/II
A Phase 1b/2, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Parallel-Group Study of B-701 Plus Docetaxel Versus Placebo Plus Docetaxel in the Treatment of Locally Advanced or Metastatic Urothelial Cell Carcinoma in Subjects who have Relapsed After, or are Refractory to Standard Therapy

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

Gynecologic Clinical Trials

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

CERVIX
STUDY GOG-3009
Phase III
Phase 3 Study of ADXS11-001 Administered Following Chemoradiation as Adjuvant Treatment for High Risk Locally Advanced Cervical Cancer: AIM2CERV

STUDY 2016-081
Phase I/II
Phase 1-2 Study of MEDI4736 Alone or In Combination with ADXS11-001 In Recurrent/Persistent or Metastatic Cervical or HPV+
Phase I/II Head & Neck Cancer

**STUDY NEW NRG-GY006**

**Phase II**
Randomized Phase II Trial of Radiation Therapy and Cisplatin Alone or in Combination with Intravenous Triapine in Women with Newly Diagnosed Bulky Stage IB2, Stage II, IIIB, or IVA Cancer of the Uterine Cervix or Stage II-IV A Vaginal Cancer

**STUDY 2017-069**

**Phase I/II**
A Phase 1/2a Study of BMS-986205 Administered in Combination with Nivolumab anti-PD-1 Monoclonal Antibody and in Combination with Both Nivolumab and Ipilimumab (anti-CTLA-4 Monoclonal Antibody) in Advanced Malignant Tumors

**STUDY 2017-064**

**Phase I/II**
A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of INCAGN01876 in Combination With Immune Therapies in Subjects With Advanced or Metastatic Malignancies

### OVARY

**STUDY 2015-110**

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

**STUDY 2015-157**

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

**STUDY 2017-064**

**Phase I/II**
A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of INCAGN01876 in Combination With Immune Therapies in Subjects With Advanced or Metastatic Malignancies

**STUDY 2017-029**

**Phase I**
An Open-Label, Phase I Trial To Determine The Maximum-Tolerated Dose And Investigate Safety, Pharmacokinetics, And Efficacy Of BI 754091 In Patients With Advanced Solid Tumours

**STUDY 2017-023**

**Phase I/II**
P/SARRO: p53 Suppressor Activation in Recurrent High Grade Serous Ovarian Cancer, a Phase Ib/II Study of Systemic Carboplatin/Pegylated Liposomal Doxorubicin Combination Chemotherapy With or Without APR-246

**STUDY 2016-025**

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

**STUDY NEW 2017-062**

**Phase II**
A Multicentre Phase II Study of AZD1775 plus Chemotherapy in Patients with Platinum-Resistant Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

**STUDY 2016-037**

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

**STUDY 2016-204**

**Phase II**
Non-Randomized, Open-Label Phase II Study to Assess Olaparib Tablets as a Treatment for Subjects with Different HRD Tumor
Status and with Platinum-Sensitive, Relapsed, High-Grade Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer That Have Received at Least 2 Prior Lines of Chemotherapy

**STUDY GOG-3015**  
**Phase III**  
A Phase III, Multicenter, Randomized, Study of Atezolizumab Versus Placebo Administered in Combination with Paclitaxel, Carboplatin, and Bevacizumab to Patients with Newly-Diagnosed Stage III or Stage IV Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

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

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

**STUDY 2015-066**  
**Phase III**  
A Phase III, Open Label, Randomised, Controlled, Multi-centre Study to assess the efficacy and safety of Olaparib Monotherapy versus Physician's Choice Single Agent Chemotherapy in the Treatment of Platinum Sensitive Relapsed Ovarian Cancer in Patients carrying germline BRCA1/2 Mutations

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

**STUDY 2017-064**  
**Phase I/II**  
A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of INCAGN01876 in Combination With Immune Therapies in Subjects With Advanced or Metastatic Malignancies

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

**OTHER**  
**STUDY 2017-023**  
**Phase I/II**  
PiSARRO: p53 Suppressor Activation in Recurrent High Grade Serous Ovarian Cancer, a Phase Ib/II Study of Systemic Carboplatin/Pegylated Liposomal Doxorubicin Combination Chemotherapy With or Without APR-246

**STUDY NEW NRG-GY006**  
**Phase II**  
Randomized Phase II Trial of Radiation Therapy and Cisplatin Alone or in Combination with Intravenous Triapine in Women with Newly Diagnosed Bulky Stage IB2, Stage II, IIIB, or IVA Cancer of the Uterine Cervix or Stage II-IVA Vaginal Cancer

**STUDY NEW 2017-062**  
**Phase II**  
A Multicentre Phase II Study of AZD1775 plus Chemotherapy in Patients with Platinum-Resistant Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer
STUDY 2016-204
Phase II
Non-Randomized, Open-Label Phase II Study to Assess Olaparib Tablets as a Treatment for Subjects with Different HRD Tumor Status and with Platinum-Sensitive, Relapsed, High-Grade Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer That Have Received at Least 2 Prior Lines of Chemotherapy

STUDY GOG-3015
Phase III
A Phase III, Multicenter, Randomized, Study of Atezolizumab Versus Placebo Administered in Combination with Paclitaxel, Carboplatin, and Bevacizumab to Patients with Newly-Diagnosed Stage III or Stage IV Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

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

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

STUDY 2016-174
Phase I/II
Phase I/II Clinical Trial of NC-6004 in Combination with 5-FU and Cetuximab as First-line Treatment in Patients with Recurrent or Metastatic Squamous Cell Carcinoma of The Head and Neck

STUDY NEW 2016-133
Phase II
A Multicenter, Randomized, Double-Blind Phase 2 Trial of Lenvatinib (E7080) in Subjects With (131) I-Refractory Differentiated Thyroid Cancer to Evaluate Whether an Oral Starting Dose of 18 mg Daily Will Provide Comparable Efficacy to a 24-mg Starting Dose, But Have a Better Safety Profile

STUDY 2017-003
Phase III
A Randomized Phase III Study of Pembrolizumab Given Concomitantly with Chemoradiation and as Maintenance Therapy versus Chemoradiation Alone in Subjects with Locally Advanced Head and Neck Squamous Cell Carcinoma

STUDY 2016-165
TITLE
A Randomized Double-Blind Phase 3 Study of Avelumab in Combination with Standard of Care Chemoradiotherapy (Cisplatin Plus Definitive Radiation Therapy) Versus Standard of Care Chemoradiotherapy in the Front-Line Treatment of Patients with Locally Advanced Squamous Cell Carcinoma of the Head and Neck

STAGES I - IV
STUDY 2016-050
Phase I

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

STUDY 2016-174
Phase I/II
Phase I/II Clinical Trial of NC-6004 in Combination with 5-FU and Cetuximab as First-line Treatment in Patients with Recurrent or Metastatic Squamous Cell Carcinoma of The Head and Neck

STUDY NEW 2016-133
Phase II
A Multicenter, Randomized, Double-Blind Phase 2 Trial of Lenvatinib (E7080) in Subjects With (131) I-Refractory Differentiated Thyroid Cancer to Evaluate Whether an Oral Starting Dose of 18 mg Daily Will Provide Comparable Efficacy to a 24-mg Starting Dose, But Have a Better Safety Profile

STUDY 2017-003
Phase III
A Randomized Phase III Study of Pembrolizumab Given Concomitantly with Chemoradiation and as Maintenance Therapy versus Chemoradiation Alone in Subjects with Locally Advanced Head and Neck Squamous Cell Carcinoma

STUDY 2016-165
TITLE
A Randomized Double-Blind Phase 3 Study of Avelumab in Combination with Standard of Care Chemoradiotherapy (Cisplatin Plus Definitive Radiation Therapy) Versus Standard of Care Chemoradiotherapy in the Front-Line Treatment of Patients with Locally Advanced Squamous Cell Carcinoma of the Head and Neck
A Phase 1 Dose Escalation and Cohort Expansion Study of ERY974, an Anti-Glypican 3 (GPC3)/CD3 Bispecific Antibody, in Patients with Advanced Solid Tumors.

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

**ANY STAGE**

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

**STUDY 2016-212**
Phase II
A Phase 2 Study to Evaluate the Safety, Tolerability and Efficacy of Cell Transfer Therapy Using Autologous Tumor Infiltrating Lymphocytes (LN-145) followed by IL-2 in Patients with Recurrent and/or Metastatic Squamous Cell Carcinoma of the Head and Neck

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

**STUDY 2017-069**
Phase I/II
A Phase 1/2a Study of BMS-986205 Administered in Combination with Nivolumab anti-PD-1 Monoclonal Antibody) and in Combination with Both Nivolumab and Iplilimumab (anti-CTLA-4 Monoclonal Antibody) in Advanced Malignant Tumors

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

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

**OTHER**

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

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

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

**STUDY NEW 2017-087**
Phase I
A Phase 1, Open-label, Dose-Escalation Study of SEA-CD40 in Adult Patients with Advanced Malignancies

**STUDY 2017-064**
Phase I/II
A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of INCAGN01876 in Combination With Immune Therapies in Subjects With Advanced or Metastatic Malignancies

STUDY 2016-152
Phase I
A Phase 1b Study to Evaluate TAK-659 in Combination With Nivolumab in Patients With Advanced Solid Tumors

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

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

STUDY 2016-146
Phase I
Phase 1 Study of SGN-CD352A in Patients with Relapsed or Refractory Multiple Myeloma

STUDY 2017-005
Phase I/II
A Phase 1/2, Open-Label Safety, Pharmacokinetic, and Efficacy Study of TAS4464 in Patients with Multiple Myeloma or Lymphoma

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

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

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

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

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

STUDY 2017-024
Phase II
A Single Arm, Open-Label, Phase 2 Study of Melflufen in Combination with Dexamethasone in Patients with Relapsed Refractory Multiple Myeloma who are Refractory to Pomalidomide and/or Daratumumab

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 2016-179
Phase II
Phase 2, Randomized, Open-Label Study Comparing Daratumumab, Lenalidomide, Bortezomib, and Dexamethasone (D-RVd) Versus Lenalidomide, Bortezomib, and Dexamethasone (Rvd) in Subjects With Newly Diagnosed Multiple Myeloma Eligible for High-Dose Chemotherapy and Autologous Stem Cell Transplantation

STUDY 2016-062
Phase I/II
Phase 1/2 Trial of Idasanutlin in Combination with Ixazomib and Dexamethasone in Patients with 17p Deleted, Relapsed 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 2016-200
Phase II
A Randomized Phase 2 Trial of Revlimid/ Dexamethasone/ Elotuzumab +/- Cyclophosphamide followed by Revlimid/ Dexamethasone/Elotuzumab Maintenance as Second-line Therapy for Patients with Relapsed AL Amyloidosis

STUDY NEW 2017-067
Phase III
Randomized Phase 3 Study to Evaluate the Efficacy and Safety of Daratumumab in Combination with Cyclophosphamide, Bortezomib and Dexamethasone (CyBorD) Compared With CyBorD Alone in Newly Diagnosed Systemic AL Amyloidosis

STUDY 2016-060
Phase I
A Phase 1, First-in-Human, Open-Label, Dose Escalation Study of JNJ-63709178, a Humanized CD123 x CD3 DuoBody in Subjects with Relapsed or Refractory AML

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

Acute Myeloid Leukemia (AML)
STUDY 2017-006
Phase I/II
A Phase 1b/2 Study of Entospletinib (GS-9973) Monotherapy and in Combination with Chemotherapy in Patients with Acute Myeloid
**Leukemia (AML)**

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

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

**STUDY 2016-169**  
Phase II  
A Randomized, Phase II Study of CX-01 Combined With Standard Induction Therapy for Newly Diagnosed Acute Myeloid Leukemia

**STUDY 2016-103**  
Phase I  
An Open-label, Multicenter Phase 1 Trial to Evaluate the Safety, Pharmacokinetics and Pharmacodynamics of Splicing Modulator H3B-8800 for Subjects With Myelodysplastic Syndromes, Acute Myeloid Leukemia, and Chronic Myelomonocytic Leukemia

**Chronic Myeloid Leukemia (CML)**

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

**LYMPHOMA**

**Hodgkin's**

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

**STUDY NEW 2017-100**  
Phase III  
Randomized, Open-label, Phase 3 Trial of Nivolumab plus Brentuximab vedotin versus Brentuximab vedotin alone in Participants with Relapsed Refractory or Ineligible for Autologous Stem Cell Transplant (ASCT) Advanced Stage Classical Hodgkin Lymphoma (CheckMate 812: CHECKpoint pathway and nivoluMAb clinical Trial Evaluation 812)

**STUDY 016-058**  
Phase III  
A Phase III, Randomized, Open-label, Clinical Trial to Compare Pembrolizumab with Brentuximab Vedotin in Subjects with Relapsed or Refractory Classical Hodgkin Lymphoma

**Non-Hodgkin's**

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

**STUDY 2017-025**  
Phase III  
Phase 3 Study of Ibrutinib in Combination with Venetoclax in Subjects with Mantle Cell Lymphoma

**STUDY 2013-178**  
Phase I/Ii  
A Multicenter Open-Label, Randomized Phase 1b/2, Study of the Brutons 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 2017-007**  
Phase I
A Multi-Center, Open label, Dose Escalation, Phase I/IIb Study to Evaluate the Safety and Efficacy of RP4010, a Calcium Release Activated Calcium (CRAC) Channel Inhibitor, in Patients with Relapsed or Refractory Non-Hodgkin Lymphoma

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

**STUDY 2016-176**  
**Phase II**  
A Phase 2, Multicenter, International, Open-Label, Safety and Efficacy Study of INCB050465 in Subjects With Relapsed or Refractory Diffuse Large B-Cell Lymphoma (CITADEL-202)

**STUDY 2016-147**  
**Phase II**  
A Phase 2, Open-label, Single-arm, Two-cohort Study of Nivolumab in Relapsed/Refractory Primary Central Nervous System Lymphoma (PCNSL) or Relapsed/Refractory Primary Testicular Lymphoma (PTL)

**STUDY 2015-150**  
**Phase I/II**  
A Phase I/ib Study Evaluating The Safety And Efficacy Of Obinutuzumab In Combination With Polatuzumab Vedotin And Lenalidomide In Patients With Relapsed Or Refractory Follicular Or Diffuse Large B-Cell Lymphoma

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

**STUDY 2016-139**  
**Phase I**  
A Phase I/ib, Dose Escalation Study to Evaluate Safety and Efficacy of RP6530, a dual PI3K δ/γ inhibitor, in Patients with Relapsed or Refractory T-cell Lymphoma

**STUDY 2016-125**  
**Phase I/II**  
A Phase 1b/2 Investigator Initiated Study of RCHOP in Combination with Selinexor (KPT-330) in B Cell Non Phase I/II Hodgkin's Lymphoma

**STUDY 2016-210**  
**Phase I/II**  
An Open-Label, Dose-Finding And Proof Of Concept Study Of The PD-L1 Probody Therapeutic, CX-072, As Monotherapy And In Combination With Yervoy (Ipilimumab) Or With Zelboraf (Vemurafenib) In Subjects With Advanced Or Recurrent Solid Tumors Or Lymphomas

**STUDY 2017-069**  
**Phase I/II**  
A Phase 1/2a Study of BMS-986205 Administered in Combination with Nivolumab anti-PD-1 Monoclonal Antibody) and in Combination with Both Nivolumab and Ipilimumab (anti-CTLA-4 Monoclonal Antibody) in Advanced Malignant Tumors

**STUDY 2017-008**  
**Phase I**  
A Phase 1, Open-Label, Dose Escalation and Dose Expansion Trial Evaluating the Safety, Pharmacokinetics, Pharmacodynamics, and Clinical Effects of Orally Administered CA-170 in Patients with Advanced Tumors and 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

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

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

**STUDY NEW 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

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

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

Immunotherapy Clinical Trials

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

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](#).

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

**STUDY 2016-210**
Phase I/II
An Open-Label, Dose-Finding And Proof Of Concept Study Of The PD-L1 Probody Therapeutic, CX-072, As Monotherapy And In Combination With Yervoy (Ipilimumab) Or With Zelboraf (Vemurafenib) In Subjects With Advanced Or Recurrent Solid Tumors Or Lymphomas

**STUDY 2017-029**
Phase I
<table>
<thead>
<tr>
<th>Study Number</th>
<th>Sponsor</th>
<th>Phase</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017-087</td>
<td></td>
<td>I</td>
<td>An Open-Label, Phase I Trial To Determine The Maximum-Tolerated Dose And Investigate Safety, Pharmacokinetics, And Efficacy Of BI 754091 In Patients With Advanced Solid Tumors</td>
</tr>
<tr>
<td>2017-064</td>
<td></td>
<td>I/II</td>
<td>A Phase 1, Open-label, Dose-Escalation Study of SEA-CD40 in Adult Patients with Advanced Malignancies</td>
</tr>
<tr>
<td>2017-053</td>
<td></td>
<td>I/II</td>
<td>A Study to Evaluate the Safety and Efficacy of the CD40 Agonistic Antibody APX005M Administered in Combination with Nivolumab in Subjects with Nonsmall Cell Lung Cancer and Subjects with Metastatic Melanoma</td>
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<tr>
<td>2016-015</td>
<td></td>
<td>II</td>
<td>A Phase 2 Study of REGN2810, a Fully Human Monoclonal Antibody to Programmed Death-1 (PD-1), in Patients with Advanced Cutaneous Squamous Cell Carcinoma (CSCC)</td>
</tr>
<tr>
<td>2017-069</td>
<td></td>
<td>I/II</td>
<td>A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of INCAGN01876 in Combination With Immune Therapies in Subjects With Advanced or Metastatic Malignancies</td>
</tr>
<tr>
<td>2016-037</td>
<td></td>
<td>I</td>
<td>A Phase 1 Study of ALKS 4230 in Subjects with Advanced Solid Tumors</td>
</tr>
<tr>
<td>2015-004</td>
<td></td>
<td>II</td>
<td>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</td>
</tr>
<tr>
<td>2013-047</td>
<td></td>
<td>I</td>
<td>A Phase 1 Multiple Ascending Dose Study of DS-3032B, an Oral MDM2 Inhibitor, in Subjects with Advanced Solid Tumors or Lymphomas</td>
</tr>
<tr>
<td>2009-139</td>
<td></td>
<td>I</td>
<td>Phase I Safety, Pharmacokinetic and Pharmacodynamic Study of PF-02341066, A C-Met/HGFR Selective Tyrosine Kinase Inhibitor, Administered Orally to Patients with Advanced Cancer</td>
</tr>
<tr>
<td>S1320</td>
<td></td>
<td>II</td>
<td>A Randomized, Phase II Trial of Intermittent Versus Continuous Dosing of Dabrafenib (NSC-763760) and Trametinib (NSC-763093) in BRAFV600E/K Mutant Melanoma</td>
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<tr>
<td>2016-017</td>
<td></td>
<td>I/II</td>
<td>A Phase 1B/2 Open-Label Study to Evaluate Safety, Clinical Activity, Pharmacokinetics and Pharmacodynamics of Avelumab* (MSB0010718C) in Combination with Other Cancer Immunotherapies in Patients with Advanced Malignancies</td>
</tr>
</tbody>
</table>
OTHER
STUDY 2015-156
Phase I
A Phase 1 Dose Escalation and Cohort Expansion Study of the Safety, Tolerability, and Efficacy of Anti-LAG-3 Monoclonal Antibody (BMS-986016) Administered Alone and in Combination with Anti-PD-1 Monoclonal Antibody (Nivolumab, BMS-936558) in Advanced Solid Tumors

STUDY 2017-064
Phase I/II
A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of INCAGN01876 in Combination With Immune Therapies in Subjects With Advanced or Metastatic Malignancies

STUDY 2017-029
Phase I
An Open-Label, Phase I Trial To Determine The Maximum-Tolerated Dose And Investigate Safety, Pharmacokinetics, And Efficacy Of BI 754091 In Patients With Advanced Solid Tumours

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

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

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

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

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

ALL SOLID TUMORS
STUDY 2012-069
Phase I
A Phase 1, Open-Label, Non-Randomized, Dose-Escalating Safety, Tolerability, And Pharmacokinetic Study Of TAS-114 In Combination With Capecitabine In Patients With Advanced Solid Tumors TAS-114
STUDY 2011-166
Phase I
A Phase I and Pharmacokinetic Single Agent Study of Romidepsin in Patients with Lymphomas, Chronic Lymphocytic Leukemia and Select Solid Tumors and Varying Degrees of Liver Dysfunction

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

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

STUDY 2016-170
Phase I/II
A Phase I/IIa, Open-Label, Dose-escalation Study Investigating the Safety, Tolerability, and Pharmacokinetics of Intravenous Liposomal Vinorelbine Tartrate Injection in Patients with Advanced Malignancy

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

STUDY NEW 2017-087
Phase I
A Phase 1, Open-label, Dose-Escalation Study of SEA-CD40 in Adult Patients with Advanced Malignancies

STUDY 2016-210
Phase I/II
An Open-Label, Dose-Finding And Proof Of Concept Study Of The PD-L1 Probody Therapeutic, CX-072, As Monotherapy And In Combination With Yervoy (Ipilimumab) Or With Zelboraf (Vemurafenib) In Subjects With Advanced Or Recurrent Solid Tumors Or Lymphomas

STUDY 2016-185
Phase I/II
A Phase 1b/2 Trial of Hu5F9-G4 in Combination with Cetuximab in Patients with Solid Tumors and Advanced Colorectal Cancer

STUDY 2017-036
Phase I
A Phase I Open-Label Pharmacokinetics and Safety Study of Talazoparib (MDV3800) in Patients With Advanced Solid Tumors and Normal or Varying Degrees of Renal Impairment

STUDY 2016-152
Phase I
A Phase 1b Study to Evaluate TAK-659 in Combination With Nivolumab in Patients With Advanced Solid Tumors

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

STUDY 2017-052
Phase I/II
A Phase 1 Dose Escalation and Cohort Expansion Study of TSR-042, an anti-PD-1 Monoclonal Antibody, in Patients with Advanced Solid Tumors

STUDY 2016-157
Phase I
Phase I Clinical Trial of VX-970 in Combination with the Topoisomerase I Inhibitor Irinotecan in Patients with Advanced Solid Tumors
STUDY 2015-156
Phase I
A Phase 1 Dose Escalation and Cohort Expansion Study of the Safety, Tolerability, and Efficacy of Anti-LAG-3 Monoclonal Antibody (BMS-986016) Administered Alone and in Combination with Anti-PD-1 Monoclonal Antibody (Nivolumab, BMS-936558) in Advanced Solid Tumors

STUDY 2015-011
Phase I
A Phase 1b Study to Assess Safety, Pharmacokinetics, Pharmacodynamics, and Preliminary Efficacy of PLX9486 as a Single Agent and in Combination with PLX3397 in Patients with Advanced Solid Tumors and Patients with Locally Advanced, Unresectable, or Metastatic Gastrointestinal Stromal Tumor (GIST) Who Have Been Previously Treated with Imatinib Mesylate, Sunitinib Malate, and Regorafenib

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

STUDY 2015-149
Phase I
A Phase I Open-Label, Dose Escalation Study to Investigate the Safety, Pharmacokinetics, Pharmacodynamics, and Clinical Activity of GSK2820151 in Subjects with Advanced or Recurrent Solid Tumors

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

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

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

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

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

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

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

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

STUDY 2017-064
Phase I/II
A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of INCAGN01876 in Combination With Immune Therapies in Subjects With Advanced or Metastatic Malignancies

STUDY 2017-053
Phase I/II
A Study to Evaluate the Safety and Efficacy of the CD40 Agonistic Antibody APX005M Administered in Combination with Nivolumab in Subjects with Nonsmall Cell Lung Cancer and Subjects with Metastatic Melanoma

STUDY 2017-029
Phase I
An Open-Label, Phase I Trial To Determine The Maximum-Tolerated Dose And Investigate Safety, Pharmacokinetics, And Efficacy Of BI 754091 In Patients With Advanced Solid Tumours

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

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

STUDY 2016-210
Phase I/II
An Open-Label, Dose-Finding And Proof Of Concept Study Of The PD-L1 Probody Therapeutic, CX-072, As Monotherapy And In Combination With Yervoy (Ipilimumab) Or With Zelboraf (Vemurafenib) In Subjects With Advanced Or Recurrent Solid Tumors Or Lymphomas

STUDY 2016-152
Phase I
A Phase 1b Study to Evaluate TAK-659 in Combination With Nivolumab in Patients With Advanced Solid Tumors

STUDY 2017-069
Phase I/II
A Phase 1/2a Study of BMS-986205 Administered in Combination with Nivolumab anti-PD-1 Monoclonal Antibody) and in Combination with Both Nivolumab and Iplilmumab (anti-CTLA-4 Monoclonal Antibody) in Advanced Malignant Tumors

STUDY 2016-081
Phase I/II
Phase 1-2 Study of MEDI4736 Alone or In Combination with ADXS11-001 In Recurrent/Persistent or Metastatic Cervical or HPV+ Head & Neck Cancer

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

STUDY NEW 2016-066
Phase I/II
A Phase 1b/2 Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of GS-5829 as a Single Agent and In Combination With Enzalutamide in Subjects with Metastatic Castrate-Resistant Prostate Cancer

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

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

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

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

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

STUDY 2016-079
Phase I
An Open-Label Multicenter Phase 1 Study to Evaluate the Safety, Pharmacokinetics and Pharmacodynamics of H3B-6527 in Subjects With Advanced Hepatocellular Carcinoma or Intrahepatic Cholangiocarcinoma

STUDY 2016-016
Phase I/II
A Phase I/II Multicenter Study of the Combination of AZD2014 and Palbociclib on a Background of Hormonal Therapy in Patients with Locally Advanced/Metastatic Estrogen Receptor Positive Breast Cancer Comprising a Safety, Pharmacokinetic and Preliminary Efficacy Evaluation followed by a Randomized, Double-Blind, Placebo-controlled, Parallel Group Extension (PASTOR)

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

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

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

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

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

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

Thoracic Clinical Trials

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

ADJUVANT
STUDY 2015-080
Phase III
A Phase III, Open-Label, Randomized Study to Investigate the Efficacy and Safety of MPDL3280A (ANTI-PD-L1 ANTIBODY) Compared with Best Supportive Care Following Adjuvant Cisplatin-Based Chemotherapy in PD-L1-Selected Patients with Completely Resected Stage IB-IIIA Non-Small Cell Lung Cancer

STUDY 2017-053
Phase I/II
A Study to Evaluate the Safety and Efficacy of the CD40 Agonistic Antibody APX005M Administered in Combination with Nivolumab in Subjects with Nonsmall Cell Lung Cancer and Subjects with Metastatic Melanoma

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 2017-053
Phase I/II
A Study to Evaluate the Safety and Efficacy of the CD40 Agonistic Antibody APX005M Administered in Combination with Nivolumab in Subjects with Nonsmall Cell Lung Cancer and Subjects with Metastatic Melanoma

STUDY 2016-110
Phase II
A Phase II, Open-label, Multicenter, Single-arm Study To Investigate The Efficacy And Safety Of Atezolizumab As Neoadjuvant And Adjuvant Therapy In Patients With Stage IB, II, Or IIIA Resectable And Untreated Non-Small Cell Lung Cancer

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 2017-053
Phase I/II
A Study to Evaluate the Safety and Efficacy of the CD40 Agonistic Antibody APX005M Administered in Combination with Nivolumab in Subjects with Nonsmall Cell Lung Cancer and Subjects with Metastatic Melanoma

STUDY 2016-110
Phase II
A Phase II, Open-label, Multicenter, Single-arm Study To Investigate The Efficacy And Safety Of Atezolizumab As Neoadjuvant And Adjuvant Therapy In Patients With Stage IB, II, Or IIIA Resectable And Untreated Non-Small Cell Lung Cancer

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

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

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

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

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

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

STUDY 2017-093
Phase II
A Phase 2 Study of MEDI4736 (durvalumab) and Tremelimumab Alone or in Combination with High or Low-Dose Radiation in Metastatic Colorectal and NSCLC

STUDY 2015-103
Phase I
A Phase 1b Open-Label Study of PEGylated Recombinant Human Hyaluronidase (PEGPH20) Combined with Pembrolizumab in Subjects with Selected Hyaluronan-High Solid Tumors

STUDY 2017-053
Phase I/II
A Study to Evaluate the Safety and Efficacy of the CD40 Agonistic Antibody APX005M Administered in Combination with Nivolumab in
Subjects with Nonsmall Cell Lung Cancer and Subjects with Metastatic Melanoma

**STUDY 2016-178**  
**Phase I**  
A Phase 1, Dose-Finding and Signal-Seeking Study of the Safety and Efficacy of Intravenous CAVATAK(TM) (coxsackievirus A21, CVA21) Alone and in Combination with Pembrolizumab in Patients with Late Stage Solid Tumours (NSCLC, Castrate-Resistant Prostate Cancer, Melanoma and Bladder Cancer)

**STUDY S1507**  
**Phase II**  
A Phase II Trial of Trametinib with Docetaxel in Patients with Kras Mutation Positive Non-Small Cell Lung Cancer (NSCLC) and Progressive Disease Following One or Two Prior Systemic Therapies

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

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

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

**STUDY NEW 2016-091**  
**Phase I**  
An Open-Label, Phase 1 Study of the Safety and Immunogenicity of JNJ-64041757, a Live Attenuated Listeria monocytogenes Immunotherapy, in Subjects With Non-Small Cell Lung Cancer

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

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

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

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

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

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

**STUDY S1507**
Phase II
A Phase II Trial of Trametinib with Docetaxel in Patients with Kras Mutation Positive Non-Small Cell Lung Cancer (NSCLC) and Progressive Disease Following One or Two Prior Systemic Therapies

**SCLC EXTENSIVE**

**STUDY 2016-099**
Phase I
An Intensive QT/QTc Study to Investigate the Effects of Rovalpituzumab Tesirine on Cardiac Ventricular Repolarization in Subjects with Small Cell Lung Cancer

**STUDY 2017-064**
Phase I/II
A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of INCAGN01876 in Combination With Immune Therapies in Subjects With Advanced or Metastatic Malignancies

**MESOTHELIOMA**

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

**STUDY 2017-064**
Phase I/II
A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of INCAGN01876 in Combination With Immune Therapies in Subjects With Advanced or Metastatic Malignancies

**STUDY 2016-172**
Phase III
A Phase III, Randomized, Open Label Trial of Nivolumab in Combination with Ipilimumab versus Pemetrexed with Cisplatin or Carboplatin as First Line Therapy in Unresectable Pleural Mesothelioma

**SARCOMA**

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

**OTHER**

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

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

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

STUDY S1403  
Phase II/III  
A Randomized Phase II/III Trial of Afatinib plus Cetuximab versus Afatinib Alone in Treatment-Naive Patients with Advanced, EGFR Mutation Positive Non-Small Cell Lung Cancer (NSCLC)(BI 1200.124)

STUDY 2016-116  
Phase II  
A Phase 2 Study of Cediranib in Combination with Olaparib in Advanced Solid Tumors

STUDY NEW 2017-087  
Phase I  
A Phase 1, Open-label, Dose-Escalation Study of SEA-CD40 in Adult Patients with Advanced Malignancies

STUDY 2016-152  
Phase I  
A Phase 1b Study to Evaluate TAK-659 in Combination With Nivolumab in Patients With Advanced Solid Tumors

STUDY 2017-064  
Phase I/II  
A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of INCAGN01876 in Combination With Immune Therapies in Subjects With Advanced or Metastatic Malignancies

STUDY 2017-069  
Phase I/II  
A Phase 1/2a Study of BMS-986205 Administered in Combination with Nivolumab anti-PD-1 Monoclonal Antibody) and in Combination with Both Nivolumab and Ipilimumab (anti-CTLA-4 Monoclonal Antibody) in Advanced Malignant Tumors

STUDY 2017-029  
Phase I  
An Open-Label, Phase I Trial To Determine The Maximum-Tolerated Dose And Investigate Safety, Pharmacokinetics, And Efficacy Of BI 754091 In Patients With Advanced Solid Tumours

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

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

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