

# CancerPACT<sup>tm</sup>



Cancer Patients' Alliance for Clinical Trials

## Denver Cancer Clinical Trials Listing

Summer 2009



CancerPACT is an alliance of the Colorado Cancer Research Program, Colorado Cancer Coalition, Colorado Department of Public Health and Environment, Colorado Foundation for Public Health and the Environment, Denver Health, La Clinica Tepeyac, Latino American Health Network (Colorado Springs), Lorenzen Cancer Foundation, and University of Colorado Cancer Center.



Cancer Patients' Alliance for Clinical Trials

The aim of the Cancer Patients' Alliance for Clinical Trials (CancerPACT) is to present comprehensive listings of cancer clinical trials to help insure access to the cutting edge of science and medicine in cancer care to all, including Latinos and other traditionally underrepresented minorities.

Call or email for additional electronic or hard copies  
Or to join the CancerPACT alliance

720-848-0650  
CancerClinicalTrials@ucdenver.edu  
www.ColoradoCancerCoalition.org



#### Denver Trial Locations:

**Colorado Cancer Research Program (CCRP) 303-777-2663**  
**Denver Health (DH) 303-436-5774**  
**Rocky Mountain Cancer Centers (RMCC) 888-259-7622**  
**University of Colorado Cancer Center (UCCC) 720-848-0650**

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# Solid Tumors

## 1. Breast Cancer

1. 24-02 Phase III Trial Evaluating the Role of Ovarian Function Suppression and the Role of Exemestane as Adjuvant Therapies for Premenopausal Women with Endocrine Responsive Breast Cancer (CCRP, RMCC, UCCC)
2. 40101 Phase III Randomized Study of Cyclophosphamide and Doxorubicin (CA x 4 Cycles) vs. Paclitaxel (4 Cycles) As Adjuvant Therapy For Breast Cancer in Women with 0-3 Positive Axillary Lymph Nodes (CCRP, RMCC)
3. B-39 Randomized Phase III Study of Conventional Whole Breast Irradiation (WBI) vs. Partial Breast Irradiation (PBI) for Women with Stage 0, I or II Breast Cancer (CCRP, RMCC)
4. B-40 Randomized Phase III Trial of Neoadjuvant Therapy in Patients With Palpable and Operable Breast Cancer Evaluating the Effect on Pathologic Complete Response (pCR) of Adding Capecitabine or Gemcitabine to Docetaxel when Administered Before AC with or without Bevacizumab and Correlative Science Studies Attempting to Identify Predictors of High Likelihood for pCR with Each of the Regimens (CCRP, RMCC)
5. B-41 Randomized Phase III Trial of Neoadjuvant Therapy for Patients with Palpable and Operable HER2-Positive Breast Cancer Comparing the Combination of Trastuzumab Plus Lapatinib to Trastuzumab and to Lapatinib Administered with Weekly Paclitaxel Following AC Accompanied by Correlative Science Studies to Identify Predictors of Pathologic Complete Response (CCRP, RMCC, UCCC)
6. B-43 Phase III Clinical Trial Comparing Trastuzumab Given Concurrently with Radiation Therapy and Radiation Therapy Alone for Women with HER2-Positive Ductal Carcinoma In Situ Resected by Lumpectomy (CCRP, RMCC)
7. B-44-I Multicenter Phase III Randomized Trial of Adjuvant Therapy for Patients with Her2-Positive Node-Positive or High Risk Node-Negative



Breast Cancer Comparing Chemotherapy Plus Trastuzumab with  
Chemotherapy Plus Trastuzumab Plus Bevacizumab (CCRP, RMCC)

8. E1105 Randomized Phase III Double-Blind Placebo-Controlled Trial of First-Line Chemotherapy and Trastuzumab with or without Bevacizumab for Patients with Her-2/Neu Over-Expressing Metastatic Breast Cancer (CCRP, RMCC)
  9. E5103 Double-Blind Phase III Trial of Doxorubicin and Cyclophosphamide Followed by Paclitaxel with Bevacizumab or Placebo in Patients with Lymph Node Positive and High Risk Lymph Node Negative Breast Cancer (CCRP, RMCC)
  10. N063D Phase III Randomized, Multi-Centre, Open-Label Study of Adjuvant Lapatinib, Trastuzumab, Their Sequence and Their Combination in Patients with HER2/ErbB2 Positive Primary Breast Cancer (CCRP, RMCC)
  11. S0307 Phase III Trial of Biophosphonates as Adjuvant Therapy for Primary Breast Cancer (CCRP, DH, RMCC)
  12. S0221 Phase III Trial of Continuous Schedule AC + G vs. Q 2 Week Schedule AC, Followed by Paclitaxel Given Either Every 2 Weeks or Weekly for 12 Weeks as Post-Operative Adjuvant Therapy in Node-Positive or High Risk Node Negative Breast Cancer (DH)
  13. S0226 Phase III Randomized Trial of Anastrozole vs. Anastrozole and Fulvestrant as First Line Therapy for Post Menopausal Women with Metastatic Breast Cancer (DH, UCCC)
  14. S0500 Randomized Phase III Trial to Test the Strategy of Changing Therapy vs. Maintaining Therapy for Metastatic Breast Cancer Patients Who Have Elevated Circulating Tumor Cell Levels at First Follow up Assessment (UCCC)
  15. SWOG 0221 Phase III Trial of Continuous Schedule AC + G vs. q2wk Schedule AC, Followed by Paclitaxel Given Either Every 2 Weeks or Weekly for 12 weeks as Post-Operative Adjuvant Therapy in Node-
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- Positive or High-Risk Node Negative Breast Cancer (UCCC)
16. SWOG 0307 Phase III Trial of Bisphosphonates as Adjuvant Therapy for Primary Breast Cancer (UCCC)
  17. USON 06090 Phase III Trial of Adjuvant TC vs. TAC in HER-2 Negative Early Stage Breast Cancer Patients (RMCC)
  18. USON 07036 Phase III Study Of SU011248 In Combination With Paclitaxel Versus Bevacizumab With Paclitaxel In The First-Line Advanced Disease Setting In Patients Having Breast Cancer (RMCC)
  19. APBIMRT Phase II Study of Accelerated Partial Breast Radiotherapy With Either a Novel Breast Brachytherapy Technique - Mammosite or Intensity Modulated Radiotherapy (RMCC)
  20. FB-5 Phase II Clinical Trial of Epirubicin Plus Cyclophosphamide Followed by Docetaxel Plus Trastuzumab and Bevacizumab Given as Neoadjuvant Therapy for HER2-Positive Locally Advanced Breast Cancer or Given as Adjuvant Therapy for HER2-Positive Pathologic Stage III Breast Cancer (CCRP)
  21. N0733 Randomized Phase II Trial of Capecitabine and Lapatinib with or without IMC-A12 in Patients with HER2 Positive Breast Cancer Previously Treated with Trastuzumab and an Anthracycline and/or Taxane (CCRP, RMCC)
  22. USON 05074 Phase II Randomized Trial of Neoadjuvant Trastuzumab and/or Lapatinib plus Chemotherapy (Sequential FEC75 and Paclitaxel) in Women with ErbB2- (HER2/neu-) Overexpressing Invasive Breast Cancer (RMCC)
  23. USON 06038 Phase II Trial of Adjuvant TC (Docetaxel/ Cyclophosphamide) plus Trastuzumab in HER2-Positive Early Stage Breast Cancer Patients (RMCC)
  24. USON 06166 Phase II, Multicenter, Open-Label, Clinical Trial of Trabectedin (Yondelis) in Metastatic Breast Cancer Patients with HER2 Overexpressing Tumors and BRCA1 or BRCA2 Mutation Carriers (RMCC)
  25. USON 06185 Randomized Phase II Trial of Letrozole with or without Dasatinib as First-Line Treatment for Hormone Receptor-Positive, HER2-Negative Post-Menopausal Breast Cancer that is Unresectable, Locally Recurrent or Metastatic (RMCC)
  26. USON 07040 Phase II, Multi-Center, Open-Label, Randomized Trial of



- Gemcitabine/Carboplatin, with or without BSI-201, in Patients with ER, PR, and HER2-Negative Metastatic Breast Cancer (RMCC)
27. USON 08065 Phase II, Single-Arm, Open-Label Study of Trastuzumab-Mcc-DM1 Administered Intravenously To Patients With HER2 Positive Metastatic Breast Cancer (RMCC)
  28. Phase II Study of Fulvestrant in Premenopausal Women with Hormone Receptor-Positive Advanced Breast Cancer (UCCC)
  29. Phase II Randomized Trial Differential Gene Regulation During Neoadjuvant Therapy Trial of Epirubicin/Cyclophosphamide (EC) vs. Docetaxel/Capecitabine (DX) Regimens in Patients with Large ER-Positive and ER-Negative Breast Cancers (UCCC)
  30. B-37 Randomized Clinical Trial of Adjuvant Chemotherapy for Radically Resected Loco-Regional Relapse of Breast Cancer (CCRP, RMCC)
  31. B-42 Clinical Trial to Determine the Efficacy of Five Years of Letrozole Compared to Placebo in Patients Completing Five Years of Hormonal Therapy Consisting of an Aromatase Inhibitor (AI) or Tamoxifen Followed by an AI in Prolonging Disease-Free Survival in Postmenopausal Women with Hormone Receptor Positive Breast Cancer (CCRP, DH, RMCC)
  32. CZOL446E2352 A Prospective Randomized Double-Blind, Stratified, MultiCenter Two-Arm Trial of the Continued Efficacy and Safety of Zometa (every 4 weeks vs. every 12 weeks) in Patients with Documented Bone Metastases From Breast Cancer (DH)
  33. MA.17R Double Blind Randomization to Letrozole or Placebo for Women Previously Diagnosed with Primary Breast Cancer Completing Five Years of Adjuvant Aromatase Inhibitor Either as Initial Therapy or After Tamoxifen (CCRP, RMCC)
  34. PACCT-1 Program for the Assessment of Clinical Cancer Tests - Trial

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Assigning Individualized Options for Treatment: The TAILORx Trial (CCRP, RMCC, UCCC)

35. Clinical Trial to Determine the Efficacy of Five Years of Letrozole Compared to Placebo in Patients Completing Five Years of Hormonal Therapy Consisting of an Aromatase Inhibitor (AI) or Tamoxifen Followed by an AI in Prolonging Disease Free Survival in Post Menopausal Women with Hormone Receptor Positive Breast Cancer (UCCC)
36. Insomnia- Study Insomnia after Breast Cancer treatment (DH, UCCC)
37. Lapatinib in Endocrine-Resistant Metastatic Breast Cancer (UCCC)
38. Molecular Predictors of Response to SU011248 in Tumor Samples from Patients with Metastatic Breast Cancer (UCCC)
39. Monitoring of Circulating Tumor Cells in Patients with Newly Diagnosed Early Stage ER+ Breast Cancer and Its Correlation with Oncotype DxScore (UCCC)
40. NIH Cognition Trial Chemotherapy and Cognition in Older Breast Cancer Patients (RMCC)
41. Preoperative Hormone Therapy for Postmenopausal Women with ER + or PR + Clinical Stage T2-4 Tumors: Exemestane with or without Tamoxifen. A Pilot Randomized Phase II Study to Identify Molecular Predictors for Hormone Responsiveness (UCCC)

## 2. Central Nervous System Tumors

1. NCCTG N047B Phase II Trial of Suberoylanilide Hydroxamic Acid (SAHA) in Patients with Recurrent Glioblastoma (RMCC, UCCC)
2. N0779 Phase II Study of Vorinostat (SAHA) in Combination with Bortezomib (PS-341) in Patients With Recurrent Glioblastoma Multiforme (CCRP)
3. RTOG 0424 Phase II Study of a Temozolomide-Based Chemoradiotherapy Regimen for High Risk Low-Grade Gliomas (UCCC)
4. Phase I Dose Escalation Study of Zactima (ZD6474) with Hypofractionated Stereotactic Radiotherapy in Patients with Recurrent Malignant Gliomas (IRUSZACT0073) (UCCC)



5. Phase I Dose per Fraction Escalation Study of Hypo-Fractionated Intensity-Modulated RT Combining with Temozolomide Chemotherapy for Patients with Newly Diagnosed Glioblastoma Multiforme (GBM) (DH, UCCC)
6. Phase I Trial of Arsenic Trioxide in the Treatment of Infiltrating Gliomas of Childhood (UCCC)

### 3. Gastrointestinal Cancers

#### A. Colorectal Cancer

1. C80405 Phase III Trial of Irinotecan, 5-FU, Leucovorin or Oxaliplatin, 5-FU, Leucovorin with Bevacizumab or Cetuximab or with the Combination of Bevacizumab and Cetuximab For Patients with Untreated Metastatic Adenocarcinoma of the Colon or Rectum (CCRP, DH, RMCC, UCCC)
2. E5202 Phase III Randomized Study Comparing 5-FU, Leucovorin and Oxaliplatin vs. 5-FU, Leucovorin, Oxaliplatin and Bevacizumab in Patients with Stage II Colon Cancer at High Risk for Recurrence to Determine Prospectively the Prognostic Value of Molecular (CCRP, DH, RMCC, UCCC)
3. E5204 Phase III Intergroup Randomized Study of Postoperative Oxaliplatin, 5-Fluorouracil and Leucovorin vs. Oxaliplatin, 5-Fluorouracil, Leucovorin and Bevacizumab for Patients with Stage II or III Rectal Cancer Receiving Pre-operative Chemoradiation (CCRP, DH, RMCC)
4. N0147 Randomized Phase III Trial of Oxaliplatin (OXAL) Plus

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5-Fluorouracil (5-FU) / Leucovorin (LV) With or Without Cetuximab (C225) After Curative Resection for Patients With Stage III Colon Cancer (CCRP, RMCC, UCCC)

5. E4203 Phase II Study of Treatment Selection Based Upon Tumor Thymidylate Synthase Expression in Previously Untreated Patients with Metastatic Colorectal Cancer (CCRP, RMCC)
6. USON 05102 Randomized Phase II Trial of Pre-Operative Chemoradiotherapy with or without Cetuximab (ERBITUX) in Locally-Advanced Adenocarcinoma of the Rectum (RMCC)
7. USON 07141 Phase II Multi-center, Open-label, Randomized Clinical Trial Evaluating Safety and Efficacy of FOLFIRI with Either Panitumumab or Bevacizumab as Second-line Treatment in Subjects with Metastatic Colorectal Cancer (RMCC)
8. 20060464 Phase IB/II Study of AMG 655 in Combination with Modified FOLFOX6 and Bevacizumab in the First-Line Treatment of Subjects with Metastatic Colorectal Cancer (RMCC)
9. Phase I/II Clinical Pharmacological and Biological Study of BAY 43-9006 in Combination with Cetuximab and Irinotecan in Patients with Advanced Colorectal Cancer (UCCC)
10. Phase IB Dose Escalation Study of the Safety and Pharmacokinetics of Apomab in Combination with Cetuximab and Irinotecan Chemotherapy in Patients with Previously Treated Colorectal Cancer (UCCC)
11. An Observational Study of Avastin in Combination with Chemotherapy for Treatment of Metastatic or Locally Advanced and Unresectable Colorectal Cancer and Locally Advanced or Metastatic Non-Small Cell Lung Cancer (RMCC)
12. R-04 Clinical Trial Comparing Preoperative Radiation Therapy and Capecitabine with Preoperative Radiation Therapy and Continuous Intravenous Infusion (CVI) of 5-Fluorouracil (5-FU) in the Treatment of Patients with Operable Carcinoma of the Rectum (CCRP, RMCC, UCCC)

## B. Esophageal Cancer



1. 80101 Phase III Intergroup Trial of Adjuvant Chemoradiation After Resection of Gastric or Gastroesophageal Adenocarcinoma (CCRP, RMCC)
2. USON 06063 Phase II Trial of Docetaxel Plus Oxaliplatin (DOCOX) with or without Cetuximab in Patients with Metastatic Gastric and/or Gastroesophageal Junction Adenocarcinoma (RMCC)

### **C. Gastric Cancer**

1. USON 06054 Randomized Phase II Study of Docetaxel in Combination with Oxaliplatin with or without 5-FU or Capecitabine in Metastatic or Locally Recurrent Gastric Cancer Previously Untreated with Chemotherapy for Advanced Disease (RMCC)

### **D. Pancreatic Cancer**

1. Phase III Randomized Double Blind Study of Sunitinib (SU011248, Sutent) vs. Placebo in Patients with Progressive Advanced/ Metastatic Well Differentiated Pancreatic Islet Cell Tumors (UCCC)
2. USON 07111 Phase II Randomized, Double-Blind, Multicenter Trial of Amplimexon plus Gemcitabine vs. Gemcitabine plus Placebo in Patients With Metastatic Chemotherapy Naïve Pancreatic Adenocarcinoma (Stage IV) (RMCC)
3. USON 08096 Phase II, Multi-Center, Open Label Study Evaluating the Efficacy and Safety of Quarfloxin in Patients With Low to Intermediate Grade Neuroendocrine Carcinoma (RMCC)
4. Phase I Study of Bortezomib Given Intravenously Once Weekly Prior to

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And During Concurrent Fixed Dose Paclitaxel and Radiation in Patients with Locally Advanced, Non-Metastatic Pancreatic or Biliary Cancer (UCCC)

5. Phase I Study of Gemcitabine, Capecitabine and ZD6474 (Zactima) in Patients with Advanced Solid Tumors with Expanded Cohort of Patients with Biliary or Pancreatic Malignancies (UCCC)

## **4. Gynecologic Cancers**

### **A. Ovarian / Peritoneal Cancer**

1. GOG-0212 Randomized Phase III Trial of Maintenance Chemotherapy Comparing 12 Monthly Cycles of Single Agent Paclitaxel or CT-2103 vs. No Treatment until Documented Relapse in Women with Advanced Ovarian or Primary Peritoneal Cancer Who Achieve A Complete Clinical Response To Primary Platinum/Taxane Chemotherapy (CCRP, RMCC, UCCC)
2. GOG-0218 Phase III Trial of Carboplatin and Paclitaxel Plus Placebo vs. Carboplatin and Paclitaxel Plus Concurrent Bevacizumab (NSC #704865, IND #7921) Followed by Placebo, vs. Carboplatin and Paclitaxel Plus Concurrent and Extended Bevacizumab, in Women with Newly Diagnosed, Previously Untreated, Stage III or IV, Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Cancer (CCRP, RMCC, UCCC)
3. Phase III Randomized, Parallel Group, Open-Label, Active Controlled, Multicenter Trial of Patupilone (EPO906) vs. Pegylated Liposomal Doxorubicin (Doxil«/Caelys) in Taxane/Platinum Refractory/Resistant Patients with Recurrent Epithelial Ovarian, Primary Fallopian or Primary Peritoneal Cancer (UCCC)
4. GOG-0215 Phase II Randomized Study of the Effect of Zoledronic Acid versus Observation on Bone Mineral Density of the Lumbar Spine in Women who Elect to Undergo Risk-Reducing Surgery that Results in Removal of Both Ovaries (CCRP, RMCC)



5. GOG 0170I Phase II Evaluation of CCI-779 (Temsirolimus, NCI Supplied Agent, NSC #683864, IND# 61010) in Treatment of Persistent or Recurrent Epithelial Ovarian or Primary Peritoneal Carcinoma (UCCC)
6. NCCTG N04C2 An Exploratory, Randomized, Placebo-Controlled Trial of Depot Octreotide (Sandostatin LAR @ Depot) for Symptomatic Ascites in Cancer Patients (RMCC)
7. Randomized, Double Blind, Placebo Controlled, Multicenter Trial of Abagovomab Maintenance Therapy in Patients with Epithelial Ovarian Cancer after Complete Response to First Line Chemotherapy (UCCC)
8. Study to Define A Protein Signature of Ovarian Cancer (UCCC)

## **B. Uterine /Cervical Cancer**

1. GOG 0209 Randomized Phase III Trial of Doxorubicin/ Cisplatin/ Paclitaxel and G-CSF versus Carboplatin/ Paclitaxel in Patients with Stage III and IV or Recurrent Endometrial Cancer (UCCC)
2. GOG 0219 Phase III, Randomized Trial of Weekly Cisplatin and Radiation Versus Cisplatin and Tirapazamine and Radiation in Stage IB2, IIA, IIB, IIIB and IVA Cervical Carcinoma Limited to the Pelvis (UCCC)
3. GOG 0130E Phase II Evaluation of Gemcitabine (NSC #613327) and Docetaxel (NSC #628503) in the Treatment of Recurrent or Persistent Carcinosarcoma of the Uterus (UCCC)
4. GOG 0215 Phase II Randomized Study of the Effect of Zoledronic Acid vs. Observation of Bone Mineral Density of the Lumbar Spine in Women who Elect to Undergo Risk Reducing Surgery That Results in Removal of Both Ovaries (UCCC)

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5. R0417 Phase II Study of Bevacizumab in Combination with Definitive RT and Cisplatin Chemotherapy in Untreated Pts with /Locally Advanced Cervical Carcinoma (DH)
6. GOG 0210 A Molecular Staging Study of Endometrial Carcinoma (UCCC)
7. GOG-0222 Prospective Evaluation of Pelvic Exenteration in Patients with Recurrent Cervical Cancer (UCCC)

## 5. Head & Neck Cancer

1. E1305 Phase III Randomized Trial of Chemotherapy with or without Bevacizumab in Patients with Recurrent or Metastatic Head and Neck Cancer (CCRP, RMCC)
2. USON 07176 Randomized Phase III Trial of Concurrent Accelerated Radiation and Cisplatin vs. Concurrent Accelerated Radiation , Cisplatin, and Cetuximab (C225) [Followed by Surgery for Selected Patients] for Stage III and IV Head and Neck Carcinomas (RMCC)
3. Open Label Multicenter Phase I Study to Assess the Maximum Tolerated Dose of ZD6474 (Zactima) Given Concomitantly with Radiation Therapy or Concomitantly with Weekly Cisplatin Chemotherapy and Radiation Therapy in Patients with Previously Untreated Unresected Stage II-IV Head and Neck Squamous Cell Carcinoma (UCCC)
4. Phase I Dose Escalation of Erlotinib Concurrently with RT in the Re-irradiation Setting for Head and Neck Cancer (DH, UCCC)
5. An Investigator-Initiated, Multicenter, Randomized, Double-Blind Placebo-Controlled Design Study to Assess the Effectiveness of CeviMeline to Improve Oral Health in Patients with XERostomia Secondary to Radiation Therapy for Treatment of Head and Neck Squamous Cell Carcinoma (UCCC)

## 6. Lung

1. 0617 Randomized Phase III Comparison of Standard-Dose (60 Gy)



- vs. High-Dose (74 Gy) Conformal Radiotherapy with Concurrent and Consolidation Carboplatin/Paclitaxel +/- Cextuximab (IND #103444) in Patients with Stage IIIA/IIIB Non-Small Cell Lung Cancer (CCRP)
2. A4021016 Phase III Randomized, Open Label Trial of CP-751,871 in Combination with Paclitaxel and Carboplatin vs. Paclitaxel and Carboplatin in Patients with NSCLC (RMCC)
  3. E1505 Phase III Randomized Trial of Adjuvant Chemotherapy with or without Bevacizumab for Patients with Completely Resected Stage IB (> 4 cm) – IIIA Non-Small Cell Lung Cancer (NSCLC) (CCRP, DH, RMCC, UCCC)
  4. E5597 Phase III Chemoprevention Trial of Selenium Supplementation in Persons with Resected Stage I Non Small Cell Lung Cancer (CCRP, RMCC)
  5. N0723 MARVEL: Marker Validation of Erlotinib in Lung Cancer Phase III Biomarker Validation Study of Second-Line Therapy in Patients with Advanced Non-Small Cell Lung Cancer (NSCLC) Randomized to Pemetrexed vs. Erlotinib (CCRP, RMCC)
  6. USON 04107 Phase III Randomized Study of Docetaxel or Pemetrexed with or without Cetuximab in Patients with Recurrent or Progressive Non-Small Cell Lung Cancer after Platinum-Based Therapy (RMCC)
  7. USON 06026 Phase III Multi-Center Randomized, Double-Blind, Placebo-Controlled Study of Single-Agent Tarceva (erlotinib) Following Complete Tumor Resection with or without Adjuvant Chemotherapy in Patients with Stage IB-IIIA Non-Small Cell Lung Carcinoma Who Have EGFR-Positive Tumors (RMCC, UCCC)
  8. USON 07050 Phase III Randomized, Open-Label, Multinational Trial Comparing Amrubicin vs. Topotecan in Patients with Extensive or Limited and Sensitive or Refractory Small Cell Lung Cancer After Failure of First-Line Chemotherapy (RMCC)
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9. USON 07155 Phase III, Randomized Open-Label Study of Oral Topotecan Plus Whole-Brain Radiation Therapy (WBRT) Compared with WBRT Alone in Patients with Brain Metastases from Non-Small Cell Lung Cancer (RMCC)
10. N0626 Phase II Randomized Study Pemetrexed with Sorafenib vs. Pemetrexed Alone as Second-Line Therapy in Patients with Advanced Non-Small Cell Lung Cancer (CCRP, RMCC)
11. N0821 Phase II First-Line Study of a Combination of Pemetrexed, Carboplatin and Bevacizumab in Advanced Nonsquamous NSCLC Evaluating Efficacy and Tolerability in Elderly Patients (Age >70 Yrs) with Good Performance Status (PS <2) (CCRP)
12. University of Colorado 05-0163 Phase I/II Study of Pemetrexed Plus Bortezomib in Elderly Patients Age > 70 Years with ECOG Performance Status 0-2 with Untreated Stages IIIB Malignant Effusion or Stage IV Non-Small Cell Lung Cancer (RMCC)
13. USON 06071 Phase II Randomized, Placebo-Controlled, Double-Blind, Multicenter Study with a Lead in Phase of Erlotinib with or without SNDX-275 in Patients with Non-Small Cell Lung Carcinoma after Failure in up to Two Prior Chemotherapeutic Regimens for Advanced Disease (SNDX-275-0401) (RMCC)
14. USON 07031 Phase I-II Multi Center, Open-Label Study Of The X-Linked Inhibitor Of Apoptosis (XIAP) Antisense AEG35156 Given in Combination with Carboplatin and Paclitaxel in Patients with Advanced Non Small Cell Lung Cancer (RMCC)
15. Phase I/II Study of Pemetrexed plus Bortezomib in Elderly Patients >=70 Years with ECOG Performance Status 0-2 with Untreated Stages IIIB Malignant Effusion or IV Non-Small Cell Lung Cancer (UCCC)
16. Phase I/IIA Study Evaluating the Safety Pharmacokinetics and Efficacy of ABT-2263 in Subjects with Small Cell Lung Cancer (SCLC) (UCCC)
17. S0429 Phase I Pilot Study of Weekly Docetaxel and Cetuximab Chemoradiation for Poor Risk Stage III Non-Small Cell Lung Cancer (DH, UCCC)
18. Phase I Safety and Tolerability Study of Vorinostat in Combination with Sorafenib in Patients with Advanced Solid Tumors with Exploration of Two Tumor Type Specific Expanded Cohorts at the Recommended



Phase II Dose (Renal Cell Carcinoma and Non Small Cell lung Carcinoma) (UCCC)

19. Phase IB Study Investigating the Combination of RAD001 with Cisplatin and Etoposide in Patients with Extensive-Stage Small-cell Lung Cancer not Previously Treated with Chemotherapy (UCCC)
20. S0533 A Pilot Trial of Cis/Etoposide/RT Followed by Consolidation Docetaxel and the Addition of Bevacizumab in Three Cohorts of Patients with Inoperable Locally Advanced Stage III NSCLC (DH, UCCC)
21. AVF3991N An Observational Study of Avastin in Combination with Chemotherapy for Treatment of Metastatic or Locally Advanced and Unresectable Colorectal Cancer and Locally Advanced or Metastatic Non-Small Cell Lung Cancer (RMCC)
22. EFC10261 A Multinational, Randomized, Double-Blind Study Comparing Afibercept vs. Placebo in Patients Treated with Second-Line Docetaxel after Failure of One Platinum-Based Therapy for Locally Advanced or Metastatic Non-Small-Cell Lung Cancer (NSCLC) (DH)
23. S0424 Molecular Epidemiology Case-Series Study of Non-Small Cell Lung Cancer in Smoking and Non-Smoking Women and Men (DH)
24. S9925 Lung Cancer Specimen Repository (DH, UCCC)
25. Lung Cancer Tissue Bank Protocol (UCCC)
26. Platelet mRNA Profiling in Metastatic NSCLC (DH)

## 7. Melanoma

1. E1697 Phase III Randomized Study of Four Weeks High Dose IFN- $\alpha$ 2b in Stage T2b No, T3a-b No, T4a-b No, and T1-4, N1a, 2a, 3 (microscopic) Melanoma (CCRP, RMCC)

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2. Phase III Clinical Trial to Evaluate the Safety and Efficacy of Treatment with 2 mg Intravesical Allovectin-7 Compared to Dacarbazine (DTIC) or Temozolomide (TMZ) in Subjects with Recurrent Metastatic Melanoma (UCCC)
3. Phase II Study of LY573636 Administered as an Intravenous Infusion on Day 1 of a 21 Day Cycle as Second Line Treatment in Patients with Unresectable or Metastatic Melanoma (UCCC)
4. Phase II Study of PI-88 with Dacarbazine in Patients with Metastatic Melanoma (UCCC)

## 8. Prostate Cancer

1. 0415 Phase III Randomized Study of Hypofractionated 3D-CRT/IMRT vs. Conventionally Fractionated 3D-CRT/IMRT in Patients Treated for Favorable-Risk Prostate Cancer (CCRP, RMCC)
2. 0521 Phase III Protocol of Androgen Suppression (AS) and 3DCTR/IMRT vs. AS and 3DCTR/IMRT Followed by Chemotherapy with Docetaxel and Prednisone for Localized, High-Risk, Prostate Cancer (CCRP)
3. 0534 Phase III Trial of Short Term Androgen Deprivation with Pelvic Lymph Node or Prostate Bed Only Radiotherapy (SPORT) in Prostate Cancer Patients with a Rising PSA After Radical Prostatectomy (CCRP, RMCC)
4. C90202 Phase III Randomized, Double-Blind, Placebo-Controlled Study of Early Versus Standard Zoledronic Acid to Prevent Skeletal Related Events in Men with Prostate Cancer Metastatic to Bone (UCCC)
5. C90203 PUNCH - Randomized Phase III Study of Neoadjuvant Docetaxel and Androgen Deprivation Prior to Radical Prostatectomy vs. Immediate Radical Prostatectomy in Patients with High Risk Clinically Localized Prostate Cancer (DH, UCCC)
6. PR11 Phase III Study of Active Surveillance Therapy Against Radical Treatment in Patients Diagnosed with Favorable Risk Prostate Cancer (START) (UCCC)
7. S0421 Phase III Study of Docetaxel and Atrasentan vs. Docetaxel



- and Placebo for Patients with Advanced Hormone Refractory Prostate Cancer (CCRP, DH, RMCC, UCCC)
8. ECOG E3803 Phase II Study of a Weekly Schedule of BMS-247550 for Patients with Hormone Refractory Prostate Cancer (RMCC)
  9. USON 06118 Randomized Phase II Study of Mitoxantrone vs. Mitoxantrone with Cetuximab in Metastatic Androgen Independent Prostate Cancer (AIPC) Previously Treated with Docetaxel-Based Chemotherapy (RMCC)
  10. USON 07068 Phase II Randomized, Double Blind, Placebo Controlled, Multicenter Study Comparing AT-101 in Combination with Docetaxel and Prednisone vs. Docetaxel and Prednisone in Men with Chemotherapy Naïve Metastatic Hormone Refractory Prostate Cancer (HRPC) (RMCC)
  11. Phase II Randomized Double Blind Placebo Controlled Study of Testosterone Replacement in Men with Non Metastatic Castrate Resistant Prostate Cancer (UCCC)
  12. NCI T98-0058 Cell Kinetic Study of Bromodeoxyuridine (BrdU) in Prostate Cancer (UCCC)
  13. Study to Define Protein Signatures for Prostate Cancer Progression (UCCC)
  14. The Application of Target Cryotherapy in the Treatment of Organ Confined Prostate Cancer (UCCC)

## 9. Urologic Cancers (other)

### A. Bladder

1. S0337 Phase III Blinded Study of Immediate Post-TURBT Instillation

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of Gemcitabine vs. Saline in Patients with Newly Diagnosed or Occasional Recurring Grade I/II Superficial Bladder Cancer (UCCC)

2. S0353 Phase II Study of Intravesical Gemcitabine in Patients with Superficial Bladder Cancer Who Have Progressed Despite Intravesical BCG (UCCC)

## **B. Kidney Cancer**

1. E2805 Phase III Randomized Double Blind Trial of Adjuvant Sunitinib vs. Sorafenib vs. Placebo in Patients with Resected Renal Cell Carcinoma (DH, RMCC)
2. E4805 Phase II Study to Determine the Effect of Two Different Doses of AVE0005 (VEGF Trap) in Patients with Metastatic Renal Cell Carcinoma (CCRP)
3. Phase II Study Testing the Biologic Activity and Safety of Autologous Renal Cell Carcinoma Total mRNA and huCD401-mRNA co-Transfected Dendritic Cell Vaccine in Patients with Newly Diagnosed Stage IV Renal Cell Carcinoma (UCCC)
4. Phase I/II Open Label Dose Escalation Study to Assess the Safety and Pharmacokinetics of Recombinant Interleukin 21 (rIL-21) Administered Concomitantly with Sorafenib (Nexavar) in Subjects with Metastatic Renal Cell Carcinoma (UCCC)
5. Phase I Safety and Tolerability Study of Vorinostat in Combination with Sorafenib in Patients with Advanced Solid Tumors with Exploration of Two Tumor Type Specific Expanded Cohorts at the Recommended Phase II Dose (Renal Cell Carcinoma and Non Small Cell lung Carcinoma) (UCCC)
6. E2805 ASSURE: Adjuvant Sorafenib or Sunitinib for Unfavorable Renal Carcinoma (CCRP)
7. USON 08036 Axitinib (AG-013736) as Second Line Therapy for Metastatic Renal Cell Cancer: AXIS Trial (RMCC)
8. USON 08060 A Study of Pazopanib vs. Sunitinib in the Treatment of Subjects with Locally Advanced and/or Metastatic Renal Cell Carcinoma (RMCC)



## Hematologic Cancers

### 1. Leukemia

1. 10501 Phase III Intergroup CLL Study of Asymptomatic Patients with Untreated Chronic Lymphocytic Leukemia Randomized to Early Intervention Versus Observation with Later Treatment in the High-Risk Genetic Subset with IGVH Unmutated Disease (CCRP, RMCC)
2. E2902 Phase III Randomized Study of Farnesyl Transferase Inhibitor R115777 in Acute Myeloid Leukemia (AML) Patients in Second or Subsequent Remission or in Remission After Primary Induction Failure or Patients over Age 60 in First Remission (CCRP, RMCC)
3. OMB110911 Phase III Open Label, Randomized Trial of Ofatumumab Added to Chlorambucil vs. Chlorambucil Monotherapy in Previously Untreated Patients with Chronic Lymphocytic Leukemia (DH)
4. Phase III Randomized, Double-Blind, Controlled Study Comparing Clofarabine and Cytarabine Versus Cytarabine Alone in Adult Patients 55 Years and Older with Acute Myelogenous Leukemia (AML) Who Have Relapsed or are Refractory after Receiving up to Two Prior Induction Regimens (UCCC)
5. CAM203 Phase II Trial to Evaluate the Efficacy and Safety of Subcutaneously Administered Campath in Patients with Previously Treated B-Cell Lymphocytic Leukemia (RMCC)
6. E1905 Randomized Phase II Trial of Azacitidine with or without the Histone Deacetylase Inhibitor Entinostat for the Treatment of Myelodysplastic Syndrome, Chronic Myelomonocytic Leukemia (dysplastic type), and Acute Myeloid Leukemia with Multilineage

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Dysplasia (CCRP, RMCC)

7. E2903 Phase II Trial of Pentostatin, Cyclophosphamide and Rituximab (PCR) followed by Campath-1H for Previously Treat Relapsed or Refractory Patients with Chronic Lymphocytic Leukemia (CCRP, RMCC)
8. E5998 Phase II Study of Initial Treatment with Methotrexate in Large Granular Lymphocytic (LGL) Leukemia (CCRP, RMCC)
9. Phase II Trial to Evaluate the Efficacy and Safety of Subcutaneously Administered Alemtuzumab (CAMPATH, MabCampath) in Patients with Previously Treated B-Cell Chronic Lymphocytic Leukemia (UCCC)
10. CP04-151 Phase I, Sequential Cohort, Dose Escalation Trial to Determine the Safety, Tolerability, and Maximum Tolerated Dose of Weekly Administration of GRN163L in Patients with Chronic Lymphoproliferative Disease (RMCC)
11. ALTE02C2 Neurobehavioral Outcomes in Childhood Acute Lymphoblastic Leukemia (UCCC)
12. S9007 Cytogenetic Studies in Leukemia Patients (UCCC)
13. Single-Arm, International, Multi-Center Trial of HuMax-CD20, a Fully Human Monoclonal Anti-CD20 Antibody, in Patients with B-Cell Chronic Lymphocytic Leukemia Who Have Failed Fludarabine and Alemtuzumab (UCCC)

## 2. Lymphoma

1. 114-NH-301 Phase III, Randomized, Double-Blind Study of Galiximab in Combination with Rituximab Compared with Rituximab in Combination with Placebo for the Treatment of Subjects with Relapsed or Refractory, Follicular Non Hodgkin's Lymphoma (CCRP, RMCC)
2. CC-5013-CLL-002 Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of the Efficacy and Safety of Lenalidomide (Revlimid) as Maintenance Therapy for Patients with B-Cell Chronic Lymphocytic Leukemia Following Second-Line Therapy [The CONTINUUM Trial] (RMCC)
3. H6Q-MC-JCBB Phase III Clinical Study to Investigate the Prevention of Relapse in Lymphoma Using Daily Enzastaurin (CCRP)
4. U4391g Phase III Multicenter, Open-Label Study of Rituximab Faster



Infusion Time in Patients with Previously Untreated Diffuse Large B-Cell or Follicular Non-Hodgkin's Lymphoma [RATE] (RMCC)

5. USON 05007 Phase III Study to Investigate the Prevention of Relapse in Lymphoma Using Daily Enzastaurin (RMCC)
6. 06-008 Phase II Study of Combination Bortezomib (VELCADE®PS-341) and Rituximab in Patients with Previously Untreated and Relapsed/Refractory Waldenstrom's Macroglobulinemia (RMCC)
7. C05011 Phase II Study of Velcade (bortezomib) in Combination with Bendamustine and Rituximab in Subjects with Relapsed or Refractory Follicular Lymphoma (RMCC)
8. USON 06102 Phase II, Multicenter, Open-Label Trial Evaluating The Activity And Tolerability of Romidepsin (Depsipeptide, FK228) in Progressive or Relapsed Peripheral T-Cell Lymphoma Following Prior Systemic Therapy (RMCC)
9. Phase II Study of Oral LBH589 in Adult Patients with Refractory Cutaneous T-Cell Lymphoma (UCCC)
10. Phase II Study of Oral LBH589 in Adult Patients with Refractory Cutaneous T-Cell Lymphoma AND Prior HDAC Inhibitor Therapy (UCCC)
11. SG040-0006 Phase I Study of SGN-40 (anti-huCD40 mAb), Lenalidomide (Revlimid, cc-5013), and Dexamethasone in Patients with Multiple Myeloma (MM) (RMCC)
12. USON 05033 Phase I Open Label, Multicenter, Dose-Escalation Study to Determine the Maximum Tolerated Dose (MTD), Dose Limiting Toxicity (DLT), Safety and Pharmacokinetics of CGC-11047 When Used in Individual Combinations with 1) Gemcitabine or 2) Docetaxel or 3) Bevacizumab or 4) Erlotinib or 5) Cisplatin or 6) 5-Fluorouracil or 7) Sunitinib in Patients with Advanced Solid Tumors or Lymphoma (RMCC)
13. USON 08031 Multicenter, Phase 1, Open-Label, Dose-Escalation

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Study to Assess the Safety, Tolerability, and Pharmacokinetics of NKTR-102 (NKT-10002; PEG-Irinotecan) in Patients with Refractory Solid Tumors (RMCC)

14. Phase I Study of PDX101 in Combination with Bortezomib (PS-341) in Patients with Advanced Solid Tumors and Lymphoma (UCCC)
15. Multiple Ascending Dose (MAD) Phase I Study of the IGF-1R Antagonist R1507 Administered as an Intravenous Infusion on QW and Q3W Schedules in Patients with Advanced Solid Tumors, Non-Hodgkin's Lymphomas or Hodgkin's Lymphomas (UCCC)
16. S8947 Central Lymphoma Serum Repository Protocol (UCCC)
17. SG035-0003 A Pivotal Study of SGN-35 in Treatment of Patients with Relapsed or Refractory Hodgkin Lymphoma (RMCC)

### 3. Myeloma

1. 10104 Phase III Randomized, Double-Blind Study of Maintenance Therapy with CC-5013 (NSC # 703813, IND # 70116) or Placebo Following Autologous Stem Cell Transplantation for Multiple Myeloma (CCRP, RMCC)
2. E1A05 Randomized Phase III Trial of Consolidation Therapy with Bortezomib (Velcade) - Lenalidomide (Revlimid) -Dexamethasone (VRD) versus Bortezomib (Velcade) -Dexamethasone (VD) for Patients With Multiple Myeloma Who Have Completed a Dexamethasone Based Induction Regimen (CCRP, RMCC)
3. KAG-301 Phase III Randomized, Open-Label Clinical Trial of Tanespimycin (KOS-953) plus Bortezomib Compared to Bortezomib Alone in Patients with Multiple Myeloma in First Relapse (TIME-1) (RMCC)
4. S0777 Randomized Phase III Trial of CC-5-13 (lenalidomide, NSD-703813) and Low Dose Dexamethasone (LLD) vs. Bortezomib (PS-341, NSC-681239), Lenalidomide and Low Dose Dexamethasone (BLLD) for Induction, in Patients with Previously Untreated Multiple Myeloma without an Intent for Immediate Autologous Stem Cell Transplant (CCRP, DH, RMCC)
5. USON 06108 Phase IIIB Study of Three Treatment Regimens in Subjects with Previously Untreated Multiple Myeloma Who Are



Not Considered Candidates for High-Dose Chemotherapy and Autologous Stem Cell Transplantation: VELCADE, Thalidomide, and Dexamethasone (VTD) versus VELCADE and Dexamethasone (VD) versus VELCADE, Melphalan, and Prednisone (VMP) (RMCC)

6. USON 06168 Phase II Randomized, Blinded, Placebo-Controlled, Multicenter Study of Bevacizumab in Combination with Bortezomib in Patients with Relapsed or Refractory Multiple Myeloma (RMCC)
7. C05008 Phase I/II Study of VELCADE(Bortezomib), Dexamethasone, and Revlimid (Lenalidomide)(VDR) versus VELCADE, Dexamethasone, Cyclophosphamide, and Revlimid (VDCR) versus VELCADE, Dexamethasone, and Cyclophosphamide (VDC) in Subjects with Previously Untreated Multiple Myeloma (RMCC, UCCC)
8. SG033-0002 Phase I Combination Trial of SGN-33 (anti-huCD33 mAb; HuM195; lintuzumab) and Lenalidomide (Revlimid) in Patients with Myelodysplastic Syndromes (RMCC)
9. CSTI571A2402 A Worldwide, Observational Registry Collecting Longitudinal Data on the Management of Chronic Myelogenous Leukemia (CML) Patients (The WORLD CML Registry) in Routine Practice (DH)
10. USON 07168 A Prospective, Non-Interventional Multicenter Registry in Iron Overloaded Lower-Risk Myelodysplastic Patients (RMCC)
11. Pilot Study of Infusional Melphalan + Bortezomib for Myeloablative Therapy Prior to Autologous Transplant for Multiple Myeloma and Related Disorders (UCCC)

## Other

1. N04CA Phase III Randomized, Double-Blind, Placebo-Controlled

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- Study using Pilocarpine for Vaginal Dryness (CCRP, RMCC)
2. N07C2 Phase III Randomized, Double-Blind, Placebo-Controlled Study of the Use of Wisconsin Ginseng (*panax quinquefolius*) to Improve Cancer-Related Fatigue (CCRP, RMCC)
  3. USON 07033 Phase I Continuous Intravenous Infusion Study of Terameprocol (EM-1421) in Patients with Refractory Solid Tumors (RMCC)
  4. Phase I Dose Escalation Study of Daily Oral OSI-930 in Patients with Advanced Solid Tumors (UCCC)
  5. Phase I Dose-Escalation Study of OSI-906 and Erlotinib (Tarceva) in Patients with Advanced Solid Tumors (UCCC)
  6. Phase I Multicenter Dose Escalation Trial to Determine the Safety and Pharmacokinetics/Pharmacodynamics of RDEA119 a MEK Inhibitor in Advanced Cancer Patients (UCCC)
  7. Phase I Multiple Ascending Dose (MAD) Study of R4733 Administered Orally in Patients with Refractory Metastatic or Locally Advanced Solid Tumors (UCCC)
  8. Phase I Open Label Dose Escalation Study of BIIB022 (Anti-IGF-1R Monoclonal Antibody) in Subjects with Relapsed or Refractory Solid Tumors (UCCC)
  9. Phase I, Open-Label, Dose Escalation Study to Evaluate Safety, Pharmacokinetics and Pharmacodynamics of PF-00562271 in Patients with Advanced Non-Hematologic Malignancies (UCCC)
  10. Phase 1, Open-Label, Dose-Escalation Study to Evaluate Safety, Pharmacokinetics and Pharmacodynamics of Two Dosing Schedules of PF-00299804 in Patients with Advanced Malignant Solid Tumors (UCCC)
  11. Phase I Open Label Study of Rhumab IGFR in Patients with Advanced Solid Tumors for Which Standard Therapy Either does not Exist or Has Been Proven Ineffective or Intolerable (UCCC)
  12. 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 (UCCC)
  13. Phase I Study of Pazopanib in Combination with Either Erlotinib or Pemetrexed in Patients with Advanced Solid Tumors (UCCC)
  14. Phase I Study of SU011248 in Combination with Oxaliplatin,



Leucovorin, and 5-Fluorouracil in Patients With Advanced Solid Malignancies (UCCC)

15. Phase I Study of SU011248 In Combination With Pemetrexed, Pemetrexed/Cisplatin and Pemetrexed/Carboplatin in Patients with Advanced Solid Malignancies (UCCC)
16. Phase I Study of TST10088 in Patients with Advanced Incurable Solid Tumors (UCCC)
17. Phase IA Open Label Dose Escalation Study of the Safety and Pharmacokinetics of GDC-0152 an IAP Protein Antagonist Administered Intravenously to Patients with Locally Advanced or Metastatic Malignancies (UCCC)
18. Carter 2005-01 Prospective Investigation of Definitive Targeted Therapy for Solid Malignancies with Oligometastases (RMCC)
19. INCB 18424-351 A Randomized, Double Blind, Placebo-Controlled Study of JAK-2 Inhibitor INCB018424 Tablets Administered Orally to Subjects with Primary Myelofibrosis (PMF), Post-Polycythemia Vera Myelofibrosis (PPV-MF) or Essential Thrombocythemia Myelofibrosis (DH)
20. N04C2 An Exploratory, Randomized, Placebo-Controlled Trial of Depot Octreotide (Sandostatin LAR Depot) for Symptomatic Ascites in Cancer Patients (CCRP)
21. USON 06141 Examination of PNH, by Level Of CD59 on Red and White Blood Cells, in Bone Marrow Failure Syndromes (EXPLORE) (RMCC)
22. Cancer Test (UCCC)
23. Novartis Registry/Gist Registry- Observational Database for All Gist Tumors (RMCC)
24. Open-Label, Dose-Escalation, Safety, and Pharmacokinetic Study of ENMD-2076 Administered Orally to Patients with Advanced Cancer (UCCC)

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25. Open Label Sunitinib Malate (SU011248) Continuation Protocol for Patients Who Have Completed a Prior Sunitinib Study and Are Judged by the Investigator to Have the Potential to Benefit from Sunitinib Treatment (UCCC)
26. Single-Center Open-Label, Dose-Escalation Safety and Pharmacokinetic Study of ENMD-1198 Administered Orally to Patients with Advanced Cancer (UCCC)
27. SPORE 24: Biomarkers and Dysplastic Respiratory Epithelium (version B) (UCCC)
28. SPORE4: Analysis of Intermediate Endpoint Biomarkers in the Respiratory Epithelium of Smokers Compared to Non Smoking Controls (UCCC)
29. Treatment Protocol for Patients Continuing from a Prior SU011248 Protocol (UCCC)

## **Pediatrics**



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