

# CancerPACT<sup>tm</sup>



Cancer Patients Alliance for Clinical Trials

## Denver Cancer Clinical Trials Listing

Spring 2010



CancerPACT is an alliance of the Cancer Patients Alliance, 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), 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.

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[www.ColoradoCancerCoalition.org](http://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. 25-02A Phase III Trial Evaluating the Role of Exemestane Plus GnRH Analogue as Adjuvant Therapy for Premenopausal Women with Endocrine Responsive Breast Cancer- TEXT (UCCC)
2. 2009-APBI Phase III Randomized Study Comparing Intensity Modulated Planning vs. 3-Dimensional Planning for Accelerated Partial Breast Radiotherapy (RMCC)
3. 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 Auxiliary Lymph Nodes (CCRP, RMCC)
4. 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, UCCC)
5. 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)



6. 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, DH, RMCC, UCCC)
7. 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, UCCC)
8. 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)
9. B-46-I Phase III Clinical Trial Comparing the Combination of TC Plus Bevacizumab to TC Alone and to TAC for Women With Node-Positive or High-Risk Node-Negative, HER2-Negative Breast Cancer (CCRP, RMCC)
10. CALGB 40502 Randomized Phase III Trial of Weekly Paclitaxel Compared to Weekly Nanoparticle Albumin Bound Nab-Paclitaxel or Ixabepilone Combined with Bevacizumab as First -Line Therapy for Locally Recurrent or Metastatic Breast Cancer (CCRP)

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11. 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)
12. 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)
13. GSK EGF108919 and NCIC MA.31 Randomized, Open-Label, Phase III study of Taxane-Based Chemotherapy with Lapatinib or Trastuzumab as First Line Therapy for Women with HER2/neu Positive Metastatic Breast Cancer (DH)
14. MCCRRC PACS 08-0610 Phase III Randomized Open Label Multicentric Trial Evaluating the Benefit of a Sequential Regimen Associating FEC100 and Ixabepilone in Adjuvant Treatment of Non-Metastatic, Poor Prognosis Breast Cancer Defined as Triple-Negative Tumor (HER2 Negative-ER Negative-PR Negative) or HER2 Negative and PR Negative Tumor; in Node Positive or Node Negative Patients (CCRP, RMCC)
15. 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, UCCC)
16. 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)
17. 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-Positive or High-Risk Node Negative Breast Cancer (DH, UCCC)

18. USON 07119 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 (RMCC)
19. USON 08200 A Phase 3, Randomized, Open-Label Study of Neratinib Versus Lapatinib Plus Capecitabine for the Treatment of ErbB-2-Positive Locally Advanced or Metastatic Breast Cancer (RMCC)
20. USON 08217 Randomized Phase III Double-Blind Placebo-Controlled Multicenter Trial of Everolimus in Combination with Trastuzumab and Paclitaxel, as First Line Therapy in Women with HER2-Positive Locally Advanced or Metastatic Breast Cancer (RMCC)
21. USON 09008 A Phase III 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)
22. Phase III Multicenter Multinational Randomized Double Blind Study of IMC-1121B Plus Docetaxel vs. Placebo Plus Docetaxel in Previously Untreated Patients with HER2-Negative Unresectable Locally Recurrent or Metastatic Breast Cancer (UCCC)
23. 04111 Phase II Trial to Determine the ORR associated with Doxil & Carboplatin Plus HER2 + in Metastatic Breast Cancer (RMCC)
24. 11270 Phase II Trial of Adj TC + Herceptin on Early Stage Breast Cancer (RMCC)

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25. 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)
26. S0622 Phase II Studies of Two Different Schedules of Dasatinib (NSC-732517) in Bone-Metastasis Predominant Metastatic Breast Cancer (UCCC)
27. 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)
28. 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)
29. 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)
30. USON 08180 Phase II Multicenter Study Evaluating the Efficacy and Safety of IPI-504 in Combination with Trastuzumab in Patients with Pretreated, Locally Advanced or Metastatic Human Epidermal Growth Factor Receptor 2 (HER2) - Positive Breast Cancer (RMCC)
31. USON 08215 Phase II Randomized Double-Blind Multicenter Study of Exemestane with and without SNDX-275 in Postmenopausal Women with Locally Recurrent or Metastatic Estrogen Receptor-Positive Breast Cancer, Progressing on Treatment with a Non-Steroidal Aromatase Inhibitor (RMCC)



32. USON 09010 Phase II Double-Blind Randomized Placebo-Controlled Study of ACE-011 for the Treatment of Chemotherapy Induced Anemia in Patients with Metastatic Breast Cancer (RMCC)
33. B-37 Randomized Clinical Trial of Adjuvant Chemotherapy for Radically Resected Loco-Regional Relapse of Breast Cancer (RMCC)
34. 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)
35. JMA.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 (RMCC)
36. PACCT-1 Program for the Assessment of Clinical Cancer Tests - Trial Assigning Individualized Options for Treatment: The TAILORx Trial (CCRP, RMCC, UCCC)
37. Insomnia-Study Cognitive-Behavioral Therapy for Insomnia after Breast Cancer Treatment (DH)
38. Lapatinib in Endocrine-Resistant Metastatic Breast Cancer (UCCC)
39. Molecular Predictors of Response to SU011248 in Tumor Samples from Patients with Metastatic Breast Cancer (UCCC)

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40. Monitoring of Circulating Tumor Cells in Patients with Newly Diagnosed Early Stage ER+Breast Cancer and Its Correlation with Oncotype DxScore (UCCC)
41. NIH Cognition Trial Chemotherapy and Cognition in Older Breast Cancer Patients (RMCC)
42. Window of Opportunity Study Targeting the Inflammatory Milieu of Pregnancy Associated Breast Cancer (UCCC)
43. S0702 A Prospective Observational Multicenter Cohort Study to Assess the Incidence of Osteonecrosis of the Jaw (ONJ) in Cancer Patients with Bone Metastases Starting Zoledronic Acid Treatment (CCRP)
44. SWOG S0715 Randomized Placebo-Controlled Trial of Acetyl L-Carnitine for the Prevention of Taxane Induced Neuropathy (UCCC)

## **2. Central Nervous System Tumors**

1. NCCTG N0574/N0547 Phase III Randomized Trial of the Role of Whole Brain Radiation Therapy in Addition to Radiosurgery in Patients with One to Three Cerebral Metastases (CCRP, UCCC)
2. CTSU/RTOG0825 Phase III Double-Blind Placebo-Controlled Trial of Conventional Concurrent Chemoradiation and Adjuvant Temozolomide Plus Bevacizumab vs Conventional Concurrent Chemoradiation and Adjuvant Temozolomide in Patients With Newly Diagnosed Glioblastoma (CCRP)
3. NCCTG N047B Phase II Trial of Suberoylanilide Hydroxamic Acid (SAHA) in Patients with Recurrent Glioblastoma (RMCC)
4. N0779 Phase II Study of Vorinostat (SAHA) in Combination with Bortezomib (PS-341) in Patients With Recurrent Glioblastoma Multiforme (CCRP, RMCC)



5. Phase I Dose Escalation Study of Zactima (ZD6474) with Hypofractionated Stereotactic Radiotherapy in Patients with Recurrent Malignant Gliomas (IRUSZACT0073) (UCCC)
6. Phase I Dose per Fraction Escalation Study of Hypo-Fractionated Intensity-Modulated Radiation Therapy (Hypo-IMRT) Combining with Temozolomide (TMZ) Chemotherapy for Patients with Newly Diagnosed Glioblastoma Multiforme (GBM) (DH, 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 Markers (CCRP, DH, RMCC, UCCC)

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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 ( DH, RMCC)
4. S0600 Phase III Trial of Irinotecan-Based Chemotherapy Plus Cetuximab (NSC-714692) or Bevacizumab (NSC-704865) as Second-Line Therapy for Patients with Metastatic Colorectal Cancer who have Progressed on Bevacizumab with either FOLFOX, OPTIMOX or XELOX (CCRP)
5. N054C Phase II Study of Sorafenib/Bevacizumab as Salvage Therapy in Patients with Metastatic Colorectal Cancer (CCRP)
6. E4203 Phase II Study of Treatment Selection Based Upon Tumor Thymidylate Synthase Expression in Previously Untreated Patients with Metastatic Colorectal Cancer (CCRP, RMCC)
7. USON 05102 Randomized Phase II Trial of Pre-Operative Chemoradiotherapy with or without Cetuximab (ERBITUX) in Locally-Advanced Adenocarcinoma of the Rectum (RMCC)
8. 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)
9. USON 08137 Phase II Randomized Double-Blind Placebo-Controlled Study Evaluating the Safety and Efficacy of FOLFIRI in Combination with AMG 479 or AMG 655 vs. FOLFIRI for the Second-Line Treatment of KRAS-Mutant Colorectal Carcinoma (RMCC)
10. 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)



11. 20060447 A Randomized, Phase IB/II Trial of AMG 102 or AMG 479 in Combination with Panitumumab vs. Panitumumab Alone in Subjects with Wild-Type KRAS Metastatic Colorectal 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. 0436 Phase III Trial Evaluating the Addition of Cetuximab to Paclitaxel, Cisplatin and Radiation for Patients with Esophageal Cancer who are Treated without Surgery (CCRP, RMCC)
2. 80101 Phase III Intergroup Trial of Adjuvant Chemoradiation after Resection of Gastric or Gastroesophageal Adenocarcinoma (RMCC)
3. 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)
4. Phase II Study of Erlotinib (Tarceva) and Radiotherapy for Elderly Patients with Esophageal Carcinoma (UCCC)

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5. Phase IB/II Multicenter Double-Blind 3-Arm Study in Subjects with Unresectable Locally Advanced or Metastatic Gastric or Esophagogastric Junction Adenocarcinoma to Evaluate the Safety and Efficacy of First-line Treatment with Epirubicin, Cisplatin, and Capecitabine(ECX) Plus AMG 102 (UCCC)

### **C. Gastric Cancer**

1. CAMN107G2301 Phase III Open-label Study of Nilotinib vs. Imatinib in GIST Patients (RMCC)
2. USON 08055 Randomized Multi-Center Phase III Study to Evaluate the Efficacy and Safety of Nilotinib vs. Imatinib in Adult Patients with Unresectable or Metastatic Gastrointestinal Stromal Tumors (GIST) (RMCC, UCCC)

### **D. Pancreatic Cancer**

1. Phase III Randomized Study of Weekly ABI-007 Plus Gemcitabine vs. Gemcitabine Alone in Patients with Metastatic Adenocarcinoma of the Pancreas (UCCC)
2. N064B Phase II Randomized Study of Erlotinib Hydrochloride and Gemcitabine Hydrochloride with vs. without Panitumumab in Patients with Previously Untreated, Metastatic Adenocarcinoma of the Pancreas (CCRP)
3. Phase II Multicenter Two-Tier Study of IMCA12 in Combination With Depot Octreotide in Patients With Metastatic, Well- or Moderately-Differentiated Carcinoid or Islet Cell Carcinoma (UCCC)



4. Phase II Study of ARRY-334543 and Gemcitabine as First Line Therapy in Patients with Metastatic Pancreatic Cancer Following a Phase IB Lead in to Assess the Safety in Patients with Advanced Cancer (UCCC)
5. Phase II Study of the Safety and Efficacy of the Therapeutic Vaccine GI-4000 in Combination with Gemcitabine vs. Placebo for the Treatment of Non-Metastatic, Post-Resection Pancreas Cancer (RMCC)
6. S0727 A Phase I and Randomized Phase II Trial of Gemcitabine + Erlotinib (NSC-718781) + IMC-112 (NSC0742460) vs. Gemcitabine + Erlotinib as First-Line Treatment in Patients with Metastatic Pancreatic Cancer (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)

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2. GOG-0213 Phase III Randomized Controlled Clinical Trial of Carboplatin and Paclitaxel Alone or in Combination with Bevacizumab (NSC #704865, IND #7921) Followed by Bevacizumab and Secondary Cytoreductive Surgery in Platinum-Sensitive, Recurrent Ovarian, Fallopian Tube and Peritoneal Primary Cancer (CCRP, UCCC)
3. 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 (RMCC)
4. GOG-0252 Phase III Clinical Trial of Bevacizumab with IV vs. IP Chemotherapy in Ovarian, Fallopian Tube and Primary Peritoneal Carcinoma (UCCC)
5. MORAb-003-004 Phase III Randomized Double-Blind Placebo-Controlled Study to Assess the Efficacy and Safety of Weekly Farletuzumab (MORAb-003) in Combination with Carboplatin and Taxane in Subjects with Platinum-sensitive Ovarian Cancer in First Relapse (DH, UCCC)
6. GOG-0214 Phase II Double Blind Randomized Trial Evaluating the Biological Effect of Levonorgestrel on the Ovarian Epithelium in Women at High Risk for Ovarian Cancer (IND 79610) (UCCC)
7. GOG-0215 Phase II Randomized Study of the Effect of Zoledronic Acid vs. 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, UCCC)
8. Phase II Multicenter Randomized Blinded Placebo Controlled Trial of Carboplatin and Gemcitabine Plus Bevacizumab in Patients with Platinum Sensitive Recurrent Ovary, Primary Peritoneal or Fallopian Tube Carcinoma (UCCC)



9. Phase II Multicenter Open Label Study of the Efficacy and Safety of AMG 479, a Fully Human Monoclonal Antibody Against Insulin-Like Growth Factor Type I Receptor (IGF-1R) as Second Line Therapy in Patients with Recurrent Platinum Sensitive Ovarian Cancer (UCCC)
10. Study to Define a Protein Signature of Ovarian Cancer (UCCC)

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

1. GOG-0240 Randomized Phase III Trial of Cisplatin Plus Paclitaxel with and without NCI-Supplied Bevacizumab (NSC #704865, IND #7921) vs. the Non-Platinum Doublet, Topotecan Plus Paclitaxel, with and without NCI-Supplied Bevacizumab, in Stage IVB, Recurrent or Persistent Carcinoma of the Cervix (CCRP, UCCC)
2. GOG 0210 A Molecular Staging Study of Endometrial Carcinoma (DH, UCCC)
3. GOG 0238 Randomized Trial of Pelvic Irradiation with or without Concurrent Weekly Cisplatin in Patients with Pelvic only Recurrence of Carcinoma of the Uterine Corpus (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)

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2. RTOG 0619 Randomized Phase II Trial of Chemoradiotherapy vs. Chemoradiotherapy and Vandetanib for High-Risk Postoperative Advanced Squamous Cell Carcinoma of the Head and Neck (UCCC)
3. Prospective Longitudinal, Multi-Center, Descriptive Registry of Patients Receiving Therapy Other than Surgical Resection Alone for Newly Diagnosed Head and Neck Carcinoma (UCCC)

## 6. Lung

1. AMR PH GL 2007 CL 001 Phase III Trial in Patients With Small Cell Lung Cancer After Failure of First-Line Chemotherapy (RMCC)
2. CALGB-30506 Phase III Trial of Chemotherapy or Observation in Treating Patients With Stage I Non-Small Cell Lung Cancer (CCRP)
3. CALGB 30610 Phase III Comparison of Thoracic Radiotherapy Regimens in Patients with Limited Small Cell Lung Cancer also Receiving Cisplatin and Etoposide (CCRP, UCCC)
4. 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)
5. C140503 A Phase III Randomized Trial of Lobectomy Versus Sublobar Resection for Small (<=2 cm) Peripheral Non-Small Cell Lung Cancer (UCCC)
6. OSI-774-302 RADIANT Phase III Study of Tarceva after Surgery with or without Adjuvant Chemotherapy in NSCLC Patients Who Have EGFR-Positive Tumors (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)
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. USON 07178/RTOG 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, RMCC, UCCC)
11. USON 08044 Randomized Open-Label Phase III Study of Pemetrexed plus Carboplatin and Bevacizumab Followed by Maintenance Pemetrexed and Bevacizumab vs. Paclitaxel Plus Carboplatin and Bevacizumab Followed by Maintenance Bevacizumab in Patients with Stage IIIB or IV Nonsquamous Non-Small Cell Lung Cancer (RMCC)

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12. USON 08094 Phase III Randomized Double-Blind Placebo-Controlled Multi-Center Study of ASA404 in Combination with Docetaxel in Second-Line Treatment of Patients with Locally Advanced or Metastatic (Stage IIIb/IV) Non-Small Cell Lung Cancer (NSCLC) (RMCC)
13. Phase III Multi-Center Randomized Double-Blind Placebo-Controlled Trial Comparing the Efficacy of Bevacizumab in Combination with Rituximab and CHOP (RA-CHOP) vs. Rituximab and CHOP (R-CHOP) in Previously Untreated Patients with CD20-Positive Diffuse Large B-Cell Lymphoma (DLBCL) (UCCC)
14. RTOG 0617 (NCCTG N0628, CALGB 30609) A Randomized Phase III Comparison of Standard-Dose (60Gy) Versus Highdose (74Gy) Conformal Radiotherapy with Concurrent and Consolidation Carboplatin/Paclitaxel ± Cetuximab in Patients with Stage IIIA/IIIB Non-Small Cell Lung Cancer (UCCC)
15. E1508 Randomized Phase II Study of Cisplatin and Etoposide in Combination with Either Hedgehog Inhibitor GDC-0449 or IGF-1R MOAB IMCA12 for Patients with Extensive Stage Small Cell Lung Cancer (CCRP)
16. Phase II Study of CS-7017 and Erlotinib in Subjects with Advanced NSCLC Who Failed First Line Therapy (DH)
17. E4508 Phase II Randomized Study of Carboplatin and Paclitaxel in Combination with Cetuximab and/or Cixutumumab in Patients with Stage IIIB or IV Non-Small Cell Lung Cancer (CCRP)
18. FAV-ID-09 Phase II Trial of FavId (Patient-Specific Idiotypic/KLH) and GM-CSF in Subjects Who Demonstrated Progressive Disease and Did Not Receive FavId on Study FavId-06 (RMCC)
19. 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)



20. 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, RMCC)
21. Phase II Trial of Erlotinib (Tarceva) in Combination with Stereotactic Body Radiation Therapy (SBRT) for Patients with Locally Advanced or Metastatic Non-Small Cell Lung Cancer (NSCLC) (UCCC)
22. Phase II Randomized Study with a Safety Lead in of the Anti-IGF-1R Monoclonal Antibody IMC-A12 in Combination with Erlotinib Compared with Erlotinib Alone in Patients with Advanced Non-Small Cell Lung Cancer (NSCLC) Who have Failed at Least One Platinum Containing Chemotherapy Regimen (UCCC)
23. Phase II Randomized Chemoprevention Study of Pioglitazone vs. Placebo in Patients at High Risk for Lung Cancer (UCCC)
24. S0636 A Phase II Trial of the Combination of OSI-774 (Erlotinib; NSC-718781) and Bevacizumab (Rhumab VEGF; NSC-704865) in Never Smokers with Stage IIIB and IV Primary NSCLC Adenocarcinomas (UCCC)
25. S0635 A Phase II Trial of the Combination of OSI-774 (Erlotinib; NSC-718781) and Bevacizumab (Rhumab VEGF; NSC-704865) in Stage IIIB and IV Bronchioloalveolar Carcinoma (BAC) and Adenocarcinoma with BAC Features (ADENOBAC) (UCCC)

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26. RTOG 0915 (NCCTG N0927) A Randomized Phase II Study Comparing 2 Stereotactic Body Radiation Therapy (SBRT) Schedules For Medically Inoperable Patients With Stage I Peripheral Non-Small Cell Lung Cancer (UCCC)
27. RTOG 0813 Seamless Phase I/II Study Of Stereotactic Lung Radiotherapy (SBRT) For Early Stage, Centrally Located, Non-Small Cell Lung Cancer (NSCLC) In Medically Inoperable Patients (UCCC)
28. 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 (UCCC)
29. Phase I/IIA Study Evaluating the Safety Pharmacokinetics and Efficacy of ABT-2263 in Subjects with Small Cell Lung Cancer (SCLC) (UCCC)
30. 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)
31. COMIRB# 07-0805 Investigator initiated Platelet mRNA Profiling in Metastatic NSCLC (DH, UCCC)
32. EFC10261 A Multinational Randomized Double-Blind Study Comparing Aflibercept 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)
33. S0424 Molecular Epidemiology Case-Series Study of Non-Small Cell Lung Cancer in Smoking and Non-Smoking Women and Men (DH, UCCC)



34. USON 08035 Randomized Double-Blind Placebo-Controlled Study to Evaluate the Long-Term Safety and Efficacy of Darbepoetin Alfa Administered at 500 µg Once-Every-3-Weeks in Anemic Subjects With Advanced Stage Non-small Cell Lung Cancer Receiving Multi-Cycle Chemotherapy (RMCC)
35. An Exploratory Analysis of Exhaled Nitric Oxide Concentration in Patients with Lung Cancer Receiving Thoracic Radiotherapy (UCCC)
36. Lung Cancer Mutation Consortium Protocol (UCCC)
37. Platelet mRNA Profiling in Metastatic NSCLC (DH)
38. Response of Intermediate Endpoint Biomarkers and Dysplastic Airway Epithelium to Chemotherapy or Targeted Therapy in Patients with Lung Cancer (UCCC)

## 7. Melanoma

1. E1697 Phase III Randomized Study of Four Weeks High Dose IFN-α2b in Stage T2b No, T3a-b No, T4a-b No, and T1-4, N1a, 2a, 3 (microscopic) Melanoma (CCRP, RMCC, UCCC)
2. Phase III Clinical Trial to Evaluate the Safety and Efficacy of Treatment with 2 mg Intralesional Allovectin-7 Compared to Dacarbazine (DTIC) or Temozolomide (TMZ) in Subjects with Recurrent Metastatic Melanoma (UCCC)

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3. N0775 Randomized Phase II Trial of Temozolomide (TMZ) and Avastin or ABI-007/Carboplatin (CBDCA) and Avastin in Patients with Unresectable Stage IV Malignant Melanoma (CCRP)
4. Phase II Study of Imatinib in Patients with Mucosal or Acral/Lentiginous Melanoma (UCCC)
5. Phase II Randomized Clinical Trial to Evaluate the Efficacy and Safety of Treatment with OncoVex Compared to Subcutaneously Administered GM-CSF in Previously Treated Melanoma Patients with Unresectable Stage IIIB, IIIC and IV Disease (UCCC)
6. Phase II Double-Blind Randomized Study to Assess the Efficacy of AZD6244 (Hyd-Sulfate) in Combination with Dacarbazine Compared with Dacarbazine Alone in First Line Patients with BRAF Mutation Positive Advanced Cutaneous or Unknown Primary Melanoma (UCCC)
7. Phase II Study of Marqibo in Patients with Metastatic Uveal Melanoma (UCCC)
8. Gene Expression in Peripheral Blood to Predict Recurrence of Malignant Melanoma (UCCC)

## 8. Prostate Cancer

1. 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, UCCC)
2. C90202 Phase III Randomized Double-Blind Placebo-Controlled Study of Early vs. Standard Zoledronic Acid to Prevent Skeletal Related Events in Men with Prostate Cancer Metastatic to Bone (UCCC)



3. 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)
4. PR11 Phase III Study of Active Surveillance Therapy Against Radical Treatment in Patients Diagnosed with Favorable Risk Prostate Cancer (START) (UCCC)
5. S0421 Phase III Study of Docetaxel and Atrasentan vs. Docetaxel and Placebo for Patients with Advanced Hormone Refractory Prostate Cancer (CCRP, DH, RMCC, UCCC)
6. Phase III Randomized Double-Blind Placebo-Controlled Study of Abiraterone Acetate (CB7630) Plus Prednisone in Asymptomatic or Mildly Symptomatic Patients with Metastatic Castration-Resistant Prostate Cancer (UCCC)
7. AFFIRM A Multinational Phase 3, Randomized, Double-Blind, Placebo Controlled Efficacy and Safety Study of Oral MDV3100 in Patients with Progressive Castration-Resistant Prostate Cancer Previously Treated with Docetaxel Based Chemotherapy (UCCC)
8. RTOG 0621 Phase II Trial of Adjuvant 3DCRT/IMRT in Combination with Androgen Suppression and Docetaxel for High Risk Prostate Cancer Patients Post-Prostatectomy (UCCC)
9. Phase II Randomized Double Blind Placebo Controlled Study of Testosterone Replacement in Men with Non Metastatic Castrate Resistant Prostate Cancer (UCCC)

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10. Phase II Randomized Trial of AZD2171 Docetaxel and Prednisone Compared to Docetaxel and Prednisone in Patients with Metastatic Hormone Refractory Prostate Cancer (UCCC)
11. Phase I & II Study of Stereotactic Body Radiation Therapy (SBRT) for Low and Intermediate Risk Prostate Cancer (UCCC)
12. E3805, CHAARTED: ChemoHormonal Therapy vs. Androgen Ablation Randomized Trial for Extensive Disease in Prostate Cancer (UCCC)

## **9. Urologic Cancers (other)**

### **A. Bladder**

1. S0337 Phase III Blinded Study of Immediate Post-TURBT Instillation of Gemcitabine vs. Saline in Patients with Newly Diagnosed or Occasional Recurring Grade I/II Superficial Bladder Cancer (UCCC)
2. CALGB-90601 A Randomized Double-blinded Phase III Study Comparing Gemcitabine, Cisplatin, and Bevacizumab (IND #7921, NSC #704865) to Gemcitabine, Cisplatin, and Placebo in Patients with Advanced Transitional Cell Carcinoma (UCCC)
3. The Effect of Treatment on Circulating Tumor Cells in Bladder Cancer Patients with Muscle Invasive or Advanced Disease (UCCC)



## B.Kidney Cancer

1. E2804 Randomized Phase II Study of VEGF, RAF Kinase and mTOR Combination Targeted Therapy (CTT) with Bevacizumab, Sorafenib and Temsirolimus in Advanced Renal Cell Carcinoma (CCRP, RMCC, UCCC)
2. E2805 Phase III Randomized Double Blind Trial of Adjuvant Sunitinib vs. Sorafenib vs. Placebo in Patients with Resected Renal Cell Carcinoma (DH, UCCC)
3. E4805 Phase II Study to Determine the Effect of Two Different Doses of AVE0005 (VEGF Trap) in Patients with Metastatic Renal Cell Carcinoma (CCRP)
4. E2805 ASSURE: Adjuvant Sorafenib or Sunitinib for Unfavorable Renal Carcinoma (CCRP, RMCC, UCCC)
5. USON 08036 Axitinib (AG-013736) as Second Line Therapy for Metastatic Renal Cell Cancer: AXIS Trial (RMCC)
6. USON 08060 A Study of Pazopanib vs. Sunitinib in the Treatment of Subjects with Locally Advanced and/or Metastatic Renal Cell Carcinoma (RMCC)

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## 1. Leukemia

1. 10501 Phase III Intergroup CLL Study of Asymptomatic Patients with Untreated Chronic Lymphocytic Leukemia Randomized to Early Intervention vs. Observation with Later Treatment in the High-Risk Genetic Subset with IGVH Unmutated Disease (CCRP, RMCC)
2. CLO34100405 Phase III Randomized Study of Myeloablative Versus Nonmyeloablative Transplant Conditioning in Patients With Myelodysplastic Syndromes or Acute Myeloid Leukemia (RMCC)
3. 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)
4. E2905 Randomized Phase III Trial Comparing the Frequency of Major Erythroid Response (MER) to Treatment with Lenalidomide (Revlimid) Alone and In Combination with Epoetin Alfa (Procrit) in Subjects with Low or Intermediate-1 Risk MDS and Symptomatic Anemia (CCRP, RMCC)
5. FHCRC-1992.00 Phase III Randomized Study of Myeloablative vs. Nonmyeloablative Transplant Conditioning in Patients With Myelodysplastic Syndromes or Acute Myeloid Leukemia (RMCC)
6. OMB110911 Phase III Open Label Randomized Trial of Ofatumumab Added to Chlorambucil vs. Chlorambucil Monotherapy in Previously Untreated Patients with Chronic Lymphocytic Leukemia (DH)



7. Phase III Open-Label Randomized Study of Amonafide L-Malate in Combination with Cytarabine Compared to Daunorubicin in Combination with Cytarabine in Patients with Secondary Acute Myeloid Leukemia (AML) (UCCC)
8. CTSU/CALGB 10603 A Phase III Randomized, Double-Blind Study of Induction (Daunorubicin/Cytarabine) and Consolidation (High-Dose Cytarabine) Chemotherapy + Midostaurin (PKC412) (IND # 101261) or Placebo in Newly Diagnosed Patients < 60 Years of Age with FLT3 Mutated Acute Myeloid Leukemia (AML) (DH)
9. RC0783 Randomized Phase II Trial of Pentostatin, Cyclophosphamide, and Rituximab With or Without Concurrent Avastin® for Previously Untreated B-Chronic Lymphocytic Leukemia (CLL) (DH)
10. CALGB 10403 Intergroup Phase II Clinical Trial for Adolescents and Young Adults with Untreated Acute Lymphoblastic Leukemia (ALL) (CCRP)
11. 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 Dysplasia (CCRP, RMCC)
12. 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)

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13. HBS407 Phase II Study to Evaluate the Safety and Efficacy of Weekly Doses of Marqibo (vincristine sulfate liposomes injection) in Adult Patients with Philadelphia Chromosome-Negative Acute Lymphoblastic Leukemia (ALL) in Second Relapse or Adult Patients with Philadelphia Chromosome-Negative ALL Who Failed Two Treatment Lines of Anti-Leukemia Chemotherapy [rALLy] (RMCC)
14. Phase II Single Arm Open Label Study to Determine the Efficacy of 100mg Twice Daily Oral Dosing of Midostarin Administered to Patients with Aggressive Systemic Mastocytosis or Mast Cell Leukemia +/- an Associated Hematological Clonal Non Mast Cell Lineage Disease (UCCC)
15. Phase IIB Multicenter Randomized Open-Label Trial of CPX-351 (Cytarabine:Daunorubicin) Liposome vs. Intensive Salvage Therapy in Adult Patients <60 years old with AML in First Relapse Following an Initial CR>1 Month Duration (UCCC)
16. FHCRC-1581.00 Phase II Study of a Non-Myeloablative Conditioning Regimen Comprising Fludarabine and Total Body Irradiation Followed By Allogeneic Peripheral Blood Stem Cell Transplantation in Patients with Imatinib Mesylate, Dasatinib, or Nilotinib-Responsive Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia or Chronic Myelogenous Leukemia in Blast Crisis (RMCC)
17. SPO-0012 Phase II/II Study to Evaluate the Safety and Tolerability Study of SNS-595 and Cytarabine Combination in Acute Myeloid Leukemia in Humans (RMCC)
18. E3903 Ancillary Laboratory Protocol for Collecting Diagnostic Material on Patients Considered for ECOG Treatment Trials for Leukemia or Related Hematologic Disorders (CCRP)
19. Transplantation of Unrelated Umbilical Cord Blood for Patients with Hematological Diseases with Cyclophosphamide/Fludarabine/Total Body Irradiation Myeloablative Preparative Regimen (UCCC)



20. Transplantation of Unrelated Donor Umbilical Cord Blood in Patients with Hematological Malignancies Using a Reduced-Intensity Preparative Regimen (UCCC)
21. 09-0889 FHCRC: A Multi-Center Study of Conditioning with Treosulfan, Fludarabine and Escalating Doses Of TBI For Allogeneic Hematopoietic Cell Transplantation in Patients with Acute Myeloid Leukemia (AML) And Myelodysplastic Syndrome (MDS) (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 (RMCC)
2. CALGB 50303 Phase III Randomized Study of R-CHOP vs. Dose Adjusted EPOCH-R with Molecular Profiling in Untreated De Novo Diffuse Large B-cell Lymphomas (CCRP)
3. 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, UCCC)

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4. H6Q-MC-JCBI Phase III Clinical Study to Investigate the Prevention of Relapse in Lymphoma Using Daily Enzastaurin (CCRP)
5. Novartis CRAD001N2301 Phase III Randomized Double-Blind Placebo-Controlled, Multi-Center Study of RAD001 Maintenance Therapy in Elderly, High Risk Patients with Advanced Diffuse Large B-Cell Lymphoma (DLBCL) to Compare the Safety and Efficacy of RAD001 vs. Matching Placebo after Patients have Achieved Complete or Partial Response with First-Line Rituximab-Chemotherapy (DH)
6. 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)
7. USON 05007 Phase III Study to Investigate the Prevention of Relapse in Lymphoma Using Daily Enzastaurin (RMCC)
8. 07-0694 A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Phase III Trial Comparing the Efficacy of Bevacizumab in Combination with Rituximab and Chop (RA-CHOP) Versus Rituximab and CHOP (R-CHOP) in Previously Untreated Patients with CD20-Positive Diffuse Large B-Cell Lymphoma (DLBCL) (UCCC)
9. Phase II Multi-Center Study of Entinostat (SNDX-275) in Patients with Relapsed or Refractory Hodgkin's Lymphoma (UCCC)
10. C14004 Phase II Trial of MLN8237, an Oral Aurora A Kinase Inhibitor, in Adult Patients with Aggressive Non-Hodgkin's Lymphoma (RMCC)
11. N0682 Phase II Study of Rituximab and Denileukin Diftitox in Patients with Previously Untreated Stage III or IV Follicular B-Cell Non-Hodgkin's Lymphoma (CCRP)
12. SG035-0004 Phase II Study of SGN-35 in Treatment of Patients with Relapsed or Refractory Systemic Anaplastic Large Cell Lymphoma (CCRP, RMCC)



13. USON 08087 Open-Label Single-Arm Phase II Study of RAD001 in Patients with Mantle Cell Lymphoma Who are Refractory or Intolerant to Velcade (RMCC)
14. Phase II Study of Oral LBH589 in Adult Patients with Refractory Cutaneous T-Cell Lymphoma and Prior HDAC Inhibitor Therapy (UCCC)
15. XT009 Phase II Single Arm Study of Xcellerated T Cells TM for Non-Hodgkin's Lymphoma (NHL) Patients (RMCC)
16. PDX-009 Phase I/IIA Open-Label Study of Pralatrexate and Gemcitabine with Vitamin B12 and Folic Acid Supplementation in Patients with Relapsed or Refractory Lymphoproliferative Malignancies (RMCC)
17. C16002 Open-Label Dose-Escalation Phase I Study of MLN9708, a Second-Generation Proteasome Inhibitor, in Adult Patients with Lymphoma (RMCC)
18. 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)

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19. USON 08031 Multicenter Phase I Open-Label Dose-Escalation Study to Assess the Safety, Tolerability, and Pharmacokinetics of NKTR-102 (NKT-10002; PEG-Irinotecan) in Patients with Refractory Solid Tumors (RMCC)
20. Phase I Dose Escalation Study of the Safety and Pharmacokinetics of IPI-493 Orally Administered to Patients with Advanced Solid Tumors or Hematologic Malignancies (UCCC)
21. Phase I Study of PDX101 in Combination with Bortezomib (PS-341) in Patients with Advanced Solid Tumors and Lymphoma (UCCC)
22. Phase I Trial of PF-03084014 in Patients with Advanced Solid Tumor Malignancy and T-Cell Acute Lymphoblastic Leukemia/Lymphoblastic Lymphoma (UCCC)
23. USON 07152 An Open-Label Randomized Parallel-Group Study of Bendamustine Hydrochloride and Rituximab (BR) Compared with Rituximab, Cyclophosphamide, Vincristine, and Prednisone (R-CVP) or Rituximab, Cyclophosphamide, Doxorubicin, Vincristine, and Prednisone (R-CHOP) in the First-Line Treatment of Patients with Advanced Indolent Non-Hodgkin's Lymphoma (NHL) or Mantle Cell Lymphoma (MCL) (RMCC)
24. Open Label Multiple Dose Escalation Study to Investigate the Safety, Pharmacokinetics and Pharmacodynamics of the MEK Inhibitor GSK 1120212 in Subjects with Solid Tumors or Lymphoma (UCCC)
25. 08-0817 A Phase I-II Study of Infusional Melphalan + Bortezomib for Myeloablative Therapy Prior to Autologous Transplant for Patients with Multiple Myeloma (UCCC)



### 3. Myeloma

1. ECOG C-10104 Phase III Randomized Double-Blind Study of Maintenance Therapy with CC-5013 or Placebo Following Autologous Stem Cell Transplantation For Multiple Myeloma (RMCC)
2. E1A05 Randomized Phase III Trial of Consolidation Therapy with Bortezomib (Velcade) - Lenalidomide (Revlimid) -Dexamethasone (VRD) vs. Bortezomib (Velcade) -Dexamethasone (VD) for Patients with Multiple Myeloma Who Have Completed a Dexamethasone Based Induction Regimen (CCRP, RMCC)
3. 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, UCCC)
4. C05009 Phase IIIB Randomized Study in Previously Untreated Multiple Myeloma Patients: VELCADE, Thalidomide, and Dexamethasone Versus VELCADE and Dexamethasone vs. VELCADE, Melphalan, and Prednisone (RMCC)

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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) vs. VELCADE and Dexamethasone (VD) vs. VELCADE, Melphalan, and Prednisone (VMP) (RMCC)
6. Phase II Study of Induction Therapy with Bortezomib + Lenalidomide + Dexamethasone + Doxorubicin (UCCC)
7. Prospective Phase II Study for Therapy with Bortezomib + Lenalidomide + Dexamethasone with Lenalidomide + Dexamethasone as Post Transplant Consolidation and Maintenance for Patients with Symptomatic Multiple Myeloma Following Autologous Transplantation (UCCC)
8. CLBH589BUS15T Phase I/II Study of Oral Melphalan Combined with LBH589 for Patients with Relapsed or Refractory Multiple Myeloma (MM) (RMCC)
9. E7373-A001-101 Phase I Open-Label Dose Escalation Study to Determine the Absolute Bioavailability of a Single Oral Dose Administration of Decitabine in Patients with Myelodysplastic Syndrome (MDS) (RMCC)
10. 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)
11. USON 07168 A Prospective Non-Interventional Multicenter Registry in Iron Overloaded Lower-Risk Myelodysplastic Patients (RMCC)
12. Bone Marker Directed Dosing of Zometa (Zoledronic Acid) for the Prevention of Skeletal Complications in Patients with Advanced with Multiple Myeloma (UCCC)



13. Pilot Study of Infusional Melphalan + Bortezomib for Myeloablative Therapy Prior to Autologous Transplant for Multiple Myeloma and Related Disorders (UCCC)
14. 06-0999 A Pilot Study of Infusional Melphalan + Bortezomib for Myeloablative Therapy Prior to Autologous Transplant for Multiple Myeloma and Related Disorders (UCCC)

## Phase I Studies

1. MI-CP187 Phase I Dose Escalation Study to Evaluate the Safety, Tolerability, and Antitumor Activity of MEDI-575, in Subjects With Advanced Tumors (RMCC)
2. USON 08008 Phase IB Multicenter Dose-Escalation Study of LY573636-Sodium in Combination with 1) Gemcitabine HCl or 2) Docetaxel or 3) Temozolomide or 4) Cisplatin in Patients with Advanced Solid Tumors (RMCC)
3. USON 08101 Multicenter Open-Label Single-Arm Dose-Escalation Study to Evaluate the Safety, Tolerability, and Antitumor Activity of MEDI-575, a Fully Human Monoclonal Antibody Directed Against Platelet-Derived Growth Factor Receptor-alpha (PDGFR-alpha), in Subjects with Advanced Solid Tumors Refractory to Standard Therapy or for Which No Standard Therapy Exists (RMCC)
4. USON 08210 Phase I Dose-Escalation Study of LY2382770, a TGF-beta Monoclonal Antibody, in Patients with Metastatic Cancer (RMCC)

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5. Phase I Dose Escalation Study of Gemcitabine and ON 01910.Na in Patients with Advanced or Metastatic Solid Tumors (UCCC)
6. Phase I Dose-Escalation Study of OSI-906 and Erlotinib (Tarceva) in Patients with Advanced Solid Tumors (UCCC)
7. Phase I Multicenter Open-Label Dose Escalation Trial of PDL192 in Subjects with Advanced Solid Tumors (UCCC)
8. 07-0537 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)
9. 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)
10. Phase I Study of IPI-926 in Patients with Advanced and/or Metastatic Solid Tumor Malignancies (UCCC)
11. Phase I Trial of Oral PX-866 (a PI-3K Inhibitor) in Patients with Advanced Solid Tumors (UCCC)
12. Phase I Multiple Ascending Dose (MAD) Study of R4733 Administered Orally in Patients with Refractory Metastatic or Locally Advanced Solid Tumors (UCCC)
13. Phase I Multiple-Dose Study of the Safety and Tolerability of Single Agent REGN421 Administered Every 3 Weeks in Patients with Advanced Solid Malignancies (UCCC)
14. Phase I Multicenter Dose Escalation Trial to Determine the Safety and Pharmacokinetics/Pharmacodynamics of RDEA119 a MEK Inhibitor in Advanced Cancer Patients (UCCC)



15. Phase I Multicenter Open Label Study of Single Agent R7112 Administered Orally in Patients with Advanced Malignancies - Except all Forms of Leukemia (UCCC)
16. Phase I Safety Pharmacokinetic and Pharmacodynamic Study of PF 04217903 in Patients with Advanced Cancer (UCCC)
17. Phase IB Study to Assess the Safety and Pharmacokinetics of ARRY 334543 with Docetaxel in Patients with Advanced Solid Tumors (UCCC)
18. Phase IB Open Label Dose Escalation Study of the Safety and Pharmacology of GDC-0941 in Combination with Erlotinib in Patients with Advanced Solid Tumors (UCCC)
19. Phase IB Open-Label Dose-Escalation Study of the Safety and Pharmacology of MNRP1685A, a Human IGG1 Antibody, in Combination with Bevacizumab with or without Paclitaxel in Patients with Locally Advanced or Metastatic Solid Tumors (UCCC)
20. Open-Label Phase IB Study to Assess the Long-Term Safety Profile of Pazopanib in Cancer Patients (UCCC)
21. Phase I Open Label Study to Determine the Safety, Tolerability, Maximum Tolerated Dose, Pharmacokinetics, and Biomarker Status of BAY 73-4506 in Patients with Advanced Malignancies (UCCC)

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**Contact Organizations:**

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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## Other

1. 014 Phase III Randomized Double-Blind Placebo-Controlled Trial of Oral Suberoylanilide Hydroxamic Acid (Vorinostat, MK-0683) in Patients with Advanced Malignant Pleural Mesothelioma Previously Treated with Systemic Chemotherapy (RMCC)
2. 557 Phase III Study of the Safety and Effectiveness of Granulocyte Transfusions in Resolving Infection in People With Neutropenia (The RING Study) (RMCC)
3. CALGB 70604 Randomized, Phase III Study of Standard Dosing vs. Longer Dosing Interval of Zoledronic Acid in Metastatic Cancer (CCRP)
4. N04CA Phase III Randomized Double-Blind Placebo-Controlled Study using Pilocarpine for Vaginal Dryness (RMCC)
5. N07C2 Phase III Randomized Double-Blind Placebo-Controlled Study of the use of Wisconsin Ginseng (*panax quinquefolius*) to Improve Cancer-Related Fatigue (CCRP, RMCC)
6. N08C3 Phase III Double-Blind Placebo-Controlled Study of Gabapentin for the Prevention of Delayed CINV (Chemotherapy Induced Nausea and Vomiting) in Patients Receiving Highly Emetogenic Chemotherapy (CCRP)
7. RTOG 0433 Phase III International Randomized Trial of Single vs. Multiple Fractions for Re-Irradiation of Painful Bone Metastases (UCC)
8. RTOG0517 Phase III Randomized Trial to Evaluate Radiopharmaceuticals and Zoledronic Acid in the Palliation of Osteoblastic Metastases from Lung, Breast and Prostate Cancer (UCC)



9. Phase III International Randomized Double Blinded Efficacy Study of XL 184 vs. Placebo in Subjects with Unresectable Locally Advanced or Metastatic Medullary Thyroid Cancer (UCCC)
10. Phase II/III Multicenter Open Label Randomized Study to Evaluate the Safety and Efficacy of Combretastatin A4 Phosphate in Combination with Paclitaxel and Carboplatin in Comparison with Paclitaxel and Carboplatin Against Anaplastic Thyroid Carcinoma (UCCC)
11. FHCRC-1938.00 Phase II Randomized Study of Postgra Fling Immunosuppression Comprising Tacrolimus and Mycophenolate Mofetil with or without Sirolimus to Prevent Acute Graft vs. Host Disease after Unrelated Donor Filgrastim (G-CSF)-Mobilized Peripheral Blood Mononuclear Cell Transplantation with Nonmyeloablative Conditioning in Patients with Hematologic Malignancies (RMCC)
12. FHCRC-1959.00 Phase II Study of a Nonmyeloablative Conditioning Regimen Comprising Alemtuzumab, Fludarabine, and Low-Dose Total Body Irradiation Followed by Immunosuppression Comprising Cyclosporine and Mycophenolate Mofetil in Patients Undergoing Allogeneic Peripheral Blood Stem Cell Transplantation for Hematologic Malignancy (RMCC)
13. XL184-203 Phase II Study of XL184 in Adults with Advanced Malignancies (RMCC)
14. Phase II Study of Bortezomib in Metastatic Papillary Thyroid Carcinoma or Follicular Thyroid Carcinoma (UCCC)

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15. Phase II Randomized Pilot Study to Identify Molecular Predictors for Hormone Responsiveness. Preoperative Hormone Therapy for Postmenopausal Women with ER+ or PR+ Clinical Stage T2-4 Tumors: Exemestane with or without Tamoxifen (UCCC)
16. Phase II Pivotal Multicenter Single Arm Two Cohort Trial Evaluating the Efficacy and Safety of GDC-0449 in Patients with Advanced Basal Cell Carcinoma (UCCC)
17. Phase I/II Study of CS-7017 an Oral PPAR $\gamma$  Agonist in Combination with Paclitaxel in Subjects with Advanced Anaplastic Thyroid Cancer (UCCC)
18. Phase I/II Study of Pentostatin and Donor Lymphocyte Infusion in Preventing Graft Rejection in Cancer Patients With Low or Falling Donor T-Cell Chimerism After Nonmyeloablative Allogeneic Stem Cell Transplantation (RMCC)
19. Carter 2005-01 Prospective Investigation of Definitive Targeted Therapy for Solid Malignancies with Oligometastases (RMCC)
20. CSTI571BUS227 reGISTry GIST Gastrointestinal Stromal Tumor (GIST) Registry Protocol (RMCC)
21. GIDEON. Global Investigation of Therapeutic Decisions in Hepatocellular Carcinoma and of its Treatment with Sorafenib (UCCC)
22. GOG 0136 Acquisition of Human Gynecologic Specimens and Serum to be used in Studying the Causes, Diagnosis, Prevention and Treatment of Cancer (UCCC)
23. NCCTGN04C2 An Exploratory Randomized Placebo-Controlled Trial of Depot Octreotide (Sandostatin LAR Depot) for Symptomatic Ascites in Cancer Patients (RMCC)



24. USON 06141 Examination of PNH, by Level Of CD59 on Red and White Blood Cells, in Bone Marrow Failure Syndromes (EXPLORE) (RMCC)
25. Cancer Test (RMCC)
26. Human Cancer and AHR/CYP1a1/1A2/1B1 Gene Polymorphisms (UCCC)
27. Novartis Registry/Gist Registry- Observational Database for All Gist Tumors (RMCC)
28. Pilot Study of Cognitive Impairment in Cancer Patients Following Chemotherapy (UCCC)
29. Rollover Protocol for Patients who Received CP-675,206 in Other Protocols (UCCC)
30. Two Stage Multi Center Open Label Study of Mapatumumab ([HGS1012] A Fully Human Monoclonal Antibody to Trail-r1) in Combination with Sorafenib as First Line Therapy in Subjects with Advanced Hepatocellular Carcinoma (UCCC)
31. 09-0817 FHCRC: Transplantation of Unrelated Donor Umbilical Cord Blood in Patients with Hematological Malignancies Using a Treosulfan Based Preparative Regimen (UCCC)

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32. 09-1115 A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Dose Escalation Study of the Safety, Tolerability and Ability of CMX001 to Prevent or Control CMV Infection in R+ Hematopoietic Stem Cell Transplant Recipients (UCCC)
33. 08-0080 A Prospective, Randomized Trial Comparing the Efficacy of Anidulafungin and Voriconazole in Combination to that of Voriconazole Alone When Used for Primary Therapy of Proven or Probable Invasive Aspergillosis (UCCC)
34. N0392 Assessment of Patient Satisfaction with Participation in Phase II/ III NCCTG Clinical Trials (DH)
35. N08C1 Paclitaxel-Associated Acute Pain Syndrome Natural History Study (DH)
36. N08C7 A Phase III, Randomized, Placebo-controlled, Double-Blind Trial of Flaxseed for the Treatment of Hot Flashes (DH)





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CancerPACT  
Clinical Investigations Core  
P O Box 6510  
Mail Stop F-700  
Aurora, Colorado 80045

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