

**DECATUR MEMORIAL HOSPITAL
IRB APPROVED ONCOLOGY PROTOCOLS**

AMYLOIDOSIS:

ECOG E4A08 (EFF) A Randomized Phase III Trial of Melphalan and Dexamethasone (MDex) versus Bortezomib, Melphalan, and Dexamethasone (BMDex) for Untreated Patients with Systemic Light-chain (AL) Amyloidosis Ineligible for Autologous Stem-cell Transplant

BRAIN:

ECOG E3F05
(EFF) Phase III Study of Radiation Therapy with or without Temozolomide for Symptomatic or Progressive Low-Grade Gliomas

BREAST: DCIS

NSABP B-43 (EFF) A 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

**BREAST:
ADJUVANT**

CTSU RTOG 1005
(EFF) A Phase III Trial of Accelerated Whole Breast Irradiation with Hypofractionation Plus Concurrent Boost Versus Standard Whole Breast Irradiation Plus Sequential Boost for Early-Stage Breast Cancer
Accrual is currently “On-Hold”

CTSU NCIC CTG
MA.32 (EFF & SIH) A Phase III Randomized Trial of Metformin versus Placebo on Recurrence and Survival in Early Stage Breast Cancer

NSABP B-47 (EFF): A Randomized Phase III Trial of Adjuvant Therapy Comparing Chemotherapy Alone (Six Cycles of Docetaxel Plus Cyclophosphamide or Four Cycles of Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel) to Chemotherapy Plus Trastuzumab in Women with Node-Positive or High-Risk Node-Negative HER2-Low Invasive Breast Cancer

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- SWOG S0221 (EFF) Phase III Trial of Continuous Schedule AC + G versus 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
- SWOG S1007 (EFF): A Phase III, Randomized Clinical Trial of Standard Adjuvant Endocrine Therapy +/- Chemotherapy in Patients with 1-3 Positive Nodes, Hormone Receptor-Positive and HER-2 Negative Breast Cancer with Recurrence Score (RS) of 25 or Less

BREAST:
METASTATIC

- ECOG E2108 (EFF) A Randomized Phase III Trial of the Value of Early Local Therapy for the Intact Primary Tumor in Patients with Metastatic Breast Cancer
- ECOG E3108 (EFF) A Phase II Prospective Trial Correlating Progression Free Survival with CYP2D6 Activity in Patients with Metastatic Breast Cancer Treated with Single Agent Tamoxifen
- SWOG S0500 (EFF) A Randomized Phase III Trial to Test the Strategy of Changing Therapy versus Maintaining Therapy for Metastatic Breast Cancer Patients who have Elevated Circulating Tumor Cell Levels at First Follow-Up Assessment
- CTSU NCCTG N0733 (EFF) 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 Anthracycline and/or a Taxane

UOC/CTSU 8788

Suspended pending budget: Phase II Randomized Trial of the

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Combination of ABT-888 With Metronomic Oral Cyclophosphamide in Refractory BRCA-Positive Ovarian, Primary Peritoneal or Ovarian High-Grade Serous Carcinoma, Fallopian Tube Cancer, Triple-Negative Breast Cancer, and Low-Grade Non-Hodgkin's Lymphoma **Cohort A On Hold which includes BRCA mutations and refractory ovarian cancer, primary peritoneal, ovarian high-grade serous, or fallopian tube ca. Cohort B On Hold which includes triple negative breast cancer.**

CARCINOID:

SWOG S0518 (EFF) Phase III Prospective Randomized Comparison of Depot Octreotide plus Interferon Alpha versus Depot Octreotide plus Bevacizumab in Advanced, Poor Prognosis Carcinoid Patients

CTSU 8233/MC0845 (EFF) **Suspended pending budget:** A Phase II Trial of Temsirolimus and Bevacizumab in Patients with Endometrial, Ovarian, Hepatocellular Carcinoma, Carcinoid or Islet Cell Cancer **This study is only open to Islet Cell Cancer, all other disease sites are closed to accrual.**

COLORECTAL:

ADJUVANT ANAL

ECOG E3205 (EFF) Phase II Trial of Cetuximab plus Cisplatin, 5-Fluorouracil and Radiation in Immunocompetent Patients with Anal Carcinoma

NEOAJUVANT RECTAL

SWOG S0713 (EFF) A Phase II Study of Oxaliplatin, Capecitabine, Cetuximab and Radiation in Pre-Operative Therapy of Rectal Cancer

ADJUVANT COLON

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CTSU/CALGB C80702 (EFF) A Phase III Trial of 6 versus 12 Treatments of Adjuvant FOLFOX plus Celecoxib or Placebo for Patients with Resected Stage III Colon Cancer

METASTATIC COLORECTAL

NSABP C-11 (EFF): A Phase III Study Evaluating the Role of Perioperative Chemotherapy in Patients with Potentially Resectable Hepatic Colorectal Metastases

ECOG E4203 (EFF) Phase II Study of Treatment Selection Based Upon Tumor Thymidylate Synthase Expression in Previously Untreated Patients with Metastatic Colorectal Cancer

CTSU/CALGB C80405 (EFF) A Phase III Trial of Irinotecan/5-FU/Leucovorin or Oxaliplatin/5-FU/Leucovorin with Bevacizumab, or Cetuximab (C225) for Patients with Untreated Metastatic Adenocarcinoma of the Colon or Rectum

GALLBLADDER

SWOG S0809 (EFF) A Phase II Trial of Adjuvant Capecitabine/ Gemcitabine Chemotherapy Followed by Concurrent Capecitabine and Radiotherapy in Extrahepatic Cholangiocarcinoma (EHCC)

GASTRIC- ESOPHAGEAL

CTSU/RTOG 1010 (EFF) A Phase III Trial Evaluating the Addition of Trastuzumab to Trimodality Treatment of HER2-Overexpressing Esophageal Adenocarcinoma

CTSU/RTOG 0436 (EFF) A Phase III Trial Evaluating the Addition of Cetuximab to Paclitaxel, Cisplatin and Radiation for Patients with Esophageal Cancer Who Are

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Treated Without Surgery **Temp On Hold 06/01/11**

ECOG E2208 (EFF) Randomized Phase II Study of Paclitaxel with or without the Anti-IGF-IR mAb Cixutumumab (IMC-A12) as Second Line Treatment for Patients with Metastatic Esophageal or GE Junction Cancer

SWOG S1201 (EFF): A Randomized Phase II Pilot Study Prospectively Evaluating Treatment for Patients Based on ERCC1 (Excision Repair Cross-Complementing 1) for Advanced/Metastatic Esophageal, Gastric or Gastroesophageal Junction (GEJ) Cancer

GENITOURINARY: *Prostate & Renal have separate categories*

BLADDER

CTSU CALGB 90601 (EFF) 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

GYNECOLOGIC:

CERVICAL:

OVARIAN:

1st Line

GOG 0252 (EFF) A Phase III Clinical Trial of Bevacizumab with IV versus IP Chemotherapy in Ovarian, Fallopian Tube and Primary Peritoneal Carcinoma: NCI-Supplied Agent: Bevacizumab (NSC-704865, IND #7921)

Maintenance

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GOG 0212 (EFF) A Randomized Phase III Trial of Maintenance Chemotherapy Comparing 12, Monthly Cycles of Single Agent Paclitaxel or CT-2103 (IND #70177) versus No Treatment Until Documented Relapse in Women with Advanced Ovarian, Primary Peritoneal or Fallopian Tube Cancer Who Achieve A Complete Clinical Response to Primary Platinum/Taxane

2nd Line

CTSU 8233/MC0845 (EFF) **Suspended pending budget:** A Phase II Trial of Temsirolimus and Bevacizumab in Patients with Endometrial, Ovarian, Hepatocellular Carcinoma, Carcinoid or Islet Cell Cancer **This study is only open to Islet Cell Cancer, all other disease sites are closed to accrual.**

EC-FV-06 (PROCEED) A Randomized Double-Blind Phase 3 Trial Comparing EC145 and Pegylated Liposomal Doxorubicin (PLD/DOXIL[®]/CAELYX[®]) In Combination Versus PLD In Participants With Platinum-Resistant Ovarian Cancer

UOC/CTSU 8788 **Suspended pending budget:** Phase II Randomized Trial of the Combination of ABT-888 With Metronomic Oral Cyclophosphamide in Refractory BRCA-Positive Ovarian, Primary Peritoneal or Ovarian High-Grade Serous Carcinoma, Fallopian Tube Cancer, Triple-Negative Breast Cancer, and Low-Grade Non-Hodgkin's Lymphoma **Cohort A On Hold which includes BRCA mutations and refractory ovarian cancer, primary peritoneal, ovarian high-grade serous, or fallopian tube ca. Cohort B On Hold which includes triple negative breast cancer.**

UTERUS:

GOG 0261(EFF): A Randomized Phase III Trial of Paclitaxel plus Carboplatin versus Ifosfamide plus Paclitaxel in Chemotherapy-Naïve Patients with Newly

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Diagnosed Stage I-IV Persistent or Recurrent Carcinosarcoma (Mixed Mesodermal Tumors) of the Uterus or Ovary

CTSU 8233/MC0845
(EFF)

Suspended pending budget: A Phase II Trial of Temezirolimus and Bevacizumab in Patients with Endometrial, Ovarian, Hepatocellular Carcinoma, Carcinoid or Islet Cell Cancer **This study is only open to Islet Cell Cancer, all other disease sites are closed to accrual.**

HEAD & NECK:

CTSU RTOG 1016
(EFF)

Phase III Trial of Radiotherapy Plus Cetuximab versus Chemoradiotherapy in HPV-Associated Oropharynx Cancer

ECOG E1305 (EFF)

A Phase III Randomized Trial of Chemotherapy with or without Bevacizumab in Patients with Recurrent or Metastatic Head and Neck Cancer

I4E-MC-JXBD (EFF)

A Randomized, Double-Blind, Phase 2 Safety Study of Cetuximab, Using ImClone versus Boehringer Ingelheim Manufacturing Processes, in Combination with Cisplatin or Carboplatin and 5-Fluorouracil in the First-Line Treatment of Patients with Locoregionally Recurrent and/or Metastatic Squamous Cell Carcinoma of the Head and Neck

UOC 16691B (EFF)

Phase II Trial of Dasatinib (BMS 354825) for Recurrent or Metastatic c-KIT Expressing Adenoid Cystic Carcinoma and for Non-Adenoid Cystic Malignant Salivary Tumors (**Arm B closed: Not enrolling non-ACC MSGT Effective 02/09/11**)

NCI 8692 (EFF)

A T1 Translational Multicenter Randomized Phase II Study of Temezirolimus Versus Cetuximab Plus Temezirolimus in Patients with Recurrent/Metastatic Head and Neck Cancer, Who Failed Prior EGFR Based Therapy

HEPATIC

CTSU 8233/MC0845
(EFF)

Suspended pending budget: A Phase II Trial of Temsirolimus and Bevacizumab in Patients with Endometrial, Ovarian, Hepatocellular Carcinoma, Carcinoid or Islet Cell Cancer **This study is only open to Islet Cell Cancer, all other disease sites are closed to accrual.**

LEUKEMIA:

**AML PREVIOUSLY
UNTREATED**

ECOG E2906 (EFF)

Phase III Randomized Trial of Clofarabine as Induction and Post-Remission Therapy vs Standard Daunorubicin & Cytarabine Induction and Intermediate Dose Cytarabine Post-Remission Therapy, Followed by Decitabine Maintenance vs Observation in Newly-Diagnosed Acute Myeloid Leukemia in Older Adults (Age > 60 Years)

SWOG S0703 (EFF)

A Phase II Trial of Azacitidine (NSC-102816) Plus Gemtuzumab Ozogamicin as Induction and Post-Remission Therapy in Patients of Age 60 and Older with Previously Untreated Non-M3 Acute Myeloid Leukemia

RELAPSED AML

SWOG S0919 (EFF)

A Phase II Study of Idarubicin and Ara-C in Combination with Pravastatin for Relapsed Acute Myelogenous Leukemia (AML)

**CLL PREVIOUSLY
UNTREATED**

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CTSU/CALGB/ECOG
E10404 (EFF) A Genetic Risk-Stratified, Randomized Phase II Study of Four
Fludarabine/Antibody Combinations for Patients with Symptomatic,
Previously Untreated Chronic Lymphocytic Leukemia

ECOG E3903 (EFF) Ancillary Laboratory Protocol for Collecting Diagnostic Material on
Patients Considered for ECOG Treatment Trials for Leukemia or Related
Hematologic Disorders

**CLL RELAPSED/
REFRACTORY**

ECOG E2903 (EFF) Phase II Trial of Pentostatin, Cyclophosphamide and Rituximab (PCR)
Followed by CAMPATH-1H for Previously Treated Relapsed or
Refractory Patients with Chronic Lymphocytic Leukemia

TISSUE BANKING **For Phase III SWOG Leukemia Studies**

SWOG 9007 (EFF) Cytogenetic Studies in Leukemia Patients

SWOG S9910 (EFF): Leukemia Centralized Reference Laboratories and Tissue Repositories,
Ancillary

LUNG:

SWOG S0720 (EFF) Phase II ERCC1 and RRM1-Based Adjuvant Therapy Trial in Patients
with Stage I Non-Small Cell Lung Cancer (NSCLC)

ECOG E1505 (EFF) A Phase III Randomized Trial of Adjuvant Chemotherapy with or
without Bevacizumab for Patients with Completely Resected Stage IB (\geq
4 CM) – IIIA Non-Small Cell Lung Cancer (NSCLC)

MAGRIT 109493
(EFF) A DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED PHASE III STUDY
TO ASSESS THE EFFICACY OF RECMAGE-A3 + AS15 ANTIGEN-SPECIFIC
CANCER IMMUNOTHERAPEUTIC AS ADJUVANT THERAPY IN PATIENTS WITH
RESECTABLE MAGE-A3-POSITIVE NON-SMALL CELL LUNG CANCER

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ECOG E6508 (EFF)	A Phase II Study of L-BLP25 and Bevacizumab in Unresectable Stage IIIA and IIIB Non-Squamous Non-Small Cell Lung Cancer After Definitive Chemoradiation
SWOG S0819 (EFF)	A Randomized, Phase III Study Comparing Carboplatin/Paclitaxel or Carboplatin/Paclitaxel/Bevacizumab with or without Concurrent Cetuximab in Patients with Advanced Non-Small Cell Lung Cancer (NSCLC)
SWOG S0709 (EFF)	A Phase II Selection Design of Pharmacodynamic Separation of Carboplatin/Paclitaxel/Erlotinib or Erlotinib Alone in Advanced Non-Small Cell Lung Cancer (NSCLC) Patients with Performance Status 2 (PS 2) Selected by Serum Proteomics
CTSU CALGB 30607 (EFF)	Randomized Phase III, Double-Blind Placebo-Controlled Trial of Sunitinib (NSC #736511, IND #74019) as Maintenance Therapy in Non-Progressing Patients Following An Initial Four Cycles of Platinum-Based Combination Chemotherapy in Advanced, Stage IIIB/IV Non-Small Cell Lung Cancer
SWOG S0635 (EFF)	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)
CTSU CALGB 30610 (EFF)	Phase III Comparison of Thoracic Radiotherapy Regimens in Patients with Limited Small Cell Lung Cancer Also Receiving Cisplatin and Etoposide
E7389-G000-302 (ELEVATE) (EFF)	A Randomized, Open-label, Multi-center, Phase III Study to Compare the Efficacy and Safety of Eribulin with Treatment of Physician's Choice in Subjects with Advanced Non-Small Cell Lung Cancer. Not open in

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Effingham at this time.

ECOG E1508 (**EFF**) A Randomized Phase II Study of Cisplatin and Etoposide in Combination with Either Hedgehog Inhibitor GDC-0449 or IGF-1R MOAB IMC-A12 for Patients with Extensive Stage Small Cell Lung Cancer

SWOG S0802 (**EFF**) A Randomized Phase II Trial of Weekly Topotecan with and without AVE0005 (Aflibercept; NSC-724770) in Patients with Platinum Treated Extensive Stage Small Cell Lung Cancer (E-SCLC)

G300504 Phase III, Randomized, Double-Blind, Placebo-Controlled Study of the Effect of GTx-024 on Muscle Wasting in Patients with Non-Small Cell Lung Cancer on First Line Platinum Plus a **Taxane** Chemotherapy

G300505 Phase III, Randomized, Double-Blind, Placebo-Controlled Study of the Effect of GTx-024 on Muscle Wasting in Patients with Non-Small Cell Lung Cancer on First Line Platinum Plus a **Non-Taxane** Chemotherapy

MESOTHELIOMA:

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

LYMPHOMA:
HODGKINS

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CTSU CALGB 50604 (EFF) Phase II Trial of Response-Adapted Chemotherapy Based on Positron Emission Tomography for Non-Bulky Stage I and II Hodgkin Lymphoma

SWOG S0816 (EFF) A Phase II Trial of Response-Adapted Therapy of Stage III-IV Hodgkin Lymphoma using Early Interim FDG-PET Imaging

**LYMPHOMA –
MANTLE CELL**

SWOG S1106 (EFF): A Randomized Phase II Trial of R-HCVAD/MTX/Ara-C Induction Followed by Consolidation with an Autologous Stem Cell Transplant vs R-Bendamustine Induction Followed by Consolidation with an Autologous Stem Cell transplant for Patients < 65 Years of Age with Previously Untreated Mantle Cell Lymphoma

**NON-HODGKIN'S
LYMPHOMA:**

ECOG E2408 (EFF) A 3-Arm Randomized Phase II Trial of Bendamustine-Rituximab (BR) Followed by Rituximab vs Bortezomib-BR (BVR) Followed by Rituximab vs BR Followed by Lenalidomide/Rituximab in High Risk Follicular Lymphoma

CTSU CALGB 50303 (EFF) Phase III Randomized Study of R-CHOP versus Dose-Adjusted Epoch-R with Molecular Profiling in Untreated De Novo Diffuse Large B-Cell Lymphomas

UOC 09-443-A (EFF) Phase I/II Investigation of Temsirolimus Plus Lenalidomide in Relapsed Non-Hodgkin Lymphomas

UOC/CTSU 8788 (EFF) **Suspended pending budget:** Phase II Randomized Trial of the Combination of ABT-888 With Metronomic Oral Cyclophosphamide in Refractory BRCA-Positive Ovarian, Primary Peritoneal or Ovarian High-Grade Serous Carcinoma, Fallopian Tube Cancer, Triple-Negative Breast

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Cancer, and Low-Grade Non-Hodgkin's Lymphoma Cohort A On Hold which includes BRCA mutations and refractory ovarian cancer, primary peritoneal, ovarian high-grade serous, or fallopian tube ca. Cohort B On Hold which includes triple negative breast cancer.

B1931008
(3129K5-3303) An Open-label, Randomized, Phase 3 Study of Inotuzumab Ozogamicin Administered in Combination With Rituximab Compared to Defined Investigator's Choice Therapy in Subjects With Relapsed or Refractory CD22-Positive Aggressive Non-Hodgkin Lymphoma Who are Not Candidates for Intensive High-Dose Chemotherapy

PIX306/PIX-R A Randomized Multicenter Study Comparing Pixastrone + Rituximab with Gemcitabine + Rituximab in Patients with Aggressive B-Cell Non-Hodgkin Lymphoma Who Have Relapsed After Therapy with CHOP-R or an Equivalent Regimen and are Ineligible for Stem Cell Transplant

MELANOMA:

SWOG S0933 (EFF) Phase II Study of R04929097 (NSC-749225) in Advanced Melanoma

ECOG E1608 (EFF) A Phase II Trial of GM-CSF Protein plus Ipilimumab in Patients with Advanced Melanoma

ECOG E1609 (EFF) A Phase III Randomized Study of Adjuvant Ipilimumab Anti-CTLA4 Therapy Versus High-Dose Interferon a-2b for Resected High-risk Melanoma

MULTIPLE MYELOMA:

ECOG E3A06 (EFF) Randomized Phase III Trial of Lenalidomide versus Observation Alone in Patients with Asymptomatic High-Risk Smoldering Multiple Myeloma

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SWOG S0777 (EFF) A Randomized Phase III Trial of CC-5013 (Lenalidomide, NSC-703813) and Low Dose Dexamethasone (LLD) versus 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

CA204009 (EFF) A Phase 2, Randomized Study of Bortezomib/dexamethasone With or Without Elotuzumab in Subjects with Relapsed/Refractory Multiple Myeloma

PANCREAS:

UOC 09-068-B (EFF) A Multi-Center, Double-Blind, Placebo-Controlled, Randomized, Phase II Trial of Gemcitabine Plus GDC-0449 (NSC 747691), a HH Pathway Inhibitor, in Patients with Metastatic Pancreatic Cancer (10052747)

CTSU 8233/MC0845 (EFF) **Suspended pending budget:** A Phase II Trial of Temsirolimus and Bevacizumab in Patients with Endometrial, Ovarian, Hepatocellular Carcinoma, Carcinoid or Islet Cell Cancer **This study is only open to Islet Cell Cancer, all other disease sites are closed to accrual.**

PROSTATE:

CTSU/ROG 0534 (EFF) A Phase III Trial of Short Term Androgen Deprivation with Pelvic Lymph Node or Prostate Bed Only Radiotherapy (SPPORT) in Prostate Cancer Patients with A Rising PSA After Radical Prostatectomy (CR 07/01/10)

CTSU ROG 0815 (EFF) A Phase III Prospective Randomized Trial of Dose-Escalated Radiotherapy with or without Short-Term Androgen Deprivation Therapy for Patients with Intermediate-Risk Prostate Cancer

ECOG E2809 (EFF) Androgen Receptor Modulation – Phase II, randomized Study of MK-2206-Bicalutamide Combination in Patients with Rising PSA at High-

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Risk Progression after Primary Tumor

- ECOG E3805 (EFF) CHAARTED: ChemoHormonal Therapy versus Androgen Ablation
Randomized Trial for Extensive Disease in Prostate Cancer
- SWOG S0925 (EFF) A Randomized Phase II Study of Androgen Deprivation combined with
IMC-A12 versus Androgen Deprivation Alone for Patients with New
Hormone-Sensitive Metastatic Prostate Cancer
- SWOG S1014 (EFF): Abiraterone Acetate Treatment for Prostate Cancer Patients with a PSA
of More Than Four Following Initial Androgen Deprivation Therapy,
Phase II
- CA184-095 (EFF) RANDOMIZED, DOUBLE-BLIND, PHASE III TRIAL TO COMPARE THE
EFFICACY OF IPILIMUMAB VS PLACEBO IN ASYMPTOMATIC OR MINIMALLY
SYMPTOMATIC PATIENTS WITH METASTATIC CHEMOTHERAPY-NAÏVE
CASTRATION RESISTANT PROSTATE CANCER
- EFC11784/FIRSTANA Randomized, Open Label Multi-Center Study Comparing Cabazitaxel at
(EFF) 25 mg/m² and at 20 mg/m² in Combination with Prednisone Every 3
Weeks to Docetaxel in Combination with Prednisone in Patients with
Metastatic Castration Resistant Prostate Cancer Not PreTreated With
Chemotherapy

RENAL:

- SWOG S0931 (EFF): EVEREST: EVERolimus for Renal Cancer Ensuing Surgical Therapy, A
Phase III Study
- CTSU-CALGB C90802 Randomized Phae III Trial Comparing Everolimus Plus Placebo versus
(EFF) Everolimus Plus Bevcizumab for Advanced Renal Cell Carcinoma
Progressing After Treatment with Tyrosine Kinase Inhibitors

SARCOMA:

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NCI 8131/UC 16227
(EFF) A Phase 1 2 Study of Doxorubicin and A12 in Advanced Soft Tissue Sarcoma **Temporarily closed**

UOC 09-442 (NCI
8121)(EFF) **Suspended pending budget:** A Phase 2 Study of Temsirolimus (CCI-779, NSC 683864) and IGF-1 Receptor Antibody IMC-A12 (NSC 742460) in Patients with Metastatic Sarcomas

SOLID TUMOR:

POP6972 Phase I Safety and Pharmacokinetic Study of XRP6258 (Cabazitaxel) in Advanced Solid Tumor Patients with Varying Degrees of Hepatic Impairment

PX-866-002 (EFF) Phase 1/2 Study of PX-866 and Docetaxel in Patients with Solid Tumors
PX-866-002 **Not yet open, check with Doña Bement at (217) 876-4760.**

TCD10870 Phase 1 study A Dose-Escalation Study Of The Safety, Tolerability, And Pharmacokinetics Of Cabazitaxel In Combination With Cisplatin Administered Every 3 Weeks In Subjects With Advanced Solid Malignancies

V212-011 A Phase III Randomized, Placebo-Controlled, Clinical Trial to Study the Safety and Efficacy of V212 in Adult Patients with Solid Tumor or Hematologic Malignancy

THYROID:

UOC 10-182-B (NCI
8317) (EFF) Phase I/II Trial of Cediranib Alone or Cediranib and Lenalidomide in Iodine 131-Refractory Differentiated Thyroid Cancer **Phase 2 is now open**

CANCER CONTROL & SYMPTOM MANAGEMENT

**Anthracycline Based
Chemo**

MDA 2007-0917 A Multi-Center Study in Patients Undergoing Anthracycline-Based
Chemotherapy to Assess the Effectiveness of Using Biomarkers to Detect
and Identify Cardiotoxicity and Describe Treatment

Brain

CCCWFU 97509 (EFF) A Phase II Double-Blind Feasibility Study of Armodafinil for Brain
Radiation-Induced Fatigue

CCCWFU 91105 (EFF) Phase III Double Blind, Placebo Controlled Study of Donepezil in
Irradiated Brain Tumor Patients

Breast

CCCWFU 97609 (EFF): Impact of Genomics and Exposures on Disparities in Breast Cancer
Radiosensitivity

NSABP DMP-1 (EFF): A Study to Evaluate Different Decision-making Approaches Used by
Women Known to be at Increased Risk for Breast Cancer

SWOG S0812 (EFF): A Randomized Double-Blind Placebo-Controlled Biomarker Modulation
Study of High Dose Vitamin D in Premenopausal Women at High Risk
for Breast Cancer, Phase IIB

URCC U10055 (EFF) Assessment of Cognitive Function in Breast Cancer and Lymphoma
Patients Receiving Chemotherapy at Pre-Treatment, Post-Treatment, and
at Six Month Follow-Up

CTSU SCUSF 0806 Phase II Placebo-Controlled Trial of Lisinopril and Coreg CR® to

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(EFF) Reduce Cardiotoxicity in Patients with Breast Cancer Receiving (Neo)Adjuvant Chemotherapy with Trastuzumab (Herceptin®)

Colon

NSABP P-5 **(EFF)** Statin Polyp Prevention Trial in Patients with Resected Colon Cancer

MDA 2009-0288 **(EFF)**: Comparative Study of Oncologist Recommended, Home-Based Exercise Program and Relaxation Training for Physical Functioning and Symptom Control in Colon Cancer Patients **(Not ready for patient registration – awaiting training)**

SWOG S0820 **(EFF)**: A Double Blind Placebo-Controlled Trial of Eflornithine and Sulindac to Prevent Recurrence of High Risk Adenomas and Second Primary Colorectal Cancers in Patients with Stage 0-III Colon Cancer, Phase III **(Drug is not ready yet – not ready for patient registration)**

Diarrhea Prevention

MDA 2008-0005 **(EFF)** Phase II, Randomized, Double Blind Comparison of CASAD vs Placebo for the Treatment and Prevention of Diarrhea in Patients with Metastatic Colorectal Cancer

Exercise

URCC 08106 **(SIH)** A Study of the Effects of Exercise on Cancer-Related Fatigue

Nausea & Vomiting

MDA 2006-0841 **(EFF)** Randomized, Double-Blind, Placebo-Controlled Trial of Palonestron/Dexamethasone with or without Dronabinol for the Prevention of Chemotherapy-Induced Nausea and Vomiting after

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Moderately Emetogenic Chemotherapy (**On Hold**)

Neuropathy Prevention

CTSU NCCTG N08CB
(**EFF**) A Phase III Randomized, Placebo-Controlled, Double-Blind Study of Intravenous Calcium/Magnesium in Two Different Versions to Prevent Oxaliplatin-Induced Sensory Neurotoxicity

Ovarian

GOG 0256 (**EFF**) A Prospective Study of Cognitive Function During Chemotherapy for Front-line Treatment of Ovarian, Primary Peritoneal or Fallopian Tube Cancer

GOG 0259 (**EFF**) Nurse-Delivered WRITE Symptoms© versus Self-Directed WRITE Symptoms© versus Care as Usual for Optimal Symptom Management for Women with Recurrent Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

Prostate

CCCWFU 98110 A Randomized Phase II Dose Finding Study of ArginMax for Its Effect on Erectile Function and Quality of Life in Survivors of Prostate Cancer Previously Treated with Radiotherapy

**Patients Receiving
Zoledronate**

SWOG S0702 (**EFF**) A Prospective Observational Multi-center Cohort Study to Assess the Incidence of Osteonecrosis of the Jaw (ONJ) in Cancer Patients with

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Bone Metastases Starting on Zoledronic Acid Treatment

CTSU CALGB 70604 (EFF) A Randomized, Phase III Study of Standard Dosing versus Longer Dosing Interval of Zoledronic Acid in Metastatic Cancer

Skin

SWOG S1013 (EFF): A Prospective Study of Epidermal Growth Factor receptor (HER-1/EGFR) Inhibitor-Induced Dermatologic Toxicity: Validation of the Functional Assessment of cancer Therapy-EGFRI 18 (FACT-EGFRI 18) Questionnaire for EGFRI-Induced Skin Toxicities