

**DECATUR MEMORIAL HOSPITAL
IRB APPROVED ONCOLOGY PROTOCOLS**

AMYLOIDOSIS:

BLADDER:

CTSU CALGB 90601
(EFF)
(DMH.09.321) 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 (Initial Review 10/01/09)

CTSU/RTOG 0524
(EFF)
(DMH.07.134) A Phase I/II Trial of a Combination of Paclitaxel and Trastuzumab with Daily Irradiation or Paclitaxel Alone with Daily Irradiation Following Transurethral Surgery for Non-Cystectomy Candidates with Muscle-Invasive Bladder Cancer (CR 12/03/09)

BREAST:

CTSU/CALGB 40502
(EFF)
(DMH.08.277) A 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 (CR 12/03/09)

CTSU/IBCSG 24-02
(EFF):
(A.XX.004) A 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
(CR 04/02/09)

ECOG E5103 (EFF):
(DMH.07.207) A 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 (CR 11/05/09)

ECOG E2Z04:
(DMH.06.011) Quality of Life in Younger Breast Cancer Survivors (CR 11/05/09)

IRB APPROVED ONCOLOGY PROTOCOLS

Page 2 of 18

- ECOG PACCT-1 (**EFF**): Program for the Assessment of Clinical Cancer Tests (*PACCT-1*): Trial Assigning Individualized Options for Treatment: The **TAILORx**
(DMH.06.031)

(CR 04/02/09)
- 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 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
- SWOG S0622 (**EFF**): Phase II Studies of Two Different Schedules of Dasatinib (NSC 732517) in Bone-Metastasis Predominant Metastatic Breast Cancer
- SWOG S0715 (**EFF**): A Randomized Placebo-Controlled Trial of Acetyl L-Carnitine (ALC) for the Prevention of Taxane Induced Neuropathy, Phase III
- E7389-G000-209: A Phase II, Multicenter, Randomized, Open-Label Study Comparing Eribulin Mesylate and Ixabepilone in Causing or Exacerbating Neuropathy in Patients with Advanced Breast Cancer
- 3144A2-3003-WW (**EFF**): 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
- 3144A2-3004-WW (**EFF**): A Randomized Double-blind Placebo-Controlled Trial of Neratinib (HKI-272) After Trastuzumab in Women with Early-Stage HER-2/neu Overexpressed/Amplified Breast Cancer

IRB APPROVED ONCOLOGY PROTOCOLS

Page 3 of 18

BREAST: NODE -:

BREAST: NODE +:

CTSUCALGB 40101 (EFF): (A.XX.012)	Cyclophosphamide and Doxorubicin (CA x 4 Cycles) versus Paclitaxel (4 Cycles) as Adjuvant Therapy for Breast Cancer in Women with 0-3 Positive Axillary Lymph Nodes: Phase III Randomized Study (CR 12/03/09)
CTSUCALGB 40302 (EFF): (DMH.09.305)	Endocrine Therapy with or without Inhibition of EGF and HER2 Growth Factor Receptor: A Randomized Double-Blind, Placebo-Controlled Phase III Trial of Fulvestrant with or without Lapatinib (GW572016) for Postmenopausal Women with Hormone Receptor Positive Advanced Breast Cancer (Initial Review 08/06/09)
CTSUCALGB 40503 (EFF): (DMH.08.249)	Endocrine Therapy in Combination with Anti-VEGF Therapy: A Randomized, Double-Blind, Placebo-Controlled Phase III Trial of Endocrine Therapy Alone or Endocrine Therapy plus Bevacizumab (NSC 704865, IND 7921) for Women with Hormone Receptor-Positive Advanced Breast Cancer (CR 07/09/09)
CTSUNCCTG N0733 (EFF) (DMH.08.278)	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 (CR 12/03/09)
NSABP B-46-I/USOR 07132(EFF)	A 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

IRB APPROVED ONCOLOGY PROTOCOLS

Page 4 of 18

- NSABP B-40 (EFF): A 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
- NSABP B-41 (EFF): A 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 Followed AC Accompanied by Correlative Science Studies to Identify Predictors of Pathologic Complete Response
- NSABP B-42 (EFF): A 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 **(Registration Program Closed)**
- 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
- CIRG (TRIO)
011/NSABP B-44-
I/BO20906 (EFF): A 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 **(Bevacizumab with Trastuzumab adjuvant therapy in HER2+ Breast cancer – BETH)**

CANCER CONTROL:

- CTSU CALGB 70604 (EFF)
(DMH.09.039) A Randomized, Phase III Study of Standard Dosing versus Longer Dosing Interval of Zoledronic Acid in Metastatic Cancer
(Initial 05/07/09)
- CTSU CALGB 170601 (EFF)
(DMH.09.325) A Phase III Double Blind Trial of Oral Duloxetine for Treatment of Pain Associated with Chemotherapy-Induced Peripheral Neuropathy (Initial Review 11/05/09)
- GOG 0259 (EFF)
(DMH.09.315) 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 (Initial Review – Expedited 09/18/09)
- MDA 2006-0198 (EFF): Complimentary and Alternative Medicine (CAM) Use and Cancer
- SWOG S0424 (EFF): Molecular Epidemiology Case-Series Study of Non Small Cell Lung Cancer in Smoking and Non-Smoking Women and Men (**Smoker Strata - Temp. Closed 03/15/07**)
- SWOG S0702 (EFF): A Prospective Observational Multi-center Cohort Study to Assess the Incidence of Osteonecrosis of the Jaw (ONJ) in Cancer Patients with Bone Metastases Starting on Zoledronic Acid Treatment
- URCC U07004 (EFF):
(DMH.07.202) Assessment of Topical Treatment Response with Amitriptyline and Ketamine: Combination Trial of Chemotherapy Peripheral Neuropathy (CR 10/01/09)
- URCC U1105 (EFF): Prevention of Delayed Nausea – A Phase III Double-Blind Placebo

IRB APPROVED ONCOLOGY PROTOCOLS

Page 6 of 18

Controlled Clinical Trial (CR 11/05/09)
URCC 08106 A Study of the Effects of Exercise on Cancer-Related Fatigue (Expedited
(DMH.09.326) Review 10/30/09)

**CENTRAL NERVOUS
SYSTEM:**

MDA 2004-0662 (EFF): A Randomized, Factorial-Design, Phase II Trial of Temozolomide Alone
and in Combination with Possible Permutations of Thalidomide,
Isotretinoin and/or Celecoxib as Post-Radiation Adjuvant Therapy of
Glioblastoma Multiforme

CTSU RTOG 0825 Phase III Double-Blind Placebo-Controlled Trial of Conventional
(EFF) (DMH.09.296) Concurrent Chemoradiation and Adjuvant Temozolomide plus
Bevacizumab versus Conventional Concurrent Chemoradiation and
Adjuvant Temozolomide in Patients with Newly Diagnosed Glioblastoma
(Initial Review 06/04/09)

CERVICAL:

CTSU GOG 0240 A Randomized Phase III Trial of Cisplatin plus Paclitaxel with and without
(DMH.09.318) NCI-Supplied Bevacizumab (NSC #704865, IND #7921) versus the Non-
Platinum Doublet, Topotecan plus Paclitaxel, with and without NCI-
Supplied Bevacizumab, in Stage IVB, Recurrent or Persistent Carcinoma
of the Cervix (Initial Review 11/05/09)

CHOLANGIOCARCINOMA

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

COLON:

IRB APPROVED ONCOLOGY PROTOCOLS

Page 7 of 18

- ECOG E3205 (**EFF**)
(DMH.09.316) Phase II Trial of Cetuximab plus Cisplatin, 5-Fluorouracil and Radiation in Immunocompetent Patients with Anal Carcinoma (Initial Review 10/01/09)
- 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
- NSABP - VELOUR
EFC10262 (**EFF**) A Multinational, Randomized, Double-Blind Study Comparing Efficacy of Aflibercept Once Every 2 Weeks versus Placebo in Patients with Metastatic Colorectal Cancer (MCRC) Treated with Irinotecan/5-FU Combination (FOLFIRI) After Failure of an Oxaliplatin Based Regimen (VELOUR)
- NSABP R-04 (**EFF**): A 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
- CTSU/CALGB C80405
(**EFF**):
(DMH.06.006) 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
(CR 09/03/09)
- ECOG E5202 (**EFF**)
(A.XX.023) A Randomized Phase III Study Comparing 5-FU, Leucovorin and Oxaliplatin versus 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
(CR 06/04/09)
- NSABP C-10 (**EFF**): A Phase II Trial of 5-Fluorouracil, Leucovorin and Oxaliplatin (mFOLFOX6) Chemotherapy plus Bevacizumab for Patients with Unresectable Stage IV Colon Cancer and Synchronous Asymptomatic

IRB APPROVED ONCOLOGY PROTOCOLS

Page 8 of 18

Primary Tumor

SWOG S0600 (EFF): Phase III Trial of Irinotecan-Based Chemotherapy plus Cetuximab (NSC-714962) with or without Bevacizumab (NSC-704865) as Second-Line Therapy for Patients with Metastatic Colorectal Cancer who have Progressed on Bevacizumab with Either FOLFOX, OPTIMOX, or XELOX

UOC 15843A (EFF): A Phase I/II Trial of Pertuzumab in Combination with Cetuximab and Irinotecan in Previously Treated Metastatic Colorectal Cancer. **(Temporary Closure 07/20/09)**

ENDOMETRIAL:

GOG 0129Q (EFF): A Phase II Evaluation of Gemcitabine (Gemzar®, LY188011) in the Treatment of Recurrent or Persistent Endometrial Carcinoma (Eli Lilly B9E-US-X472) (Initial Review 07/09/09) **(Temporary Closure 07/27/09)**
(DMH.09.299)

UOC 15579A A Phase II Study of Sunitinib Malate in Recurrent or Metastatic
(NCI 7713): (EFF) Endometrial Carcinoma **(Temporary Closure 09/14/09)**

ESOPHAGUS:

CTSU/RTOG 0436 A Phase III Trial Evaluating the Addition of Cetuximab to Paclitaxel,
(EFF) Cisplatin and Radiation for Patients with Esophageal Cancer Who Are
(DMH.08.262) Treated Without Surgery (CR 09/03/09)

GALLBLADDER

IRB APPROVED ONCOLOGY PROTOCOLS

Page 9 of 18

SWOG S0801 (EFF): A Phase II Study of Iodine-131-Labeled Tositumomab in Combination with Cyclophosphamide, Doxorubicin, Vincristine, Prednisone and Rituximab Therapy for Patients with Advanced Stage Follicular Non-Hodgkin's Lymphoma

GASTRIC:

SWOG S0502 (EFF): A Phase III Randomized Trial of Imatinib, with or without Bevacizumab (NSC-704865), in Patients with Metastatic or Unresectable Gastrointestinal Stromal Tumors

HEAD/NECK:

ECOG E3F05 (EFF)
(DMH.09.116) Phase III Study of Radiation Therapy with or without Temozolomide for Symptomatic or Progressive Low-Grade Gliomas (Initial Review 12/03/09)

ECOG E1305 (EFF):
(DMH.08.265) A Phase III Randomized Trial of Chemotherapy with or without Bevacizumab in Patients with Recurrent or Metastatic Head and Neck Cancer (CR 10/01/09)

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

HEPATOBIILIARY:

HEPATOMA:

IRB APPROVED ONCOLOGY PROTOCOLS

Page 10 of 18

UOC 15426A: A Phase II Trial of Dasatinib (BMS-354825) in Advanced Hepatocellular
(DMH.07.195) Carcinoma **(On Hold)**

HODGKIN'S:

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

LEUKEMIA:

ECOG E1905: A Randomized Phase II Trial of Azacitidine with or without Histone
(DMH 08.250) Deacetylase Inhibitor Entinostat for the Treatment of Myelodysplastic
Syndrome, Chronic Myelomonocytic Leukemia (dysplastic type) and Acute
Myeloid Leukemia with Multilineage Dysplasia (CR 08/06/09)

(Patient cohort for non-treatment related disease closed 05/14/09)

ECOG E2903 **(EFF):** Phase II Trial of Pentostatin, Cyclophosphamide and Rituximab (PCR)
(A.XX.036) Followed by CAMPATH-1H for Previously Treated Relapsed or
Refractory Patients with Chronic Lymphocytic Leukemia
(CR 12/03/09)

ECOG E2905 **(EFF)** Randomized Phase III Trial Comparing the Frequency of Major Erythroid
(DMH) 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 (Initial Review
12/03/09)

ECOG E3903 **(EFF)** Ancillary Laboratory Protocol for Collecting Diagnostic Material on
(DMH.08.269) Patients Considered for ECOG Treatment Trials for Leukemia or Related
Hematologic Disorders (X/R 10/13/09)

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

IRB APPROVED ONCOLOGY PROTOCOLS

Page 11 of 18

- (DMH.08.248) Previously Untreated Chronic Lymphocytic Leukemia (CR 07/09/09)
- CTSU/CALGB 10603:
(DMH.08.237)
(EFF) A Phase III Randomized, Double-Blind Study of Induction (Daunorubicin/Cytarabine) and Consolidation (High-Dose Cytarabine) Chemotherapy + Midostaurin (PKC 412) (IND #101261) or Placebo in Newly Diagnosed Patients <60 years of Age with FLT3 Mutated Acute Myeloid Leukemia (AML) (Initial 05/07/09)
- SWOG 9007 (EFF): Cytogenetic Studies in Leukemia Patients
- SWOG S9910 (EFF): Leukemia Centralized Reference Laboratories and Tissue Repositories, Ancillary
- SWOG S0521 (EFF): A Randomized Trial of Maintenance versus Observation for Patients with Previously Untreated Low and Intermediate Risk Acute Promyelocytic Leukemia (APL), Phase III
- SWOG S0605 (EFF) A Phase II Study of Lenalidomide (Revlimid®) (MSC-703813) for Previously Untreated Non-M3 Deletion 5Q Acute Myeloid Leukemia (AML) in Patients Age 60 or Older who Decline Remission Induction Chemotherapy
- 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
- SWOG S0919 (EFF) A Phase II Study of Idarubicin and Ara-C in Combination with Pravastatin for Relapsed Acute Myelogenous Leukemia (AML)

LUNG:

IRB APPROVED ONCOLOGY PROTOCOLS

Page 12 of 18

- CTSU CALGB 30607
(EFF)
(DMH.08.257) 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 (CR 08/06/09)
- CTSU CALGB 30610
(EFF)
(DMH.08.258) Phase III Comparison of Thoracic Radiotherapy Regimens in Patients with Limited Small Cell Lung Cancer Also Receiving Cisplatin and Etoposide (CR 08/06/09)
- ECOG E1505 **(EFF)**:
(DMH.07.173) A 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)
(CR 06/04/09)
- ECOG E1508 **(EFF)**:
(DMH.09.313) 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 (Initial Review 09/03/09)
- SWOG S9925 **(EFF)**: Lung Cancer Specimen Repository Protocol, Ancillary
- CP-05-232 A Multicenter Phase 2 Study Comparing ^{99m}Tc -EC-DG SPECT/CT with ^{18}F -FDG PET/CT in the Evaluation of Patients with Non-small Cell Lung Cancer (NSCLC)
- 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)
- SWOG S0636 **(EFF)** 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

IRB APPROVED ONCOLOGY PROTOCOLS

Page 13 of 18

- 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
- SWOG S0720 (EFF) Phase II ERCC1 and RRM1-Based Adjuvant Therapy Trial in Patients with Stage I Non-Small Cell Lung Cancer (NSCLC)
- 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)
- 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)
- CASA404A2302
DMH.08.272 A phase III, randomized, double-blind, placebo-controlled multi-center study of ASA404 in combination with docetaxel as second-line treatment for locally advanced or metastatic (Stage IIIb/IV) non-small cell lung cancer (NSCLC)

MELANOMA:

- ECOG E1697 (EFF)
(A.XX.045) Phase III Randomized Study of Four Weeks High Dose IFN- α 2b in Stage T₃-T₄ or N₁ (microscopic) Melanoma (CR 06/05/08)
- ECOG E2602 (EFF):
(A.XX.046) Phase II Study of Low Dose Peginterferon Alfa-2B in Patients with Metastatic Melanoma Over-Expressing Basic Fibroblast Growth Factor (CR 06/04/09)
- SWOG S0826 (EFF): A Phase II Study of SCH 727965 in Stage IV Melanoma

IRB APPROVED ONCOLOGY PROTOCOLS

Page 14 of 18

UOC 16077A (EFF): A Phase 2 Study of AZD0530 in Metastatic Melanoma. **ON HOLD**
DMH.08.260 **10/12/09**

MESOTHELIOMA:

SWOG S0722 (EFF): A Phase II Trial of mTOR Inhibitor, Everolimus (RAD001; NSC-733504) in Malignant Pleural Mesothelioma (MPM) (**Temporary Closure 09/15/09**)

MULTIPLE MYELOMA:

ECOG E1A05 (EFF): Randomized Phase III Trial of Consolidation Therapy with Bortezomib (Velcade) – Lenalidomide (Revlimid) – Dexamethasone (VRD) versus (DMH.08.259) Bortezomib (Velcade) – Dexamethasone (VD) for Patients with Multiple Myeloma Who Have Completed a Dexamethasone Based Induction Regimen (CR 09/03/09))

SWOG S0309 (EFF): Myeloma Specimen Repository, Ancillary

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 (DMH.08.232) Induction, in Patients with Previously Untreated Multiple Myeloma without an Intent for Immediate Autologous Stem Cell Transplant

MELP-T2-PVFS-1 A Single Dose, Two-Period, Two-Treatment, Two-Sequence Crossover Bioequivalence Study of Melphalan 2 mg Tablets under Fasted Conditions (Multiple Myeloma and Ovarian Cancer, Refractory cancers)

MYELOFIBROSIS:

NEUROPATHY

**NON-HODGKIN'S
LYMPHOMA:**

CTSU CALGB 50303 (EFF)
(DMH.08.281) Phase III Randomized Study of R-CHOP versus Dose-Adjusted Epoch-R with Molecular Profiling in Untreated De Novo Diffuse Large B-Cell Lymphomas (CR 01/07/10)

SWOG S8947: Central Lymphoma Serum Repository Protocol

SWOG S0350 (EFF): Phase II Trial of Cisplatin plus Etoposide plus Gemcitabine plus Solumedrol (PEGS) in Peripheral T-Cell Non-Hodgkin's Lymphoma

UOC 11965 (EFF):
(B.04.005) Phase II Trial of Epothilone B Analog BMS-247550 (NSC 710428) in Patients with Relapsed Aggressive Non-Hodgkin's Lymphoma

OTHER:

SWOG S0518 (EFF) Phase III Prospective Randomized Comparison of Depot Octreotide plus Interferon Alpha versus Depot Octreotide plus Bevacizumab (NSC #704865) in Advanced, Poor Prognosis Carcinoid Patients **Step 2 – Temporary Closure – effective 01/22/10**

OVARIAN:

IRB APPROVED ONCOLOGY PROTOCOLS

Page 16 of 18

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 (Initial Review 10/01/09)
(DMH.09.323)

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) (Initial Review 10/01/09)
DMH. 09-322

MELP-T2-PVFS-1 A Single Dose, Two-Period, Two-Treatment, Two-Sequence Crossover Bioequivalence Study of Melphalan 2 mg Tablets under Fasted Conditions (Multiple Myeloma and Ovarian Cancer, refractory cancers)

PAIN:

PANCREAS:

AB07012 (EFF): A Prospective, Multicenter, Randomized, Double-blind, Placebo-controlled, 2-Parallel Group, Phase III Study to Compare Efficacy and Safety of Masitinib at 9 mg/kg/Day in Combination with Gemcitabine, to Placebo in Combination with Gemcitabine, in Treatment of Patients with Advanced/Metastatic Pancreatic Cancer

SWOG S0727 (EFF): A Phase I and Randomized Phase II Trial of Gemcitabine + Erlotinib (NSC-718781) + IMC-A12 (NSC-724460) vs Gemcitabine + Erlotinib as First-Line Treatment in Patients with Metastatic Pancreatic Cancer
(Pending Opening of Phase II)

PROSTATE:

IRB APPROVED ONCOLOGY PROTOCOLS

Page 17 of 18

CCCWFU 97405 (EFF): Randomized Study of Soy Protein and Effexor on Vasomotor Symptoms of Men with Prostate Cancer

CTSU/RTOG 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 08/06/09)

CTSU RTOG 0815 (EFF) DMH-09-332 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 (Initial Review 01/07/10)

ECOG E3805 (EFF) (DMH.08.256) CHAARTED: ChemoHormonal Therapy versus Androgen Ablation Randomized Trial for Extensive Disease in Prostate Cancer (CR 08/06/09)

CA184-043 (EFF) A Randomized, Double-Blind, Phase III Trial Comparing Ipilimumab vs Placebo Following Radiotherapy in Subjects with Castration Resistant Prostate Cancer (CRPC) That Have Received Prior Treatment with Docetaxel

ID 00-156 (EFF): A Prospective Randomized Phase III Trial Comparing Consolidation Therapy with or without Strontium-89 Following Induction Chemotherapy in Androgen-Independent Prostate Cancer

SWOG S0421 (EFF): Phase III Study of Docetaxel and Atrasentan versus Docetaxel and Placebo for Patients with Advanced Hormone Refractory Prostate Cancer (**On hold pending revision – 9/1/08**)

UOC 14954A (NCI 7659) (EFF): A Randomized, Phase II Study of GW786034 (Pazopanib) in Stage D0 Relapsed Androgen Sensitive Prostate Cancer Following Limited GnRH Agonist Therapy

RENAL:

IRB APPROVED ONCOLOGY PROTOCOLS

Page 18 of 18

ECOG E2804 (EFF): The BeST Trial: A Randomized Phase II Study of VEGF, RAF Kinase and
(DMH.07.201) mTOR Combination Targeted Therapy (CTT) with Bevacizumab,
Sorafenib and Temsirolimus in Advanced Renal Cell Carcinoma (CR
11/06/08)

ECOG E2805 (EFF): ASSURE: Adjuvant Sorfenib or Sunitinib for Unfavorable Renal
(DMH.06.049) Carcinoma (CR 06/04/09)

SARCOMA:

UOC 16227A (EFF): A Phase 1/2 Study of Doxorubicin and A12 in Advanced Soft Tissue
DMH.08.254 Sarcoma

THYROID:

THROMBOCYTOSIS:

UTERUS:

GOG 0261 A Randomized Phase III Trial of Paclitaxel plus Carboplatin versus
(DMH.09.320) Ifosfamide plus Paclitaxel in Chemotherapy Naïve Patients with Newly
Diagnosed Stage I-IV Persistent or Recurrent Carcinosarcoma (Mixed
Mesodermal Tumors) of the Uterus (Initial Review 11/05/09)