



MetroHealth Medical Center
Cancer Care Center Clinical Trials Protocol Listings
July – September 2010



BRAIN

CNS LYMPHOMA

E1F05 A Phase II Study of Rituximab given in Conjunction with Standard Chemotherapy in Primary CNS Lymphoma

ANAPLASTIC GLIOMA

N0577 A Phase III Intergroup Study of Radiotherapy vs Temozolomide Alone versus Radiotherapy w/ Concomitant and Adjuvant Temozolomide for Patients with 1p/19q Codeleted Anaplastic Glioma (Pending: RT Issues)

R0834 A Phase III Trial Comparing no Adjuvant Chemotherapy vs Adjuvant Therapy until Progression for Anaplastic Glioma without 1p/19q loss. The CATNON Intergroup Trial (EORTC 26053 22054)

NEWLY DIAGNOSED GLIOBLASTOMA

R0825 A Phase III Double-Blind, Placebo-Controlled Trial of Conventional Concurrent Chemoradiation and Adjuvant Temozolomide + Bevacizumab vs Conventional Concurrent Chemoradiation and Adjuvant Temozolomide in Patients with Newly Diagnosed Glioblastoma

BREAST

ADJUVANT – Node - / Node + (Pre and Post Menopausal)

C40101 Cyclophosphamide and Doxorubicin (CA 4 vs 6 cycles) vs Paclitaxel (4 vs 6 cycles) as Adjuvant Therapy for Breast Cancer in Women with 0-3 Positive Axillary Lymph Nodes: A 2x2 Factorial Phase III Randomized Study

ADJUVANT/(Pre-Menopausal)

I 25-02 TEXT – (Tamoxifen and Exemestane Trial): A PH III Trial Evaluating the Role of Exemestane Plus GnRH Analogue as Adjuvant Therapy for Pre-Menopausal Women with Endocrine Responsive Breast Ca (IBCSG)

ER/PR+ / NODE NEG.

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

ER/PR +/- , Node +/- (0-4)

E5103 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

EARLY STAGE HER-2/NEU AMPLIFIED BREAST CANCER

3144A2-3004-WW – A Randomized Double-Blind Placebo Controlled With Early Stage HER2/Neu Overexpressed/Amplified Breast Cancer (Wyeth)

METATSTATIC ER/PR+

CALGB40503 - 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

METASTATIC, FIRST LINE:

C40502 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

NEOADJUVANT ER/PR/HER2 NEG:

C40603 Randomized Phase II 2 X 2 Factorial Trial Of The Addition Of Carboplatin +/- Bevacizumab To Neoadjuvant (P) Weekly Paclitaxel Followed By Dose-Dense AC In Hormone Receptor-Poor/HER2-Negative Resectable Breast Cancer – Pending IRB

OTHER – BONE METS

C70604 A Randomized Phase III Study of Standard Dosing vs Longer Dosing Interval of Zoledronic Acid in Metastatic Cancer (Breast, Prostate, Myeloma)

GASTRO-INTESTINAL (GI)**COLON, STAGE II, HIGH RISK RECURRENCE**

E5202 Randomized Phase III 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

COLO-RECTAL

CASE 2204 A Phase IB Study in Patients with Metastatic Colorectal Cancer to Evaluate Pharmacodynamic Effects of Erlotinib and Safety and Efficacy of Erlotinib in Combination with Modified FOLFOX6 (mFOLFOX6) and Bevacizumab

E4203 (P) A Phase II Study of Treatment Selection Based Upon Tumor Thymidylate Synthase Expression in Previously Untreated Patients with Metastatic Colorectal Cancer – Pending IRB

LOCAL ADVANCED / METASTATIC (No Prior Rx)

C80405 A Phase III Study of Irinotecan/5-FU/Leucovorin or Oxaliplatin/5-FU/ Leucovorin with Bevacizumab or Cetuximab (C225) or with the combination of Bevacizumab and cetuximab for patients with untreated metastatic Adenocarcinoma of the colon or rectum.

COLORECTAL, SECOND LINE:

S0600 Phase III Trial of Irinotecan-Based Chemotherapy Plus Cetuximab (NSC-714692) 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

ANAL:

E3205 (P) Phase II Trial of Cetuximab Plus Cisplatin, 5-Fluorouracil and Radiation in Immunocompetent Patients with Anal Carcinoma (Limited institution participation) – Pending IRB

PANCREAS

CASE 5206 (P) - Phase II Study of Dasatinib in Patients with Metastatic Adenocarcinoma of the Pancreas Pending IRB

CARCINOID, HIGH RISK

S0518 A Phase III Prospective Randomized Comparison of Depot Octreotide Plus Interferon Alpha vs Depot Octreotide Plus Bevacizumab in Advanced, Poor Prognosis Carcinoid Patients

HEPATOCELLULAR

E1208 Phase III Randomized Trial of Chemoembolization with or without Sorafenib in Unresectable Hepatocellular Carcinoma (HCC) in Patients with and without Vascular Invasion

C80802 Phase III Randomized Study of Sorafenib plus Doxorubicin Versus Sorafenib in Patients with Advanced Hepatocellular Carcinoma (HCC)

ESOPHAGEAL

R0436 A Phase III Trial Evaluating the Addition of Cetuximab to Paclitaxel, Cisplatin, and RT for Patients with Esophageal Cancer who are Treated Without Surgery

GENITO-URINARY (GU)

PROSTATE

E3805 CHARTED: Chemo-Hormonal Therapy vs Androgen Ablation Randomized Trial for Extensive Disease in Prostate Cancer

METASTATIC PROSTATE CA TO BONE

C90202 - A Randomized, Double Blind, Placebo-Controlled Phase III Study of Early versus Standard Zoledronic Acid to Prevent Skeletal Related Events in Men with Prostate Cancer Metastatic to Bone

C70604 - A Randomized Phase III Study of Standard Dosing vs Longer Dosing Interval of Zoledronic Acid in Metastatic Cancer (Prostate, Breast, Myeloma)

BLADDER

RTOG 0524 - 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

RENAL CELL

E2805 ASSURE: Adjuvant Sorafenib or Sunitinib for Unfavorable Renal Carcinoma

E2804 The BEST Trial: A Randomized Phase II Study of VEGF, RAF Kinase and mTOR Combination Targeted Therapy (CTT) with Bevacizumab, Sorafenib, and Temsirolimus in Advanced Renal Cell Carcinoma **ACRIN RADIATION REVIEW SUB-STUDY NOT OPEN**

E4805 A Randomized Phase II Study to Determine the Effect of Two Different Doses of AVE0005 (VEGF Trap) in Patients with Metastatic Renal Cell Carcinoma

HEAD AND NECK

RECURRENT OR METASTATIC

E1305 - A Phase III Randomized Trial of Chemotherapy With or Without Bevacizumab in Patients with Recurrent or Metastatic Head and Neck Cancer

CNS LYMPHOMA

E1F05 A Phase II Study of Rituximab given in Conjunction with Standard Chemotherapy in Primary CNS Lymphoma

LOCALLY ADV SQUAMOUS CELL:

CASE 5307 (P) A PHII Study of the Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitor, Erlotinib in Combination with Docetaxel and RT in locally adv. squamous cell cancer of the Head/Neck - Pending IRB

LEUKEMIA / HEMATOLOGY

ANCILLARY LAB – MANDATORY FOR ALL ECOG LEUKEMIA STUDY ENROLLMENTS

E3903 Ancillary Lab Protocol for Collecting Diagnostic Material on Patients Considered for ECOG Treatment Trials for Leukemia or Related Hematologic Disorders.

CLL

E2903 A Phase II Trial of pentostatin, cyclophosphamide, and Rituximab (PCR) followed by Campath -1H for previously treated relapsed or refractory patients with CLL.

C10404 Randomized Phase II Study of Three Fludarabine/Antibody Combinations for Patients with Symptomatic Previously Untreated Chronic Lymphocytic Leukemia

MDS/AML/CML

E1905 A Randomized Phase II Trial of Azacitidine with or without the Histone Deacetylase Inhibitor MS-275 for the Treatment of Myelodysplastic Syndrome, Chronic Myelomonocytic Leukemia (dysplastic type), and Acute Myeloid Leukemia with Multilineage Dysplasia

E2905 Randomized Phase III Trial Comparing the Frequency of Major Erythroid Response (MER) to Treatment with Lenalidomide (Revlimid) Alone in Combination with Epoetin Alfa (procrit) in Subjects with Low or Intermediate-1 Risk MDS and Symptomatic Anemia

LUNG

NONSMALL CELL, RECURRENT, LOC. ADV. OR METASTATIC

E1505 A Phase II Randomized Trial of Adjuvant Chemotherapy With or without Bevacizumab for Completely Resected Stage IB-IIIa Non-Small Cell Lung Cancer

C30607 A Randomized, PH3 Double-Blind Placebo-Controlled Trial of Sunitinib as Maintenance Therapy in Non-Progressing Pts Following an Initial 4 Cycles of Platinum-Based Combination Chemotherapy in Advanced, Stage IIIB/IV NSCLC

S0819 A Randomized, PH III Study Comparing Carboplatin/Paclitaxel or Carboplatin/Paclitaxel/Bevacizumab w/wo Concurrent Cetuximab in Pts w/Adv NSCLC – Must enroll in S9925 as well

NONSMALL CELL – FIRST LINE TREATMENT

CASE 2507 - Randomized Phase II Trial, Comparing Pemetrexed plus Erlotinib to Pemetrexed Alone in ECFR TKI-Responsive NSCLC

IMCL CP11-0805 - A Randomized, Multicenter, Open-Label Phase 3 Study of Pemetrexed-Cisplatin Chemotherapy (P) Plus IMC-11F8 versus Pemetrexed-Cisplatin Chemotherapy Alone in the First-Line Treatment of Patients with Non-squamous Stage IIIb or IV Non-Small Cell Lung Cancer (NSCLC) - IRB Pending

IMCL CP11-0806 - A Randomized, Multicenter, Open-Label, Phase 3 Study of Gemcitabine-Cisplatin Chemotherapy (P) Plus IMC-11F8 versus Gemcitabine-Cisplatin Chemotherapy Alone in the First-Line Treatment of Patients with Squamous Stage IIIb or IV Non-Small Cell Lung Cancer (NSCLC) - IRB Pending

NONSMALL CELL – SECOND LINE TREATMENT

ASA404A2302 - Phase III Randomized, Double-Blind, Placebo-Controlled Multi-Center Study of ASA404 in Combination with Docetaxel in Second Line Treatment of Patients with Advanced or Metastatic (Stage IIIb/IV) NSCLC (Novartis)

SMALL CELL, EXTENSIVE STAGE (MAINTENANCE THERAPY)

CASE 8507 - Phase II Trial of Sorafenib in Conjunction with Chemotherapy and as Maintenance Therapy in (P) Extensive-Stage Small Cell Lung Cancer – Pending IRB

LYMPHOMA

FIRST-LINE TREATMENT OF PATIENTS WITH ADVANCED INDOLENT NON-HODGKIN'S LYMPHOMA (NHL) AND MANTLE CELL LYMPHOMA (MCL).

C18083/3064/NL/MN - 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) and Mantle Cell Lymphoma (MCL).

UNTREATED DIFFUSE LARGE-B CELL OR FOLLICULAR NHL

U4391g - A Phase III Multi-Center, Open-Label study of Rituximab Faster Infusion Time in patients with Previously Untreated Diffuse Large-B Cell or Follicular Non-Hodgkin's Lymphoma (Genentech)

UNTREATED DE NOVO DIFFUSE LARGE B-CELL LYMPHOMAS

C50303 A Phase III Randomized Study of R-CHOP v. Dose-adjusted EPOCH-R with Molecular Profiling in Untreated De Novo Diffuse Large B-Cell Lymphomas
Pending Contract Issues

CNS LYMPHOMA

E1F05 A Phase II Study of Rituximab given in Conjunction with Standard Chemotherapy in Primary CNS Lymphoma

MELANOMA

LOCALLY ADVANCED, METASTATIC

E2602 PH II Study of Low-Dose Peginterferon Alfa-2b in Patients with Metastatic Melanoma Over-Expressing Basic Fibroblast Growth Factor

E2607 A Phase II Trial of Dasatinib in Patients with Unresectable Locally Advanced or Stage IV Mucosal, Acral, and Solar Melanomas

STAGE IIA

E1697 Randomized Study of 4 wks High Dose Interferon Alpha 2b in Stage IIA Melanoma

METASTATIC

C70604 A Randomized Phase III Study of Standard Dosing vs Longer Dosing Interval of Zoledronic Acid in Metastatic Cancer (Prostate, Breast, Myeloma)

MYELOMA

NEWLY DIAGNOSED / ELDERLY, NON-TRANSPLANT CANDIDATES:

E1A06 - An Intergroup Phase III Randomized Controlled Trial Comparing Melphalan, Prednisone, and Thalidomide (MPT) vs Melphalan, Prednisone and Lenalidomide (revlimid (MPR) in Newly Diagnosed Myeloma Patients Who Are Not Candidates for High Dose Therapy.

OTHER:

C70604 A Randomized Phase III Study of Standard Dosing vs Longer Dosing Interval of Zoledronic Acid in Metastatic Cancer (Prostate, Breast, Myeloma)

SYMPTOM MANAGEMENT/NON-THERAPEUTIC

CASE 3Y05 - Auditory Function Trial (open to any patient receiving Oxaliplatin)