Cancer Care Center Clinical Trials Protocol Listings

BRAIN

CNS LYMPHOMA
E1F05 (S) A Phase II Study of Rituximab given in Conjunction with Standard Chemotherapy in Primary CNS Lymphoma - Suspended

ANAPLASTIC GLIOMA
N0577 (S) A Phase III Intergroup Study of Radiotherapy vs Temozolomide Alone versus Radiotherapy w/ Concomitant and Adjuvant Temozolomide for Patients with 1p/19q Co-deleted 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 26063 22054)

SEE RTOG Section for additional studies

BREAST

EARLY STAGE BREAST CANCER

S1007 A Phase III, Randomized Clinical Trial of Standard Adjuvant Endocrine Therapy +/- Chemotherapy in Patients with 1-3 Positive Nodes, Hormone Receptor-Positive and HER2-Negative Breast Cancer with Recurrence Score (RS) of 25 or Less

NSABP-B47: A Randomized Phase III Trial of Adjuvant Therapy Comparing Chemotherapy Alone ( 6 Cycles of Docetaxel + Cyclophosphamide or 4 Cycles of Doxorubicin + Cyclophosphamide Followed by Weekly Paclitaxel) to Chemotherapy + Trastuzumab in Women with Node-positive or High-Risk Node-negative HER2-Low Invasive Breast Ca

BREAST (DCIS)
NSABP-B43 - A PH 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
*HER2 STUDIES DONE CENTRALLY

METASTATIC BREAST CANCER (Non-Therapeutic)
HER2-GEN - An Observational Cohort Study of Treatment Patterns and Outcomes Patients with HER2 Positive (HER2+) Metastatic Breast Cancer - ML28257
GASTRO-INTESTINAL (GI)

ADVANCED, K-RAS WILD-TYPE COLORECTAL CA POST PROGRESSION ON BEVACIZUMAB-CONTAINING CHEMOTHERAPY

E7208 (S) A Randomized Phase II Study of Irinotecan and Cetuximab with or without the Anti-Angiogenic Antibody, Ramucirumab (IMC-1121B) in Advanced, K-ras Wild-Type Colorectal Cancer Following Progression on Bevacizumab-Containing Chemotherapy - Suspended 6/14/12 Data Analysis

COLON, STAGE III, RESECTED

C80702 A Phase III Trial of 6 Versus 12 Treatments of Adjuvant FOLFOX Plus Celecoxib or Placebo for Patients with Resected Stage III Colon Cancer

RECTAL CA – LOC. ADV.

N1048 A Phase II/III trial of NeoAdjuvant FOLFOX, with Selective Use of Combined Modality ChemoRadiation vs Preoperative Combined Modality/ChemoRT for Locally Advanced Rectal Cancer Patients Undergoing Low Anterior Resection with Total Mesorectal Excision

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

R1010 A Phase III Trial Evaluating the Addition of Trastuzumab to Tri-modality Treatment of HER2-Overexpressing Esophageal Adenocarcinoma

E2208 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

PANCREAS

R0848 A Phase III Trial Evaluating Both Erlotinib and Chemoradiation as Adjuvant Treatment for Patients with Resected Head of Pancreas Adenocarcinoma

METASTATIC PANCREATIC CA

S1115 Randomized Phase II Clinical Trial of AZD6244 Hydrogen Sulfate NSC-748727) and MK-2206 (NSC-749607) vs mFOLFOX in Patients with Metastatic Pancreatic Cancer after Prior Chemotherapy

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)
GENITO-URINARY (GU)

PROSTATE, METASTATIC
C90203  A Randomized Phase III Study of Neo-Adjuvant Docetaxel and Androgen Deprivation Prior to Radical Prostatectomy Versus Immediate Radical Prostatectomy in Patients with High-Risk, Clinically Localized Prostate Cancer

E2809  Androgen Receptor Modulation Phase II, Randomized Study of MK-2206 - Bicalutamide Combination in Patients With Rising PSA at High-Risk of Progression After Primary Therapy

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

RENNAL CELL
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

TCC
C90601  A Randomized Double-Blinded Phase III Study Comparing Gemcitabine, Cisplatin, and Bevacizumab to Gemcitabine, Cisplatin, and Placebo in Patients with advanced transitional cell carcinoma

GYNECOLOGIC / GOG

OVARIAN / FALLOPIAN TUBE, OR PRIMARY PERITONEAL – Advanced, Primary, Recurrent
GOG-1861  – A randomized phase II evaluation of single-agent bevacizumab (IND#113912) (NSC#704865) and combination bevacizumab with fosbretabulin tromethamine (CA4P) (NSC#752293) in the treatment of recurrent or persistent epithelial ovarian, fallopian tube or primary peritoneal carcinoma

GOG-0187  – A Phase II study of paclitaxel for ovarian stromal tumors as second line therapy

GOG-0212  – A randomized phase III trial of maintenance chemotherapy comparing 12 monthly cycles of single agent paclitaxel or xyotax (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 chemotherapy.

GOG-0213  – A Phase III randomized controlled clinical trial of Carboplatin and Paclitaxel alone or in combination with Bevacizumab (NSC #704865, IND #113912) followed by Bevacizumab and secondary cytoreductive surgery in platinum-sensitive, recurrent ovarian, primary peritoneal and fallopian tube cancer. NCI-SUPPLIED AGENTS: BEVACIZUMAB (NSC #704865, IND #113912)

GOG-0225  – Can diet and physical activity modulate ovarian, fallopian tube and primary peritoneal cancer progression-free survival?

GOG-0235  – A prospective, longitudinal study of YKL-40 in patients with FIGO stage III or IV invasive epithelial ovarian, primary peritoneal, or fallopian tube cancer undergoing primary chemotherapy.

GOG-0241  – MEOC: A GCIG Intergroup Multicenter Phase III Trial of Open Label Carboplatin and Paclitaxel +/- Bevacizumab Compared with Oxaliplatin and Capecitabine +/- Bevacizumab as First Line Chemotherapy in Patients with Mucinous Epithelial Ovarian Cancer (MEOC)

GOG-0254  – A phase II evaluation of SU 11248 (sunitinib malate) (IND#74019, NSC# 736511) in the treatment of persistent or recurrent clear cell ovarian carcinoma

GOG-0260  – A phase II Evaluation of Elecsclomol Sodium and Weekly Paclitaxel in the Treatment of Recurrent or Persistent Platinum-Resistant Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (Sponsor: GOG, IND#110072)

GOG 0262/ACRIN 6695: A Randomized phase III trial of every 3 week paclitaxel versus dose dense weekly paclitaxel in combination with carboplatin with or without concurrent and consolidation bevacizumab (NSC#704865, IND #7921) in the treatment of primary stage II, III or IV epithelial ovarian, peritoneal or fallopian tube cancer.
GYNECOLOGIC / GOG (cont’d)

OVARIAN / FALLOPIAN TUBE, OR PRIMARY PERITONEAL – Advanced, Primary, Recurrent

GOG-0264 – A randomized phase II trial of paclitaxel and carboplatin VS bleomycin, etoposide, and cisplatin for newly diagnosed advanced stage and recurrent chemo-naive sex cord-stromal tumors of the ovary.

GOG-0268 – A phase II evaluation of TEMSIROLIMUS (CCI-779) (NCI SUPPLIED AGENT: NSC# 683864, IND# 61010) in combination with Carboplatin and Paclitaxel Followed by TEMSIROLIMUS (CCI-779) CONSOLIDATION as first-line therapy in the treatment of STAGE III-IV clear cell carcinoma of the ovary

CA184-201: A phase II safety and efficacy study of Ipilimumab monotherapy following completion of chemotherapy in (P) recurrent platinum sensitive ovarian cancer subjects with residual measurable disease – IRB Pending

TRINOVA-3 - A Phase 3 Randomized, Double-blind, Placebo-controlled, Multicenter Study of AMG 386 With Paclitaxel and Carboplatin as First-line Treatment of Subjects With FIGO Stage III-IV Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Cancers Protocol Number: Amgen 20101129/ENGOT-ov2/GOG-3001

CERVICAL / Locally Advanced, Recurrent, Persistent

GOG-0076HH – A Limited Access Phase I/II Trial of Paclitaxel, Cisplatin and CTEP Supplied Agent ABT-888 (Velaparib) (IND#77840, NSC#737664) in the Treatment of Advanced, Persistent, or Recurrent Carcinoma of the Cervix

GOG-0274 – A Phase III Trial of Adjuvant Chemotherapy Following Chemoradiation as Primary Treatment for Locally Advanced Cervical Cancer Compared to Chemoradiation Alone: THE OUTBACK TRIAL (ANZGOG 0902/GOG-0274/RTOG 1174)

CORPUS UTERUS & ENDOMETRIAL: Recurrent / Persistent, Endometrial

GOG-229K – GOG 0229K A phase II evaluation of BIBF 1120 (IND#113086) in the treatment of recurrent or persistent endometrial carcinoma

GOG-229L - A phase II trial of AMG 386 (IND#111071), a selective angiopoietin 1/2 neutralizing peptibody, in patient (S) with persistent/recurrent carcinoma of the endometrium

GOG-0258 – A randomized phase III trial of cisplatin and tumor volume directed irradiation followed by carboplatin and paclitaxel vs carboplatin and paclitaxel for optimally debulked, advanced endometrial cancer.

GOG-0261 – A Randomized Phase III trial of Paclitaxel plus Carboplatin versus Ifosfamide Plus Paclitaxel in Chemotherapy-Naive Patients with Newly Diagnosed Stage I-IV, Persistent or Recurrent Carcinosarcoma (Mixed Mesodermal Tumors) of the Uterus or Ovary

SARCOMA

GOG0230D – A phase II evaluation of pazopanib (NSC# 737754,IND# 75648)in the treatment of recurrent or persistent carcinosarcoma of the uterus

GOG0250 – A randomized phase III evaluation of docetaxel (NSC#628503) and gemcitabine (NSC#613327) plus G-CSF with bevacizumab (NSC#704865, IND#7921) versus docetaxel (NSC#628503) and gemcitabine (NSC#613327)plus G_CSF with placebo in the treatment of recurrent or advanced leiomyosarcoma of the uterus NCI-supplied agent bevacizumab (NSC#704865, IND #113912)

OTHER

DUKE1810 – Epidemiology of Ovarian Cancer in African-American Women (ACES)

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

LOCALLY ADVANCED RESECTED H/N CANCER:

R0920 A Phase III Study of Postoperative Radiation Therapy (IMRT) +/- Cetuximab For Locally-Advanced Resected Head and Neck Cancer
LEUKEMIA / HEMATOLOGY

ANCILLARY LAB – MANDATORY FOR ALL ECOG LEUKEMIA STUDY ENROLLMENTS

**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. – **Applicable only to E2906.**

**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.

**MDS/AML/CML**

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

**AML (Newly Diagnosed, Older Adults)**

E2906 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) – **Must enroll in E3903 to determine eligibility**

**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-ProgressingPts Following an Initial 4 Cycles of Platinum-Based Combination Chemotherapy in Advanced, Stage IIIIB/IV NSCLC

S0819 A Randomized, PH III Study Comparing Carboplatin/Paclitaxel or Carboplatin/Paclitaxel/Bevacizumab w/wo Concurrent Cetuximab in Pts w/Adv NSCLC

E5508 Randomized PH III Study of Maintenance Therapy with Bevacizumab, Pemetrexed, or a Combination of Bevacizumab + Pemetrexed Following Carboplatin, Paclitaxel + Bevacizumab for Advanced Non-Squamous NSCLC -

**ADV / METASTATIC NSCLC**

ENSPIRIT - A Multinational, Randomized, Open-Label Ph III Study of Custirsen (TV-1011/OGX-011) In Combination With Docetaxel vs Docetaxel As A Second-Line Treatment In Patients With Advanced or Metastatic (Stage IV) Non-Small Cell Lung Cancer (TV1011-LC303)

**TWO-STAGE STUDY FOR NSCLC**

CBKM120D2201: An open label two-stage study of orally administered BKM120 in patients with metastatic non-small cell lung cancer with activated PI3K pathway. (Novartis)

**NONSMALL CELL – FIRST LINE TREATMENT**

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

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

HIGH RISK FOLLICULAR LYMPHOMA
E2408  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

LYMPHOMA (MANTLE CELL)
E1411  Intergroup Randomized PH II Four Arm Study In Patients >/= 60 with Previously Untreated Mantle Cell Lymphoma of Therapy with: Arm A=Rituximab+Bendamustine Followed by Rituximab Consolidation (RB->R); Arm B= Rituximab+Bendamustine+Bortezomib Followed by Rituximab Consolidation (RBV->R); Arm C=Rituximab+Bendamustine Followed by Lenalidomide+Rituximab Consolidation (RB->LR), or Arm D= Rituximab+Bendamustine+Bortezomib Followed by Lenalidomide and Rituximab Consolidation (RBV->LR).

LARGE B-CELL LYMPHOMA
NCI-MET 9177 – Phase II Study of Dose-Adjusted EPOCH +/- Rituximab in Adults With Untreated Burkitt Lymphoma, C-Myc Positive Diffuse Large B-Cell Lymphoma and Plasmablastic Lymphoma

MELANOMA

LOCALLY ADVANCED, METASTATIC
E2607  A Phase II Trial of Dasatinib in KIT-positive Patients with Unresectable Locally Advanced or Stage IV Mucosal, Acral, and Vulvovaginal Melanomas - Suspended

RESECTED HIGH RISK MELANOMA
E1609  A Phase III Randomized Study of Adjuvant Ipilimumab Anti-CTLA4 Therapy vs High-Dose Interferon Alfa-2b for Resected High-Risk Melanoma

MYELOMA

ASYMPTOMATIC, SMOLDERING
E3A06  Randomized Phase III Trial of Lenalidomide Versus Observation Alone in Patients with Asymptomatic Smoldering Multiple Myeloma

PREAMBLE - Prospective Research Assessment in Multiple Myeloma: An Observational Evaluation (PREAMBLE) – CA204008 ST

OTHER: NON-THERAPEUTIC / SYMPTOM MANAGEMENT

CASE CCR – COMMUNICATION AT CANCER RECURRENCE: Female, 18+ yrs, diagnosed advanced or distance Recurrence of breast, colorectal, liver, or GYN cancer

HER2-GEN  An Observational Cohort Study of Treatment Patterns and Outcomes Patients with HER2 Positive (HER2+) Metastatic Breast Cancer - ML28257

PREAMBLE - Prospective Research Assessment in Multiple Myeloma: An Observational Evaluation (PREAMBLE) – CA204008 ST

DUKE1810 – Epidemiology of Ovarian Cancer in African-American (ACES)
RTOG Studies via CTSU

BRAIN/HEAD AND NECK:

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R0920  A Phase III study of post-op RT (IMRT) with or without Cetuximab for locally advanced Resected Head and Neck Cancer

GI:

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GU:

RTOG 0524 - A Phase III 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