

UT CANCER INSTITUTE CLINICAL TRIALS

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BREAST

HER2 positive

ACOSOG Z1041 : A Randomized Ph III Trial Comparing a Neoadjuvant Regimen of FEC-75 Followed by Paclitaxel Plus Trastuzumab With a Neoadjuvant Regimen of Paclitaxel Plus Trastuzumab Followed by FEC-75 Plus Trastuzumab in Patients with Palpable and Operable Breast Cancer (Coordinator – Shanna) **OPEN**

Eligibility:

- Dx of adeno carcinoma of the breast by core needle biopsy
- Palpable measurable dz ≥ 2 cm
- HER2 positive
- No synchronous lesions
- No surgical axillary staging prior to study start
- No history of invasive breast cancer
- No stage T4 dz

Required Studies:

H&P, weight, height, cardiac hx
within 2 wks-
preg test, CBC w/ diff, plts, creat
bili, AST, Alk Phos
within 3 mos-
EKG, Bone scan, MUGA,
Tumor imaging, liver imaging

SWOG N063D: ALTTO: Adjuvant Lapatinib and/or Trastuzumab Treatment Optimisation Study Randomized, Multi-Centre, Open-Label, Phase III Study of Adjuvant Lapatinib, Trastuzumab, Their Sequence and Their Combination in Patients with HER2 Positive Primary Breast Cancer (Coordinator – Shanna) **OPEN**

Eligibility:

- Non-metastatic operable primary invasive adenocarcinoma of the breast
- Axilla dissected
- HER2 2+, 3+, or FISH positive
- Axillary node positive OR node negative with tumor >1.0 cm
- Must have received at least four cycles of neoadj chemo
- No bilateral or multifocal tumors

Required Studies:

H&P, weight, height, vitals
ECG, LVEF (within 7-14 days)
CXR or CT within 6 months
Mammography within 1 year
Preg. test within 7 days
Labs within 14 days

**Genentech
TOC4129g
CLEOPATRA** A Randomized, Double-Blind, Placebo-Controlled Clinical Trial to Evaluate the Efficacy and Safety of Pertuzumab + Trastuzumab + Docetaxel vs. Trastuzumab + Docetaxel in Previously Untreated HER2-Positive Metastatic Breast Cancer (Coordinator – Shanna) **OPEN**

Eligibility:

- Adenocarcinoma of the breast with locally recurrent or metastatic disease
- Measurable or non-measurable disease
- HER2-positive
- LVEF $\geq 50\%$ at baseline
- No prior anticancer therapy for MBC (one prior hormonal regimen is ok)
- Must be <12 months from adjuvant setting to metastatic diagnosis

Required Studies:

H&P, weight, height, PS, vitals
Hem, Chem, preg test (≤ 7 days)
ECG, CXR, ECHO or MUGA
Bone scan

SWOG 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 Anthracycline and/or a Taxane (Coordinator – Shanna) **OPEN**

Eligibility:

- Locally adv. or met. breast ca; progressed after anthracycline and/or taxane and Herceptin
- 1-2 prior regimens in neoadj., adj., or met. setting.
- Measurable disease
- No chemo within 6 weeks prior to start, no RT within 4 weeks of study start
- No prior tx with any agent targeting IGF-I, IGF-II or HER pathway (except Herceptin)

Required Studies:

H&P, weight, height, PS, vitals
Preg test, CBC w/ diff
Chemistry group, fasting glucose
Electrolytes, Lipid profile, INR, UA
CXR or CT, Bone scan, Brain MRI
or CT, KEG, MUGA/ECHO

DCIS : HER2 positive

NSABP B-43 A Phase III Clinical Trial Comparing Trastuzumab Given Concurrently with Radiation Therapy and Radiation Therapy Alone for Women with HER2 Positive DCIS Resected by Lumpectomy (Coordinator – Shanna) **OPEN**

Eligibility:

- Females w/ HER2 pos DCIS (determined by central testing)
- Must have received lumpectomy (no mastectomy)
- < 120 out from surgery
- No confirmed microinvasion
- No multicentric DCIS
- No RT prior to study start (no PBI at all)
- No prior treatment or history of breast cancer

Required Studies:

H&P, weight, height, vitals
RT eval (post-op)
Mammogram (within 6 mos)
Preg. Test (within 2 wks)

Node-neg

PACCT-1 TAILORx Program for the Assessment of Clinical Cancer Tests (PACCT-1): *Trial Assigning Individualized Options for Treatment: The TAILORx Trial* (Coordinator – Shanna) **OPEN**

Eligibility:

- Operable histologically confirmed adenocarcinoma of the female breast with completed primary surgical treatment.
- ER and/or PR positive, Her2 negative
- Negative axillary nodes
- Tumor size 1.1 cm to 5 cm (or 5 mm-1 cm) plus unfavorable histology – poor nuclear grade, lymphovascular invasion)
- No prior chemo or RT for this malignancy, Age range 18-75
- Does NOT have to be post-menopausal

Required Studies:

H&P, weight, height
CBC, Leuk, Plts, creat., AST
Oncotype DC Assay
Biospecimen submission

NSABP B42 A Clinical Trial to Determine the Efficacy of 5 Years of Letrozole Compared to Placebo in Patients Completing 5 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 (Coordinator – Randi) **OPEN**

Eligibility:

- Must be postmenopausal
- Must be disease-free from time of initial diagnosis until randomization
- Stage I, II or IIIA IBC that is ER and/or PR positive
- Must have undergone lumpectomy with axillary node staging followed by RT or a total mastectomy with axillary node staging or sentinel node biopsy.
- 57-63 months from first dose of hormonal therapy which consisted of an AI or a combination of up to 3years of tamoxifen followed by an AI.
- Must randomize within 6 mos following completion of 5 years of initial adj. hormonal therapy.
- **NOTE:** There is an optional letrozole registration program and consent form for those who have not completed 5 years of hormonal therapy

Required Studies:

H&P, cardiac risk factors
Fasting lipid panel (depending on cardiac risk factors)
Mammogram and bone density (w/i 1 yr)

Node-pos.

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 (Coordinator – Shanna) **Temporarily Closed**

Eligibility:

- Histologically confirmed breast cancer at risk of recurrence based on at least H&P, ECOG PS, weight, height one of the following:
 - Involvement n at least one axillary lymph node
 - ER neg tumor more than 1 cm
 - ER pos tumor more than 5 cm
 - ER pos between 1 and 5 cm with recurrence score >11
- May also be enrolled in TailorX trial.

Required Studies:

Hem, chem., PT/PTT/INR
UA
Preg. test
CXR or CT, Mammo, ECG (within 8 wks)
MUGA or Echo (within 8 wks)
Bone scan (if clin. indicated)

CALGB 40502 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 (Coordinator – Shanna) **OPEN**

Eligibility:

- Stage IV or IIIB breast cancer
- May have rec'd prior adj. or neoadj. tx (> 12 mos)
- No prior chemo in met. setting
- RT completed (> 2 weeks from study start)
- Measurable dz
- Prior Avastin and Herceptin allowed

Required Studies:

H&P, PS, vitals, height, weight
CBC, diff, plts, creat, BUN, AST/ALT,
Bili, INR/PT, Urinalysis
Bone Scan
CT of chest/ab/pel (within 28 days)

SWOG S0500: A Randomized Ph 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 (Coordinator – Randi) **OPEN**

Eligibility:

- Histologically or cytologically confirmed adenocarcinoma of the breast
- Must have measurable disease or bone-only disease. Those with non-measurable dz that does not include bone are ineligible.
- No prior chemo for met. disease
- Those with brain mets. Must have stable disease > 90 days after RT

Required Studies:

H&P, ECOG PS, vitals, height, weight
CBC, diff, plts, hemoglobin, ALT, AST
Bili, creatinine, HER2 status, HCG
CT scan or MRI of chest/ab
Bone scan (whole body)

Genentech Ribbon 3 A Phase III, Multicenter, Randomized, Placebo-Controlled Trial Evaluating the Efficacy and Safety of Continued Bevacizumab in Combination with Chemotherapy Regimens for Patients with Locally Recurrent or Metastatic Breast Cancer Who Have Progressed After First-Line Chemotherapy and Bevacizumab Treatment (Coordinator – Shanna) **Pending**

BMS CA-163-131 A Randomized Phase 2 Study to Evaluate the Combinations of Ixabepilone plus Capecitabine or Docetaxel plus Capecitabine in the Treatment of Metastatic Breast Cancer (Coordinator – Shanna) **OPEN**

Eligibility:

- Metastatic breast cancer with up to one prior treatment in metastatic setting.
- Previous tx with anthracyclines, paclitaxel, allowed. No taxotere or capecitabine.
- HER2 positive patients allowed if progressed on Herceptin or Tykerb
- Triple-negative patients are eligible.
- Must have measurable disease

Required Studies:

H&P, weight, height, vitals, PS
Preg test, Hem/Chem, AST, ALT
Total bili, BUN, calcium, chloride
Creatinine, glucose, LDH,

CALGB 40302 Endocrine Therapy With or Without Inhibition of EGF and HER2 Growth Factor Receptors: A Randomized, Double-Blind, Placebo-Controlled Phase III Trial for Postmenopausal Women with Estrogen-Receptor Positive Advanced Breast Cancer (Coordinator – Randi) **Temporarily Closed**

Eligibility:

- Postmenopausal, Stage IV breast cancer or locally advanced Stage III
- ER and/or PR positive, Measurable disease
- HER2 negative or positive
- Must have had 1 or 2 prior treatments for breast cancer in either adjuvant or metastatic setting
- Must have received prior AI therapy
- Up to 1 prior chemo for stage IV breast cancer
- Prior Herceptin tx is allowed.

Required Studies:

H&P, weight, height
CBC, diff, plts, SGOT, SGPT
Bili, INR
CXR or CT
Bone Scan (if met dz in bone)

Partial Breast Irradiation

SAVI A Prospective Phase III Study of the Use of Partial Breast Irradiation (PBI) With the Strut-Adjusted Volume Impact (SAVI™) Breast Brachytherapy Device After Magnetic Resonance Imaging (MRI) of the Breast For Women With Unifocal Stage 0, 1 and Node-negative Stage 2 Breast Carcinoma After Partial Mastectomy, and, in Patients With Invasive Carcinoma, Axillary Sentinel Lymph Node Sampling (Coordinator – Randi) **OPEN**

Eligibility:

- Stage 0, I, or node neg 2 female breast cancer ≤ 3 cm
- Invasive or DCIS
- Partial mastectomy and SLN for invasion
- No axillary nodal dz
- No multifocal or multicentric dz
- No known BRCA mutations

Required Studies:

H&P, med. history
CBC, diff, alk phos, SGOT, SGPT
Mammogram
Ultrasound
MRI
Chest CT

CARCINOID

SWOG S0518: Phase III Prospective Randomized Comparison of Depot Octreotide Plus Interferon Alpha Versus Depot Octreotide Plus Bevacizumab in Advanced Poor Prognosis Carcinoid Patients (Coordinator – Shanna) **OPEN**

Eligibility:

- Unresectable met. or locally adv. low- or intermediate- grade neuroendocrine H&P, weight, height, BP, PS
- High risk by either a) progressive disease, b) refractory, c) atypical histology
d) met. colorectal carcinoid, e) met. gastric carcinoid
- Must have measurable dz
- Up to 1 prior cytotoxic chemo allowed
- No previous interferon, Avastin or other VEGF drugs

Required Studies: (within 28 days)

CBC, diff, plts, serum creat, bili
SGOT/SGPT, PT, PTT
Serum chromogranin A
Neurospecific enolase
Urinary 5HIAA
CT or MRI
Octreotide scan (recommended)

Gastrointestinal: COLON, RECTAL, STOMACH

Adjuvant colon

CTSU E5202: 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 (Coordinator – Shanna) **OPEN**

Eligibility:

- Tumor must be ≥12 cm from the anal verge on endoscopy, then the distal extent of the tumor must be ≥12 cm from the anal verge as determined by surgical examination.
- No history of metastases
- Must be stage II carcinoma, T3,4, N0, M0.
- Must have ≥ 8 lymph nodes evaluated
- No obstruction or perforation of the bowel upon presentation.
- No systemic or radiation therapy for this malignancy

Required Studies:

H&P, weight, height, BP, ECOG PS
CBC, diff, plts, serum creat, bili, AST,
CEA, PT, PTT
Colonoscopy prior to surgery
Urine protein/creat. ratio

Adjuvant rectal

SWOG S0713 A Phase II Study of Oxaliplatin, Capecitabine, Cetuximab and Radiation in Pre-Operative Therapy of Rectal Cancer (Coordinator – Randi) **OPEN**

Eligibility:

- Stage II-III biopsy-proven (non-recurrent) primary adeno of the rectum
- 12 cm from the anal verge by proctoscopic exam
- KRAS mutation testing of tissue required (tissue submitted to outside lab)
- Measurable or nonmeasurable dz

Required Studies:

H&P, weight, PS, vitals
CBC, diff, plts, bili, Alk phos
SGOT or SGPT, creat. Clearance, CEA
CT chest, ab, pelvis

- No prior chemo, RT, or targeted therapy for this tumor

Adv/met. colon or rectum

CALGB 80405: A Phase III Trial of Irinotecan/5-FU/Leucovorin or Oxaliplatin/5-FU/Leucovorin with Bevacizumab, or Cetuximab (C225), or with Combination of Bevacizumab and Cetuximab for Patients with Untreated Metastatic Adenocarcinoma of the Colon or Rectum (Coordinator – Shanna) *Temporarily Closed*

Eligibility:

- Histologically or cytologically locally adv. or met. colorectal cancer
- No prior tx for adv. or met. colorectal cancer
- No prior RT to >25% of bone marrow
- Must be at least 4 weeks out since surgery
- No evidence of Gilbert's syndrome for FOLFIRI patients and no grade 2+ sensory peripheral neuropathy for FOLFOX patients

Required Studies:

H&P, weight, height, vitals, PS
 CBC, diff, plts, creat, BUN, AST, ALT
 Electrolytes, Alk Phos, Bili, Albumin,
 LDH, Magnesium, PT/INR, Urinalysis
 Chest x-ray
 CT scan or MRI

Biocompatibles Precision Irinotecan Therapy of Liver Metastasis from Colon Cancer with Concomitant Systemic Oxaliplatin, Fluorouracil and Leucovorin Chemotherapy, and Anti-Angiogenic Therapy (Coordinator – Shanna) **Pending**

ImClone CP12-0715 Phase 3, Randomized, Double-Blind Study of IMC-1121B and Best Supportive Care (BSC) Versus Placebo and BSC in the Treatment of Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma Following Disease Progression on First-Line Platinum or Fluoropyrimidine-Containing Combination Therapy (Coordinator – Randi) **Pending**

Genitourinary

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Sanofi Aventis: CILAB study Randomized Study of LOROTAXEL + Cisplatin (LC) vs. Gemcitabine + Cisplatin (GC) in the First Line Treatment of Locally Advanced/Metastatic Urothelial Tract or Bladder Cancer (Coordinator – Randi) **OPEN**

Eligibility:

- TCC w/ locally advanced T4b or met. urothelial tract or bladder cancer
- No prior palliative chemo
- Must be > 6 months since end of prior therapy and relapse

Required Studies:

H&P, vitals, height, weight, pS
 CT or MRI (chest, ab, pelvis) < 3 wks
 Hem, chem., preg test within 8 days
 ECG within 3 weeks

Adjuvant Renal

ECOG E2805 A Randomized Double-Blind Phase III Trial of Adjuvant Sunitinib versus Sorafenib versus Placebo in Patients with Resected Renal Cell Carcinoma (Coordinator – Randi) *Temporarily Closed*

Eligibility:

- Tumors must be > 4 cm and/or macroscopic, surgically resectable
- Must have RCC T1B, T2, T3, T4 with N0-2 with resection
- No history of distant mets.
- No prior anti-cancer therapy in either adj. or neoadj. setting
- Must be between 3-10 weeks from surgery at randomization

Required Studies:

H&P, vitals, height, weight, PS
 CBC, chemistries, AGC, plts, creat
 Bili, SGOT, SGPT, PT/PTT/INR, UA
 Urine for DNA methylation (3wks prior to or at resection)
 BETA HCG, EKG, Bone Scan, MUGA
 CT chest/ab/pelvis w/ contrast

Renal Advanced/Met.

ECOG E2804 The BeST Trial: A Randomized Phase II Study of VEGF, RAF kinase, and mTOR Combination Targeted Therapy (CTT) with Bevacizumab, Sorafenib and Temozolimus in Advanced Renal Cell Carcinoma (Coordinator – Randi) **OPEN**

Eligibility:

- Renal cell carcinoma clear cell
- Measurable metastatic dz
- Prev. nephrectomy required unless tumor >5cm or extensive liver or bone mets
- No more than 1 prior regimen for advanced dz, no prior anti-angiogenic tx

Required Studies:

H&P, vitals, height, weight, BP, PS
 UA for protein/creatinine ratio
 CBC, diff, plts, Hematology, electrolytes
 Serum phos, INR, PTT, lipid profile

- Prior RT is permitted
- No major surgery within 28 days

Brain CT and Bone scan (if clin indicated)
CT of chest, ab, pelvis

ESOPHAGEAL

RTOG 0436 A Phase III Trial Evaluating the Addition of Cetuximab to Paclitaxel, Cisplatin, and Radiation for Patients with Esophageal Cancer who are Treated Without Surgery (Coordinator – Shanna) **OPEN**

Eligibility:

- Endoscopy proven esophagus or gastroesophageal junction cancer w/ 6 wks
- All disease encompassed in RT field
- No tracheoesophageal fistula or invasion into major bronchi
- No prior chemo for esophageal cancer or RT to the same field/area
- No prior EGFR therapy, no prior platinum or paclitaxel

Required Studies:

History/physical exam
PET/PET-CT or CT within 6 wks
EKG within 6 wks
CBC w/ diff, ANC, platelets, Hgb, creatinine
bili, AST, magnesium, calcium, potassium

HEAD and NECK

ECOG 1305 A Phase III Randomized Trial of Chemotherapy With or Without Bevacizumab in Patients With Recurrent or Metastatic Head and Neck Cancer (Coordinator – Randi) **OPEN**

Eligibility:

- Squamous cell H&N from any primary site, no nasopharyngeal ca
- Must be recurrent or metastatic
- No prior chemo or targeted therapy for recurrent or met. dz
- Previous palliative RT is allowed
- Measurable dz

Required Studies:

History/physical, PS, height, weight
CBC, diff, plts, creatinine, electrolytes
Calcium, Mg, liver function tests, PT/PTT
UPC (after baseline, Arm B only)
CT chest and neck, EKG

LEUKEMIA/ LYMPHOMA/ MULTIPLE MYELOMA

Leukemia

SWOG 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 (Coordinator – Shanna) **OPEN**

Eligibility:

- AML based on bone Myelodysplastic Syndromes
- Chronic Myelomonocytic Leukemia (Dysplastic subtype)
- Acute myeloid leukemia with multilineage dysplasia
- No prior treatment with Azacitidine, decitabine or MS-275.
- No AML induction chemo or stem cell transplant.
- No CNS or pulmonary leukostasis, disseminated intravascular coagulation, or CNS leukemia.
- Patients who have therapy-induced MDS or AML-TLD are excluded.
- **NOTE:** patients must be registered on SWOG-9007

Required Studies:

H&P, PS, CBC, diff, plts, reticulocytes
Electrolytes, calcium, phosphorus
BUN, creat, protein, albumin, bili, AST
ALT, Alk Phos
Chest CXR or CT, EKG
Bone marrow aspirate and biopsy

CML

Novartis AMN107A Multi-center, Open-label, Exploratory Study of Bcr-Abl Kinetics in Adult Patients on Nilotinib (Tasigna) with Philadelphia Chromosome Positive (Ph+) CML in Chronic Phase and a Suboptimal Molecular Response to Gleevec (Coordinator – Shanna) **OPEN**

Eligibility:

- CML-CP and CCyR defined as:
 - Cytogenetic confirmation of undetectable levels of Philadelphia chromosome
 - < 15% blasts in peripheral blood and bone marrow
 - < 30% blasts plus promyelocytes in peripheral blood and bone marrow
 - < 20% basophils in the peripheral blood
 - > 100 platelets
 - no evidence of extramedullary leukemic involvement, with the exception of

Required Studies:

H&P, height, weight, vitals, PS
Hem, chem (incl. amylase, lipase)
ECG (triplicate), ECHO
Peripheral blood Bcr-Abl RQ-PCR
Bone marrow (standard cytogenetics)
Mutational analysis

- hepatosplenomegaly
- No prior accelerated phase or blast phase CML
- No prior CCyR on imatinib and lost cytogenetic response
- No other treatment for CML except hydroxyurea and/or anagrelide

AML

SWOG S0605 A Phase II Study of Lenalidomide (Revlimid) for Previously Untreated Non-M3 Deletion 5Q Acute Myeloid Leukemia (AML) in Patients Age 60 or Older Who Decline Remission Induction Chemotherapy (Coordinator – Shanna) **OPEN**

Eligibility:

- AML based on bone marrow aspiration and biopsy
- Patients must have declined standard AML cytotoxic chemo regimens
- Must have cytogenetic evidence of 5q deletion
- Must be 60 years or older
- No prior systemic chemo for acute leukemia with the exception of hydroxyurea
- Can have had prior myelodysplastic syndrome
- After induction, patients can be registered to maintenance therapy as long as they do not have progressive disease

Required Studies:

H&P, weight, PS
CXR, HIV test
CBC, diff, plts, bili, AST, ALT, creat

Genzyme CLASSIC A Phase III Randomized, Double-Blind, Controlled Study Comparing Clofarabine and Cytarabine versus Cytarabine Alone in Adult Patients ≥ 55 Years Old with Acute Myelogenous Leukemia (AML) who have Relapsed or are Refractory after Receiving up to Two Prior Induction Regimens (Coordinator – Shanna) **OPEN**

Eligibility:

- AML patients who have not received more than 2 prior induction regimens
- Refractory or relapsed and at least 55 years old
- No prev. tx with clofarabine
- No intermediate or high dose cytarabine
- No grade 2 or higher GvHD

Required Studies:

H&P, weight, height, BSA, vitals, PS
ECG
CBC, diff, plts, creat, chemistries, UA
Bone marrow biopsy and aspirate
Cytogenetics, and imaging studies

Lymphoma

Millennium C05012 A Two-Arm, Non-Randomized Study of Velcade-R-CP or Velcade-R-CAP in Relapsed Follicular Lymphoma (Coordinator – Shanna) **OPEN**

Eligibility:

- FL (any grade) with documented relapse or progression
- At least 1 measurable tumor mass that is greater than 1.5 cm
- No active CNS lymphoma
- No prior Velcade

Required Studies:

H&P, weight, height, PS, vitals
FBV surface antigen, Chem, Hem.
ECHO or MUGA (arm A only)
ECG
CT of neck, chest, ab, pelvis (within 35 d)
PET scan (within 35 days)

Myeloma

Millenium C05009 Randomized Phase 3b 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 (Bortezomib), Thalidomide, and Dexamethasone (VTD) versus VELCADE and Dexamethasone (VD) versus VELCADE, Melphalan, and Prednisone (VMP) (Coordinator – Shanna) **OPEN**

Eligibility:

- Not a candidate for high dose chemo and transplant
- Karnofsky PS >50%
- Measurable disease by M-protein or urine light-chain excretion
- No smoldering or MGUS
- No Waldenström's disease

Required Studies:

H&P, weight, height, vitals, PS
Bone marrow biopsy/aspirate
Pregnancy test
M-protein (SPEP, UPEP, immunofixation)

ECOG E1A05 Randomized Phase III Trial of Consolidation Therapy with Bortezomib (VELCADE)-Lenalidomide (Revlimid)-Dexamethasone (VRD) versus Bortezomib (VELCADE)-Dexamethasone (VD) for Patients With Multiple Myeloma Who Have Completed a Dexamethasone Based Induction Regimen (Coordinator – Shanna) **OPEN**

Eligibility:

- Patients w/ MM that was symptomatic at initial dx
- No prior bortezomib (Revlimid)
- At least 2 cycles of a dexamethasone-based induction regimen
- Must have met the following criteria at one point in these dz course:
 - bone marrow plasmacytosis with 10% plasma cells or sheets of plasma or biopsy proven plasmacytoma

Required Studies: (within 28 days)

H&P, PS, weight, height, vitals
CBC, chem., preg test
Albumin, LDH, TSH, C-reactive protein
24-hr urine
Serum Beta-2 immunoglobulin
Quan. immunoglobulins

and b) symptomatic dz at initial dx as well as evidence of end-organ damage at initial dx

Bone marrow aspirate/biopsy
ECG
Met. Bone Scan (within 42 days)

LUNG

Adjuvant

GSK MAGRIT 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 (Coordinator – Shanna) **OPEN**

Eligibility:

- Complete resection of Stage IB, II, IIIA NSCLC
- Lobectomy or sleeve lobectomy – NO wedge resection allowed
- Mediastinal LN sampling as per protocol
- Tx of adjuvant platinum-based chemo allowed bet. surgery and randomization
- Must be enrolled 4-12 weeks after surgery for those not scheduled for chemo
- Must be enrolled 3-6 weeks after platinum-based chemo (up to 4 cycles) for those receiving chemo
- Please note: It takes approximately 8 days to receive MAGE A-3 analysis results

Required Studies:

H&P, height, weight, ECOG PS
MAGE A-3 analysis
CT chest/ab, CXR, Brain CT or MRI
CBC, Hematology

CALGB 140503 A Phase III Randomized Trial of Lobectomy Versus Sublobar Resection for Small (≤ 2 cm) Peripheral NSCLC (Coordinator – Randi) **OPEN** **NOTE:** Contains imaging substudy CALGB 580602

Eligibility:

- Peripheral lung nodule ≤ 2 cm on CT and presumed to be lung cancer
- Tumor location suitable for lobar or sublobar resection
- No prior malignancy within 5 yrs
- No prior chemo or RT for this malignancy
- No evidence of locally advanced or met. dz
- Intraoperatively:** histologic confirmation of NSCLC, and N₀ status
- NOTE:** Randomization is done intra-operatively

Required Studies:

Phy. Exam, PS
Pulmonary function tests
CXR
Chest CT or PET/CT within 42 days

SWOG S0720 Phase II ERCC1 and RRM1-Based Adjuvant Therapy Trial in Patients with Stage I NSCLC (Coordinator – Randi) **OPEN**

Eligibility:

- Resected Stage IA (≥ 2 cm) or Stage IB NSCLC
- Tumor tissue sent out for gene expression analysis
- No prior tx other than surgery for NSCLC

Required Studies:

H&P, PS, weight, vitals
CT of chest/ab
Whole PET or PET/CT
ANC, Plt, Hgb, Bili, SGOT/SGPT, CrCl

ECOG E1505 A Phase III Randomized Trial of Adjuvant Chemotherapy With or Without Bevacizumab for Patients with Completely Resected Stage IB (≥ 4 cm) – IIIA NSCLC (Coordinator – Shanna) **OPEN**

Eligibility:

- Complete resection of T2-3N0, T1-3N1, T1-3N2 NSCLC
- If tumor is stage IB, must be at least 4 cm in size
- 6-12 weeks post-thoracotomy
- No prior systemic chemo, hormonal tx, or RT (unless more than 5 yrs)

Required Studies:

H&P, PS, weight, BP
Chem, CBC, PT/INR/PTT
UPC
CXR, CT, smoking status survey

Brachytherapy

ACOSOG Z4032 A Randomized Phase III Study of Sublobar Resection versus Sublobar Resection plus Brachytherapy in High Risk Patients with Non-Small Cell Lung Cancer (NSCLC), 3 cm or smaller (Coordinator – Randi) **OPEN**

Eligibility:

- Suspicious lung nodule for clinical stage I NSCLC
- Mass less than or equal to 3 cm max diameter by CT
size estimate: clinical stage Iaa or selected Ibb
- Must meet one major criteria or at least two minor criteria as described below:
Major: FEV% $\leq 50\%$, DLCO $\leq 50\%$
Minor: Age ≥ 75
FEV1 51-60% predicted
DLCO 51-60% predicted

Required Studies:

H&P, ECOG PS
Pulmonary function (incl. DLCO)
CT chest and ab

Pulmonary hypertension as estimated by echocardiography or right heart catheterization
Poor left ventricular function
Resting or Exercise Arterial pO₂ ≤ 55 mmHg or SpO₂ ≤ 88%
pCO₂ > 45 mmHg
Dyspnea Scale ≥ 3

Adv./Met.

SWOG S0819 A Randomized, Phase III Study Comparing Carboplatin/Paclitaxel or Carboplatin/Paclitaxel/Bevacizumab with or without Concurrent Cetuximab in Patients with Advanced NSCLC (Coordinator – Randi) **Pending**

Pfizer
A4021016 Randomized, Open Label, Phase III Trial of CP-751,871 in Combination with Paclitaxel and Carboplatin Versus Paclitaxel and Carboplatin in Patients with **non-adeno** NSCLC (Coordinator – Randi) **Temporarily Closed**

Eligibility:

- NSCLC predominantly squamous cell, large cell or adenosquamous
- Stage IIIB (with pleural effusion) or Stage IV or recurrent disease
- No prior tx for NSCLC, except for adjuvant chemotherapy >12 mos prior
- No CNS mets

Required Studies:

H&P, ECOG PS, weight, height, vitals
ECG
hemoglobin A1C, total IgG ARM A only
Hematology, Chem, preg test
CT within 28 days

Small Cell

CALGB 30610
RTOG 0538 Phase III Comparison of Thoracic Radiotherapy Regimens in Patients with Limited SCLC Also Receiving Cisplatin and Etoposide (Coordinator – Randi) **OPEN**

Eligibility:

- Histo or cyto confirmed SCLC
- Limited stage dz, no complete resection
- Measurable dz
- No prior treatment for SCLC

Required Studies:

H&P, vitals, height, weight, PS
CBC, diff, plts, bili, LDH, AST, Cr., BUN
Mg, Na, Ca
DLCO, FEV-1, FVC
CT chest, ab
Bone or PET scan,
MRI or CT of brain

SWOG S0802 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) Study (Coordinator – Randi) **OPEN**

Eligibility:

- Extensive stage small cell lung cancer
- Progression or recurrence after ONE standard first-line platinum tx
- Stable brain mets ok
- No prior Avastin or anti-angiogenic tx

Required Studies:

H&P, weight, PS, BP
CBC, diff, UPC, PT/INR, PTT
Brain CT or MRI
Bone scan if clin. indicated

PET

UTMCK Early, Prospective Prediction of Response to Chemotherapy in Non-Small Cell Lung Cancer (NSCLC) Patients Using FDG PET/CT (Coordinator – Shanna) **OPEN**

Mesothelioma

SWOG S0722 A Phase II Trial of MTOR Inhibitor, Everolimus (RAD001), in Malignant Pleural Mesothelioma (Coordinator – Randi) **Temporarily Closed**

Eligibility:

- Unresectable malignant pleural mesothelioma
- Measurable or non-measurable disease
- Must have had prior platinum-based chemo
- No more than two prior systemic therapies (including biologics)
- May have received prior surgery if > 28 days, prior RT ok if > 14 days
- No prior mTOR inhibitor

Required Studies:

H&P, vitals, height, weight, PS
CBC, diff, plts, bili, SGOT/SGPT, CrCl
Chest CT

MELANOMA

Lilly JZAO A Randomized Phase 3 Study of Tasisulam Administered as an IV Infusion on Day 1 of a 28-Day Cycle vs. Paclitaxel as Second-Line Treatment in Patients with Metastatic Melanoma **Pending**

ILI-Lewis Isolated Limb Infusion (ILI) with Melphalan and Actinomycin-D for Recurrent and In-transit Extremity Melanoma (Coordinator – Shanna) **OPEN**

Eligibility:

- Stage IIIB, IIIC, limited stage IV dz to an extremity
- Palliative ILI will be considered for pain control/limb salvage

Required Studies:

H&P, vitals
CT/MRI
FACT M, FACT G evals

PANCREATIC**Adjuvant**

ACOSOG Z5041 A Phase II Study of Preoperative Gemcitabine and Erlotinib Plus Pancreatectomy and Postoperative Gemcitabine and Erlotinib for Patients with Operable Pancreatic Adenocarcinoma (Coordinator – Shanna) **OPEN**

Eligibility:

- Adeno of the pancreatic head or uncinate process
- NO neck, body or tail pancreatic cancer
- Locally potentially resectable tumors
 - a) no tumor extension to the celiac axis, hep. artery or sup. mesenteric artery
 - b) no encasement or occlusion of the SMV or SMV/portal vein confluence
 - c) no evidence of visceral or peritoneal mets

Required Studies:

H&P, PS, vitals, height, weight, BSA
Smoking hx, CBC w/ diff, electrolytes, BUN creat., glucose, calc., albumin, total protein
SGOT, SGPT, Alk phos, total bili, CA 19-9
PT/INR/PTT, preg test
CXR or chest CT, ab CT

PROSTATE**Cyberknife**

UTMCK Virtual HDR CyberKnife Radiosurgery for Localized Prostatic Carcinoma: A Phase II Study (Coordinator – Randi) **OPEN**

Eligibility:

- Histologically confirmed, locally confined prostate adenocarcinoma
- Stage T1b-T2b
- Gleason score at least 7
- PSA less than 20 ng/mL

Required Studies:

H&P, vitals, height, weight, PS
PSA within 120 days
Transrectal ultrasound volume study
Completion of patient questionnaires

Met. Prostate

ECOG E3805 CHAARTED ChemoHormonal Therapy versus Androgen Ablation Randomized Trial for Extensive Disease in Prostate Cancer (Coordinator – Randi) **OPEN**

Eligibility:

- Prostate cancer patients. If hormonal tx has begun, it must not be > 120 days
- Metastatic dz
- Just have discontinued hormonal tx in adj. setting 12 mos prior to study entry

Required Studies:

H&P, vitals, CBC, diff, plts
Creatinine clearance, PTT, PT, INR
ALT (Arm A)
CT ab/pelvis, CXR or CT chest
Bone scan, PSA

MISCELLANEOUS

RTOG 0517 Randomized Phase III Trial to Evaluate Radiopharmaceuticals and Zoledronic Acid in the Palliation of Osteoblastic Metastases from Lung, Breast, and Prostate Cancer (Coordinator – Randi) **OPEN**

Eligibility:

- Lung, breast, or prostate cancer
- Bone mets
- If patient received RT, must be > 14 days
- If patient has received oral bisphosphonates, must be discontinued

Required Studies:

H&P, weight, height, vitals, PS
CBC w/ diff, ANC, plts, Hgb, bili, preg test
Dental eval
Bone scan

- No prior Strontium-89 or Samarium-153 for bone mets

Quality of life questionnaires

ODAM ODAM as a Novel Biomarker of Human Breast Cancer **OPEN**

Eligibility:

- Breast cancer patients scheduled to receive surgery.
- Willingness of patient have extra tube of blood drawn prior to surgery (at pre-op visit) and again between 26-52 weeks after surgery

Fry IRON Preliminary Validation of an Enzyme-linked Immunosorbent Assay (ELISA) to Measure Serum Hepcidin Concentration in Clinical Samples **OPEN**

Eligibility:

- Patients who have received 3 or more blood transfusions within a year or patients who are to receive injectable iron therapy
- Willingness to have extra tube of blood drawn 2 hrs to 1 wk after receiving a blood transfusion or 30 min to 48 hrs after iron tx

Repositories

SWOG 9910: Leukemia centralized reference laboratories and tissue repositories – consent to perform cellular and molecular studies in leukemia patients **(In conjunction with SWOG-E1905) OPEN**

SWOG 9007: Cytogenetic Studies in Leukemia Patients **(In conjunction with SWOG-E1905) OPEN**

QUESTIONS REGARDING PROTOCOLS Call the <i>Clinical Trials Office</i> at (865) 305-9773
