

Providence Cancer Clinical Trials

Open Clinical Trials

Current as of June 19, 2009

Includes Columbia River Oncology Program protocols (CROP), pharmaceutical and Earle A. Chiles protocols

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Brain

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NCCTG N0776 TEMPORARILY CLOSED.

Bevacizumab and Sorafenib in Treating Patients With Recurrent Glioblastoma Multiforme

Eligibility:

- Histologically confirmed glioblastoma multiforme as determined by pre-registration central pathology review (Gliosarcoma allowed)
- Must have evidence of tumor progression by MRI or CT scan following radiotherapy or the most recent anti-tumor therapy
- Bidimensionally measurable or evaluable disease by MRI or CT scan
- No evidence of CNS hemorrhage on baseline CT or MRI

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ADJUVANT THERAPY**Her2 Negative Chemotherapy****CTSU ECOG PACCT-1**

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

Eligibility:

- Operable histologically confirmed adenocarcinoma of the female breast who have completed primary surgical treatment
- ER and/or PR positive
- Negative axillary nodes
- Tumor size 1.1-5.0 cm. Tumor must be Her2/neu negative by either FISH or immunohistochemistry.
- Pt must be >18-<76.
- Must be disease free of prior invasive malignancies for greater than 5 years.

CTSU ECOG 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 Negative Breast Cancer

Eligibility:

- Histologically confirmed adenocarcinoma of the breast.
- Significant risk of distant recurrence based on ≥ 1 of the following criteria:
 - At least 1 axillary lymph node positive on routine histologic, examination (must be demonstrated by more than immunohistochemistry alone)
 - Estrogen receptor (ER)-negative tumor ≥ 1 cm
 - ER+ tumor ≥ 5 cm regardless of recurrence score
 - ER+ tumor ≥ 1 cm but < 5 cm with a recurrence score ≥ 11
- Patients enrolled on ECOG-PACCT-1 clinical trial are eligible,
- Has undergone definitive breast surgery within the past 29-84 days, including total mastectomy and axillary dissection (modified radical mastectomy), total mastectomy and sentinel node biopsy, lumpectomy and axillary dissection, or lumpectomy and sentinel node biopsy.
- Surgical margins must be histologically free of invasive breast cancer and ductal carcinoma in situ.
- Resection margins positive for lobular carcinoma in situ allowed. Planned post-lumpectomy radiation therapy required, including any of the following: Whole breast radiation therapy after chemotherapy, Accelerated partial breast radiation therapy after chemotherapy, Accelerated partial breast radiation therapy prior to chemotherapy, Planned post-mastectomy radiation therapy required for patients with a primary tumor of > 5 cm or involvement of ≥ 4 lymph nodes
- No HER2/neu positive breast cancer (i.e., 3+ by immunohistochemistry or positive by fluorescent in situ hybridization [FISH])
- No clinical evidence of inflammatory disease or fixed axillary nodes (N2) at diagnosis
- May have synchronous bilateral breast cancer (diagnosed ≤ 1 month) if the higher TNM stage tumor meets the eligibility criteria for this trial.

Her2 Positive Chemotherapy**NCCTG N063D ALTTO**

Adjuvant Lapatinib and/or Trastuzumab Treatment Optimisation (ALTTO) Study: A Randomised, Multi-Centre, Open-Label, Phase III Study of Adjuvant Lapatinib, Trastuzumab, Their Sequence and Their Combination in Patients with HER2/ErbB2 Positive Primary Breast Cancer

Eligibility:

- Non-metastatic operable primary invasive adenocarcinoma of the breast fulfilling the following:
 - Histologically confirmed;
 - Adequately excised (exceptions: patients who have 'non-resectable' deep margin invasion are eligible provided they have had or will receive radiotherapy encompassing the region concerned; patients with histologically documented infiltration of the skin (pT4) are eligible provided they have undergone or will receive radiotherapy encompassing the tumour bed);
 - Axilla dissected; sentinel node sampling is allowed provided that axillary dissection follows confirmation of a positive sentinel node; sentinel node sampling alone is NOT acceptable after neoadjuvant chemotherapy (in patients receiving neoadjuvant chemotherapy lymph node status will be considered unknown, regardless of the results of post-chemotherapy axillary dissection)
 - Axillary node positive patient OR node negative patient with a tumour greater than or equal to 1.0 cm in greatest diameter ($\geq T1c$) according to TNM. Known hormone receptor status (ER/PgR or ER alone); Must have received at least four cycles of an approved anthracycline-based (neo-) adjuvant chemotherapy regimen.

NSABP B44-I CIRG TRIO

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

Eligibility:

- tumor must be unilateral invasive adenocarcinoma of the breast on histologic examination.
- The breast cancer must be HER2-positive based on test results as follows: Local testing (if available) should demonstrate that the tumor is IHC 2+ or 3+ or is considered to be HER2-positive for gene amplification by FISH, CISH, or other in situ hybridization (ISH) method. (If local ISH test results are considered equivocal, the tumor can be submitted for central HER2 testing.) Central testing (a requirement for ALL patients) must demonstrate that the tumor is HER2-positive which is defined as FISH-positive and/or IHC 3+.
- ECOG performance status of 0 or 1.
- All of the following staging criteria (according to the 6th edition of the AJCC Cancer Staging Manual) must be met: By pathologic evaluation, primary tumor must be pT1-3; By pathologic evaluation, ipsilateral nodes must be pN0, pN1 (pN1mi, pN1a, pN1b, pN1c), pN2a, pN3a, or pN3b. If pN0, at least one of the following criteria must be met: Pathologic tumor size > 2.0 cm; ER negative and PgR negative; Histologic and/or nuclear grade 2 (intermediate) or 3 (high); or Age < 35 years.

NSABP FRPFB5 TEMPORARILY CLOSED

A Phase II Clinical Trial of Epirubicin Plus Cyclophosphamide Followed by Docetaxel Plus Trastuzumab and Bevacizumab Given as Neoadjuvant Therapy for HER2-Positive Locally Advanced Breast Cancer or Given as Adjuvant Therapy for HER2-Positive Pathologic Stage III Breast Cancer

Eligibility:

- The tumor must be invasive adenocarcinoma of the breast on histologic examination.
- The breast cancer must be determined to be HER-2-positive prior to study entry. Assays performed using FISH require gene amplification.
- Assays using HIC require a strongly positive 3+ staining score.
- ECOG performance status of 0-1.
- At the time of entry, blood counts must meet the following criteria: ANC must be > 1200/mm³, Platelets must be > 100,000/mm³, Hemoglobin must be >10 g/dL

Her2 Any Chemotherapy

SWOG S0221

Phase III Trial of Continuous Schedule AC+G Vs. 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"

Eligibility:

- Histologically confirmed operable stage I, II, or III invasive breast carcinoma with known ER/PR status
- Bilateral synchronous breast cancer diagnosed within 1 month of one another eligible if the higher TNM stage primary tumor meets eligibility criteria.
- High risk as defined by tumor \geq 2 cm or \geq 1 axillary or intramammary node with metastatic breast cancer (node positive patients must have minimum of 6 nodes sampled)
- Modified radical mastectomy or local excision of all tumors + axillary dissection or sentinel node resection
- Registration within 84 days of final surgical procedure.
- No prior cytotoxic chemo for this cancer. No prior chemo with anthracycline, anthracenedione, or a taxane.
- No prior RT for current malignancy (other than for DCIS)

CALGB 40101

Cyclophosphamide and Doxorubicin (CA) (4 vs. 6 Cycles) Versus 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

Eligibility:

- Histologically confirmed invasive carcinoma of the breast
- High risk Node Negative that warrants chemotherapy (>1 cm or ER/PR neg)
- Margins must be free of invasive and DCIS; LCIS is acceptable at margin
- No prior chemo or HRT except Tamoxifen
- Bilateral cancers okay, must not have locally advanced or inflammatory cancers

Companion Studies

CTSU IBCSG 24-02

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

Eligibility:

- Premenopausal women with histologically proven, resected breast cancer
- Hormone receptor positive
- No mets
- ALD (> 5 nodes examined) or negative sentinel node. Positive axillary nodes require axillary dissection
- No bilateral invasive breast cancer
- No locally advanced inoperable breast ca or supraclavicular node involvement or with enlarged internal mammary nodes (unless pathologically negative)
- No detectable residual axillary disease
- No hx of prior ipsilateral or contralateral invasive breast cancer
- No bilateral oophorectomy or ovarian irradiation
- No endocrine therapy for more than 6 months after diagnosis
- No tamoxifen or other SERM or HRT within one year prior to diagnosis. Oral contraceptives allowed.

SWOG S0307

Phase III Trial of Bisphosphonates as Adjuvant Therapy for Primary Breast Cancer

Eligibility:

- Primary disease within the breast must be resected with either mastectomy or breast sparing surgery
- No evidence of metastatic disease.
- Must have undergone lumpectomy or total mastectomy for primary disease within the past 12 weeks ; Axillary lymph node dissection allowed.
- Patients must receive standard adjuvant therapy; chemotherapy, hormone therapy or combined chemo/hormone therapy.
- Patients who are at low risk for disease recurrence and for whom adjuvant therapy will not be prescribed are not eligible.
- Patients with skeletal pain are eligible provided bone scan and/or roentgenological exam are negative for metastatic disease.
- No other concurrent bisphosphonates as adjuvant therapy or for treatment of osteoporosis
- Pts receiving HT alone should be enrolled within 84 days of final surgical procedure; pts receiving adjuvant post-operative chemotherapy may be enrolled up to 8 weeks after completion of chemotherapy.
- No concurrent enrollment in clinical trials with bone density as an endpoint (i.e., CAN-NCIC-MA27)

NSABP B39

NSABP B39/RTOG 0413, A Randomized Phase III Study of Conventional Whole Breast Irradiation (WBI) Versus Partial Breast Irradiation (PBI) for Women with Stage 0, I, or II Breast Cancer

Eligibility:

- Histologically confirmed DCIS or adenocarcinoma
- Lumpectomy with negative margins
- Unifocal disease ≤ 3 cm. Pts with microscopic multifocal disease eligible as long as total pathological tumor size ≤ 3 cm
- Pts with invasive disease must have axillary staging
- Pt must be randomized within 42 days of last surgery for breast cancer
- ER/PR analysis
- Target lumpectomy cavity must be clearly delineated and cavity to breast volume $\leq 30\%$ by post-op CT
- Not > 3 positive axillary nodes
- No positive non-axillary sentinel nodes
- No suspicious ipsilateral or contralateral axillary, supraclavicular, infraclavicular, or internal mammary nodes
- No suspicious microcalcifications, densities, or palpable abnormalities (in the ipsilateral or contralateral breast)
- No Paget's disease of the nipple
- No hx of invasive breast cancer or DCIS
- No RT, chemo, biotherapy, or hormonal therapy given prior to randomization with exception of hormonal therapy given <28 total days anytime after diagnosis and before randomization
- No breast implants
- Prior breast or thoracic RT for any condition
- No collagen vascular disease

NSABP B42

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

Eligibility:

- Histologically confirmed invasive carcinoma of the breast as seen by core needle or open biopsy.
- Stage I, II, or IIIA primary tumor.
- Received adjuvant hormonal therapy in duration of 57-63 months from the first dose (regardless of the number of missed doses) after breast cancer diagnosis meeting 1 of the following criteria: Aromatase inhibitor (AI), Combination of AI and up to 3 years of tamoxifen citrate for a total of 5 years, No tamoxifen citrate during years 4 and 5 of the 5-year adjuvant hormonal therapy. Must have completed

- adjuvant hormonal therapy within the past 6 months.
- Must have undergone a lumpectomy with axillary nodal staging followed by breast RT or a total mastectomy with axillary nodal staging.
- Must have undergone a bone mineral density test within the past year
- No evidence of recurrent breast cancer by history and physical within the past 3 months.
- Sentinel node biopsy alone allowed provided sentinel nodes were negative on H&E staining.
- No diagnosis of contralateral breast cancer including ductal carcinoma in situ
- Estrogen receptor (ER)-positive and/or progesterone receptor-positive tumor.
- Patients with a tumor considered to be borderline ER-positive and treated with tamoxifen citrate and/or AI are allowed.

METASTATIC THERAPY

Her2 Negative Hormonal

SWOG S0226

Phase III Randomized Trial of Anastrozole Versus Anastrozole and Fulvestrant as First Line Therapy for Post Menopausal Women With Metastatic Breast Cancer

Eligibility:

- Pathologically confirmed metastatic breast cancer (M1) or multiple sites of new disease that is clinically obvious metastatic disease
- Postmenopausal
- ER or PR positive
- No prior chemo, hormone therapy, or immunotherapy for recurrent or metastatic disease.
- Adjuvant or neoadjuvant chemo > 12 months prior allowed.
- No prior adjuvant or neoadjuvant aromatase inhibitors
- No bleeding diathesis or long-term anticoagulant therapy
- No known CNS mets
- Zubrod PS 0-2
- Adjuvant LHRH analogues allowed if stopped > 12 months prior and menstrual periods have not resumed.

CALGB 40503

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

Eligibility:

- Histologic confirmation of invasive cancer of the female breast in either the primary or metastatic setting. Stage IIIB disease not amenable to local therapy or stage IV disease.
- Must have measurable or nonmeasurable disease by RECIST criteria, with radiologic scans (CT scan of the chest/abdomen). Measurable disease is defined as lesions that can be accurately measured in at least one dimension (longest diameter to be recorded) as ≥ 2.0 cm with conventional techniques or as ≥ 1.0 cm with spiral CT scan. Nonmeasurable disease is defined as all other lesions, including small lesions (longest diameter < 2.0 cm with conventional techniques or < 1.0 cm with spiral CT scan) and truly nonmeasurable lesions, including any of the following: Bone lesions, Leptomeningeal disease, Ascites, Pleural/pericardial effusion, Inflammatory breast disease, Abdominal masses that are not confirmed and followed by imaging techniques, Cystic lesions. Baseline bone scans required for all patients for determination of metastatic bone disease. CT scan with bone windows required only for patients with bone metastases as the only site of disease.
- No known CNS metastases or leptomeningeal disease (screening with brain imaging is not required for asymptomatic patients).
- Hormone receptor status: tumors (from either primary or metastatic sites) must express estrogen receptor (ER) and/or progesterone receptor (PgR) in $\geq 1\%$ of cells..

Her2 Negative Chemotherapy

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 or Second-Line Therapy for Locally Recurrent or Metastatic Breast Cancer

Eligibility:

- Histologically confirmed invasive breast cancer
- Stage IIIB or IV (locally recurrent or metastatic) disease not amenable to local therapy.
- Measurable disease (target lesions), defined as ≥ 1 lesion that can be accurately measured in ≥ 1 dimension (longest diameter to be recorded) as ≥ 2.0 cm with conventional techniques or as ≥ 1 cm with spiral CT scan.
- No non-measurable lesions, including any of the following: Ascites, Pleural/pericardial effusion, Inflammatory breast disease, Lymphangitis cutis/pulmonitis, Bone lesions, Leptomeningeal disease, Cystic lesions, Abdominal masses not confirmed and followed by imaging techniques.
- No prior chemotherapy regimen for metastatic or locally advanced breast cancer.
- HER2/neu status must be known, HER2- positive disease allowed, provided patient received prior trastuzumab (HerceptinR) or lapatinib (documentation of progression on HER2-directed therapy is not required).
- No progressing or untreated CNS metastases or leptomeningeal disease. History of resected brain metastases with stable MRI scans for 3 months including within the past 4 weeks allowed. History of gamma-knife radiosurgery or whole-brain radiation with stable MRI scans for 3 months, including within the past 4 weeks allowed.
- Hormone receptor status must be known, Estrogen receptor (ER)- and progesterone receptor (PgR)-positive if $\geq 1\%$ cells are positive.

Her2 Positive Chemotherapy

CTSU ECOG E1105

A Randomized Phase III Double-Blind Placebo-Controlled Trial of First-line Chemotherapy and Trastuzumab with or without Bevacizumab for Patients with HER-2/NEU Over-expressing Metastatic Breast Cancer

Eligibility:

- Histologically confirmed breast cancer that overexpresses HER2/neu, HER2/neu overexpression is defined as 3+ HER2/neu positivity as measured by immunohistochemistry using the Herceptest (DAKO) OR HER2/neu gene amplification as measured by FISH.
- Evidence of metastatic disease and/or chest wall recurrence. Evaluable (measurable or non-measurable) disease is allowed if confirmed within 4 weeks prior to study randomization.
- No history or radiologic evidence of CNS disease (brain CT scan with contrast or brain MRI required within 6 weeks prior to study randomization).
- Hormone receptor status not specified.

GSK LPT11111 (E, W, S)

A Single-arm, Multicenter Phase II Study to Evaluate The Combination of Weekly Nanoparticle Albumin-bound Paclitaxel (Nab-Paclitaxel or Abraxane) and Lapatinib (TYKERB®) in Women who have received no more than one prior chemotherapeutic regimen in the treatment of ErbB2 Overexpressing Metastatic Breast Cancer

Eligibility:

- Subjects must have histologically confirmed invasive breast cancer with Stage IV disease at primary diagnosis or at relapse after curative-intent surgery. Where the disease is restricted to a solitary lesion, the neoplastic nature of the lesion should be confirmed by cytology or histology
- Documented amplification of ErbB2 3+ by immunohistochemistry or a positive score (>2.2) by FISH using a local laboratory result (which will be considered sufficient in this study with no further verification by a central laboratory).
- Subjects must have received no more than one prior chemotherapeutic regimen in the metastatic setting
- If a taxane had been administered in the neoadjuvant, adjuvant or metastatic setting, progression must have occurred ≥12 months after completion of this treatment.
- Prior therapy with radiation for this breast cancer population is permitted if it was administered in the neoadjuvant or adjuvant non metastatic setting. Radiotherapy given in the metastatic setting, prior to initiation of study medication, is allowed to a limited area (e.g., palliative therapy and involving less than 25% of bone marrow), if it is not the sole site of disease. Subjects must have completed radiation treatment and recovered from all acute radiation treatment related toxicities (e.g., bone marrow suppression) prior to commencement of combination treatment.
- The subject must have received all prior chemotherapy treatment at least 4 weeks prior to enrollment in this study and must have recovered from all related toxicities. Subjects who have received weekly dose of prior chemotherapy e.g. gemcitabine or capecitabine may enroll 2 to 3 weeks after cessation of treatment provided that they have recovered from all related toxicities.
- Prior therapy with trastuzumab in the neoadjuvant, adjuvant or metastatic setting is permitted. The subject must have received all prior trastuzumab treatment at least 4 weeks prior to enrollment in this study and must have recovered from all related toxicities.
- Prior endocrine therapy is permitted in the neoadjuvant or adjuvant or metastatic setting. The subject must have received all prior endocrine treatment at least 1 week prior to enrollment in this study and must have recovered from all related toxicities.

Tragara APRICOT-B (E, W)

APRICOT-B: Apricoxib in Combination Oncology Treatment – Breast - “A Randomized, Double-blind, Placebo-controlled, Multicenter, Phase 2 Study of the Efficacy and Safety of Apricoxib in Combination with Lapatinib and Capecitabine in the Treatment of Patients with HER2/neu+ Breast Cancer Who Have Failed Trastuzumab and Chemotherapy including a Taxane”

Eligibility:

- Females with pathologically determined locally advanced or metastatic HER2/neu+ breast cancer.
- HER2/neu status will be considered positive if local laboratory reports grade 3+ staining (scale of 0 to 3) by IHC or 2+ staining by IHC with gene amplification on the fluorescence in situ hybridization test.
- Have progressed after treatment with chemotherapy including a taxane and trastuzumab.
- Have been treated with trastuzumab alone or in combination for locally advanced or metastatic disease for at least 6 weeks.
- Patients must have measurable disease by Response Evaluation Criteria in Solid Tumors (RECIST) at least 20mm for conventional CT scan or at least 10mm for spiral CT scan.

Companion Studies

SWOG S0500

A Randomized Phase III Trial to Test the Strategy of Changing Therapy Versus Maintaining Therapy for Metastatic Breast Cancer Pts who have elevated Circulating Tumor Cell Levels at First Follow-Up Assessment

Eligibility:

- Histologically confirmed breast cancer
- Clinical evidence of metastatic disease (stage IV disease).
- Newly metastatic disease OR progressive metastatic disease while on hormonal therapy.
- Prior hormonal therapy, bisphosphonate therapy, trastuzumab (Herceptin®), and/or bevacizumab for metastatic disease allowed.
- Any number of exogenous hormonal therapies for metastatic disease and/or as adjuvant therapy allowed. At least 1 year since prior adjuvant chemotherapy.
- No prior chemotherapy for metastatic disease.
- At least 4 weeks since prior major surgery and recovered.

MDACC 2004-0728

Prevention of Cisplatin or Oxaliplatin Induced Peripheral Neuropathy with Alpha-lipoic Acid: A Placebo Controlled Phase III Trial

Eligibility:

- Scheduled to receive a cisplatin- or oxaliplatin-containing chemotherapy regimen for cancer.
- No established clinical neuropathy.
- No clinically evident CNS metastases, including leptomeningeal metastases
- No carboplatin, vincristine, vinblastine, paclitaxel, or docetaxel for 6 months prior, during, and 6 months after study treatment.
- Concurrent medications that can modify peripheral neuropathy (e.g., gabapentin, lamotrigine, carbamazepine, phenytoin, or tricyclic antidepressants) are allowed provided there is no dose adjustment within 2 weeks before study entry and during study participation
- No concurrent vitamin E = 100 IU per day . No concurrent physical modality.

MDACC 01-06

Chemotherapy and Mindfulness Relaxation: A Randomized Trial at M. D. Anderson Cancer Center and M.D. Anderson Community Clinical Oncology Program

Eligibility:

- Newly diagnosed malignant solid tumor.
- Undergoing at least 4 courses of chemotherapy.
- No evidence of distant metastatic disease.

NCCTG N08C1

Paclitaxel-Associated Acute Pain Syndrome Natural History Study

Eligibility:

- Diagnosis of cancer.
- Planning to receive paclitaxel (excluding paclitaxel albumin-stabilized nanoparticle formulation [nab-paclitaxel]) according to one of the following dosing schedules: At least 175 mg/m² at 2-4 week intervals (course duration of 2, 3, or 4 weeks, respectively), 70-90 mg/m² weekly (3 out of 4 weeks allowed).
- No prior paclitaxel or neurotoxic chemotherapy drugs, including other taxanes, platinum agents, vinca alkaloids, or epothilones.
- No concurrent neutrophil colony-stimulating factor therapy.

NCCTG N07C2

The Use of Wisconsin Ginseng (panax quinquefolius) to Improve Cancer-Related Fatigue: A Randomized, Double-Blind, Placebo-Controlled Phase III Study

Eligibility:

- Diagnosis of histologically or cytologically proven cancer within the past 2 years.
- Currently undergoing curative intent therapy (including anti-hormonal therapies such as tamoxifen or leuprolide) or completed curative intent therapy.
- Must have completed >1 course of chemotherapy or targeted therapy or > 1 week of radiation therapy.
- Not planning to start new or complete cancer therapy during study.
- History of cancer-related fatigue as defined by an average score of => 4 over the past 30 days on the numeric analogue scale (0–10).
- Experiencing fatigue for > 1 month.
- No known brain metastasis or primary CNS malignancy.

RTOG 0537 TEMPORARILY CLOSED

A Phase II/III Study Comparing Acupuncture-like Transcutaneous Electrical Nerve Stimulation (ALTENS) Versus Pilocarpine in Treating Early Radiation-Induced Xerostomia

Eligibility:

- Pts must have newly diagnosed, primary, histologically confirmed Stage I, II or IIIB (T4 or N3, excluding patients w/ malignant pleural effusion) NSCLC;

SWOG S0424

Molecular Epidemiology Case-Series Study of Non-Small Cell Lung Cancer in Smoking and Non-Smoking Women and Men

Eligibility:

- Pts must have newly diagnosed, primary, histologically confirmed Stage I, II or IIIB (T4 or N3, excluding patients w/ malignant pleural effusion) NSCLC;
- Pts w/effusion are eligible if: a) fluid tapped is benign cytology and all physicians concur that it is from a benign etiology, b) fluid present after mediastinoscopy or thoracotomy, but not before, c) fluid deemed too small to tap under CT or U/S guidance;
- May be registered concurrently to a therapeutic study but not required to be on a therapeutic study;
- Must have tumor block/slides available and willing to provide tissue and blood sample for testing;
- Must have specific tissue specimens available as outlined in Section 4.2

SWOG S0702

A Prospective Observational Multicenter Cohort Study to Assess the Incidence of Osteonecrosis of the Jaw (ONJ) in Cancer Patients with Bone Metastases Starting Zoledronic Acid Treatment

Eligibility:

- Bone metastasis from multiple myeloma, solid tumor, other malignancy where bisphosphonate is indicated; planned treatment with zoledronic acid
- < / = 3 doses IV ibandronate, pamidronate or zoledronic acid in past 3 years for osteopenia or osteoporosis
- < / = 90 days IV ibandronate, pamidronate, or zoledronic acid for metastatic bone disease
- Zubrod PS 0-3
- willing to provide information regarding smoking history, alcohol consumption, pain assessments
- willing to undergo dental assessments per protocol
- willing to provide access to prior and future dental information
- participation in other therapeutic or non-therapeutic trials is o.k.

URCC U07004

Assessment of Topical Treatment Response with Amitriptyline and Ketamine Combination Trial in Chemotherapy Peripheral Neuropathy

Eligibility:

- Pain in lower extremities beginning in association with cancer chemotherapy and persisting for at least 29 days following the conclusion of the chemotherapy
- an average score of equal to or less than 4 for the 7 daily ratings of the baseline week on the 11-point rating scale of lower-extremity pain associated with chemotherapy, with a minimum of 5 daily diary rating completed during the baseline week.

Head and Neck

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Amgen Prism (E)

Phase2, Single Arm, Open Label, Multi-Center Trial of Second-Line panitumumab Monotherapy in Patients with Metastatic or Recurrent Squamous Cell Carcinoma of the head and Neck

Eligibility:

- Histologically or cytologically confirmed SCCHN of oropharynx, oral cavity, hypopharynx, or larynx
- Diagnosis of recurrent disease determined to be incurable by surgery or radiotherapy and/or metastatic disease according to investigator
- Documented disease progression or intolerance to chemotherapy following treatment with only one prior chemotherapy regimen for metastatic or recurrent disease
- Subjects who have received radiation as primary therapy are eligible if locoregional recurrence in the field of radiation has occurred > 24 weeks after the completion of radiation therapy.
- ECOG PS of 0-1
- No CNS mets
- No pulmonary embolism, DVTs, or other significant thromboembolic event <8 weeks prior to enrollment

GI

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Carcinoid

IPSEN 2-55-52030-726 (E)

Phase III, Randomised, Double Blind, Stratified Comparative, Placebo Controlled, Parallel Group, Multicentre Study to Assess the Effect of Deep Subcutaneous Injections of Lanreotide Autogel 120 mg Administered Every 28 Days on Tumour Progression Free Survival in Patients with Non-Functioning Entero-Pancreatic Endocrine Tumour

Eligibility:

- Has an endocrine tumour confirmed by centrally assessed histological criteria
- Has metastatic disease and/or locally advanced inoperable tumour, or the patient has refused surgery (documented),
- Has a tumour measurable according to RECIST criteria (central assessment),
- Has no hormone related symptoms,
- Has a non functioning entero-pancreatic tumour of unknown origin; or with a known primary localisation in the pancreas, mid-gut, or hindgut, or a gastrinoma adequately controlled by proton-pump inhibitors (4 months stable prior to study entry),
- Has a well or moderately differentiated tumour (central assessment),
- Has a tumour with a proliferation index (Ki67) <10% or, in samples where the Ki67 antigen cannot be reliably quantified, a mitotic index ≤ 2 mitosis/10HPF (central assessment),
- Has a \geq grade 2 octreoscan assessed using the Krenning scale, during the screening period or within 6 months prior to study entry (Visit 1) for the organ of target lesions,
- Has a World Health Organisation (WHO) performance score lower or equal to 2

Tercica TR321 (E)

Double-Blind, Randomized Placebo-Controlled Clinical Trial Investigating the Efficacy and Safety of Somatuline Depot (lanreotide) Injection in the Treatment of Carcinoid Syndrome

Eligibility:

- Patients with histopathologically confirmed diagnosis of carcinoid tumor and a history of carcinoid syndrome (flushing and/or diarrhea) that are either naïve to treatment with an SSTa or responsive (according to the opinion of the PI) to conventional doses of LAR (\leq 30 mg every 4 weeks) or to daily doses of \leq 600 ug of subcutaneous octreotide.
- Confirmation of positive somatostatin receptor status by SRS (up to 6 months prior to study entry at Screening visit).
- Age 18-75 years inclusive.
- Absence of tumor progression documented by 2 sequential CAT scans (\geq 3 months apart); the last scan must have been performed within 6 months of study entry (screening visit).
- Patients previously treated with LAR must have received their last dose of LAR at least 4 weeks prior to first dose of study drug (no later than at the screening visit).

Colon (stage II/III) – Neoadjuvant/Adjuvant

NCCTG N0147

A Randomized Phase III Trial of Oxaliplatin (OXAL) Plus 5-Fluorouracil (5-FU)/Leucovorin (CF) with or without Cetuximab (C225) after Curative Resection for Patients with Stage III Colon Cancer

Eligibility:

- Histologically proven adenocarcinoma of the colon; No rectal cancer allowed
- At least 1 pathologically confirmed positive lymph node
- ECOG PS 0-2
- More than 1 synchronous primary colon cancer allowed
- No evidence of residual involved lymph node disease (recommended that at least 4 nodes are sampled)
- No mets
- No prior chemo or RT for this colon cancer
- No uncontrolled concurrent medical conditions
- Randomization must occur \leq 6 days post surgery. (Requirement for pre-randomization pathology review – lab will report KRAS results [wild-type or mutant] for pt. assignment within \leq 10 business days from receipt of all required pathology materials.)

Colon (stage IV) – Advanced/Metastatic

Duke PANVAC (E)

A Phase II Study of Active Immunotherapy with PANVAC or Autologous, Cultured Dendritic Cells Infected with PANVAC After Complete Resection of Hepatic or pulmonary Metastases of Colorectal Carcinoma.

Eligibility:

- Potential patients will be approached about enrollment prior to surgery if possible in order to request that we obtain tumor tissue to be used as targets for immunologic studies.
- Histologically confirmed hepatic metastases or pulmonary metastases of colorectal adenocarcinoma, resected with curative intent. Patients must have no evidence of disease at the time of study enrollment.
- Must have had a minimum of 2 months of peri-operative systemic chemotherapy (includes pre-operative, post-operative or both) chosen at the discretion of their physicians. Patients may be screened starting any time after their chemotherapy is completed, but may not start the tx related procedures until at least 1 month after completion of chemotherapy.
- Karnofsky PS of $>70\%$
- Estimated life expectancy >6 months
- No prior radiotherapy for this cancer.
- More than 28 days since prior major surgery or open biopsy. More than 7 days since prior core biopsy or other minor procedure except, placement of a vascular access device.

CALGB 80405

A Phase III Trial 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.

Eligibility:

- Histologically or cytologically confirmed colorectal cancer. Metastatic disease: The site of the primary lesion must be or must have been confirmed endoscopically, surgically, or radiologically. Separate histological or cytological confirmation is not required from patients with a history of colorectal cancer (previously treated by surgical resection) who have now developed radiological or clinical evidence of metastatic disease, unless 1 of the following is true: An interval of > 5 years has elapsed between the primary surgery and the development of metastatic disease. The primary cancer was stage I.
- The intent of this treatment must be indicated as follows: Palliative or neoadjuvant treatment with the potential for resection of all sites of metastatic disease.
- At least 1 paraffin block of previously resected primary tumor or tumor deposit available.
- No known CNS metastases or carcinomatous meningitis.

- Biologic therapy: No prior agents that target vascular endothelial growth factor (VEGF) or EGF receptors including protein products, monoclonal antibodies, or antisense therapies. No prior bevacizumab or cetuximab. No concurrent prophylactic filgrastim (G-CSF), pegfilgrastim, or sargramostim (GM-CSF).
- Chemotherapy: See Radiotherapy, More than 12 months since prior adjuvant chemotherapy (≤ 6 months in duration) that included fluorouracil alone or in combination with oxaliplatin or irinotecan hydrochloride, No other concurrent chemotherapy. Endocrine therapy: No concurrent hormonal therapy except steroids for adrenal failure, hormones for noncancer-related conditions (e.g., insulin for diabetes), or intermittent dexamethasone as an antiemetic.
- Radiotherapy: Prior radiotherapy with radiosensitizing chemotherapy allowed. Prior standard adjuvant chemoradiotherapy for rectal cancer allowed. At least 4 weeks since prior radiotherapy. No prior radiotherapy to $> 25\%$ of bone marrow. No concurrent palliative radiotherapy except whole brain irradiation for documented CNS disease.
- Surgery: See Disease Characteristics, At least 4 weeks since prior major surgery, At least 2 weeks since prior minor surgery, Insertion of a vascular access device is not considered a prior surgery, Recovered from all prior surgery.
- Other: At least 4 weeks since prior itraconazole or ketoconazole. No prior tyrosine kinase inhibitor therapy. No prior treatment for metastatic colorectal cancer. No concurrent aprepitant. Concurrent full-dose anticoagulation (i.e., warfarin) allowed provided all of the following criteria are met: In-range INR (usually 2-3) on a stable dose of oral anticoagulant or stable dose of low molecular weight heparin. No active bleeding. No pathological condition with a high risk of bleeding (e.g., tumor involving major vessels or known varices). Concurrent antiplatelet agents allowed. Concurrent daily prophylactic aspirin or anticoagulation for atrial fibrillation allowed.

Amgen AMG 386 (E)

A Phase 2, Randomized, Double-Blind, Placebo Controlled Study of AMG 386 in Combination with FOLFIRI in Subjects with Previously Treated Metastatic Colorectal Carcinoma

Eligibility:

- Histologically confirmed adenocarcinoma of the colon or rectum in patients who are presenting with metastatic disease
- One and only one prior chemotherapy regimen for metastatic disease consisting of the combination of a fluoropyrimidine-based chemotherapy and an oxaliplatin-based chemotherapy. Prior adjuvant chemotherapy used prior to the onset of metastatic disease is permitted
- At least one uni-dimensionally measurable lesion per modified RECIST criteria. All sites of disease must be evaluated ≤ 28 days before randomization
- Radiographically documented disease progression per modified RECIST criteria either while receiving or ≤ 6 months after the last dose of prior chemotherapy regimen for metastatic disease
- ECOG performance status of 0 or 1
- No prior irinotecan therapy
- Experimental or approved proteins/antibodies (e.g., bevacizumab) must be > 30 days prior to randomization
- Ineligible if: currently or previously treated with AMG 386, or other molecules that inhibit the angiopoietins or Tie2 receptor including but not limited to: AZD-5180, XL-820, CEP 11981/SSR-106462, BSF-486,895, CGI-1842, LOC-590, XL-184, or CP-8681596
- Ineligible if: active inflammatory bowel disease or other bowel disease causing chronic diarrhea (defined as \geq CTC Grade 2).

Esophageal

ACOSOG Z4051

A Phase II Study of Neoadjuvant Therapy with Cisplatin, Docetaxel, Panitumumab Plus Radiation Therapy Followed By Surgery in Patients with Locally Advanced Adenocarcinoma of the Distal Esophagus

- Biopsy-proven resectable primary (nonrecurrent) adenocarcinoma of the distal esophagus or GE junction (Siewert Type I or II).
Siewert Type definitions:
 - Siewert Type I: adenocarcinoma of the distal esophagus
 - Siewert Type II: adenocarcinoma of the esophago-gastric junction/real cardia
- Pre-registration EUS, CT of chest and upper abdomen, and PET must support a clinical stage of T1-3N1M0, T3N0M0 or T1-3N0-1M1a (celiac adenopathy must be ≤ 2 cm by EUS). Clinically staged T1N0M0 and T2N0M0 tumors are not eligible. N1 does not require biopsy/FNA.
- No definitive radiological evidence of distant metastases.
- No pre-existing grade 2 or greater peripheral neuropathy of any etiology.
- No prior chest or upper abdomen radiotherapy; prior therapy with cisplatin, docetaxel, panitumumab or other anti-EGFR therapy; or prior esophageal or gastric surgery

Extrahepatic Cholangiocarcinoma

SWOG S0809

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

Eligibility:

- Patient must have a histopathological diagnosis of extrahepatic cholangiocarcinoma (gallbladder or bile duct). Patient must not have ampullary cancer.
- Patient must have at least one of the following: pathological T2-4 disease; pathological N1 disease, or positive margins (any T or N stage)
- Patient must not have distant metastatic disease as indicated by a CT or MRI of the chest, abdomen, and pelvis within 42 days prior to registration. Positive resected regional lymph nodes are allowed.
- Patient must have received a potentially curative radical resection with negative (R0) or microscopically positive (R1) margins. Resection must have been performed within 56 days prior to registration and patient must have recovered from any complications.
- Patient must not have received any prior chemotherapy or radiotherapy for this disease.
- Patient must have had no previous upper abdominal radiation therapy for any reason at any time.

GIST

SWOG S0502

A Phase III Randomized Study of Imatinib, with or without Bevacizumab (NSC-704865), in Patients with Metastatic or Unresectable Gastrointestinal Stromal Tumors

Eligibility:

- Histologically confirmed gastrointestinal stromal tumor (GIST).
- Metastatic or unresectable disease
- Determined to be unresectable for cure.
- Measurable and/or nonmeasurable disease.
- No known brain metastasis.
- No prior imatinib mesylate, bevacizumab, or other agents targeting KIT, vascular endothelial growth factor (VEGF), VEGF receptor, or platelet-derived growth factor receptor (PDGFR) for advanced disease. These agents may have been used in the adjuvant setting provided no recurrence for ≥ 12 months after completion of therapy.

Hepatocellular

Bayer STORM (E)

A Phase III randomized, double-blind, placebo-controlled study of sorafenib as adjuvant treatment for hepatocellular carcinoma after surgical resection or local ablation

Eligibility:

- Confirmation of diagnosis of HCC. For subjects undergoing surgical resection histological confirmation is mandatory (a post surgery pathology report is required for both histological confirmation and risk stratification). For subjects undergoing local ablation either histological confirmation or clinical diagnosis by AASLD criteria in cirrhotic subjects is required. For subjects without cirrhosis histological confirmation is mandatory
- Maximum tumor load of: single lesion any size for surgical resection, or single lesion ≤ 5 cm (largest diameter, unidimensional measurement) for local ablation; 2-3 lesions, each ≤ 3 cm in size (largest diameter, unidimensional measurement)
- Subjects who have undergone surgical resection or local ablation (PEI or percutaneous or intraoperative RFA) for treatment of HCC with curative intent within 4 months from staging to potentially curative treatment. A maximum of 2 local ablation courses may be administered during this time period.
- 4 weeks (28 days \pm 7 days) from resection or last local ablation course, to CT/MRI scan date.
- Confirmation of CR (absence of residual tumor after curative treatment), on the eligibility scan by independent radiological review.
- For subjects undergoing surgical resection pathology proven complete removal of tumor.
- Intermediate or High Risk of recurrence as assessed by tumor characteristics.
- Child-Pugh score 5-7 points. A Child-Pugh score of 7 points is allowed only in the absence of ascites.
- ECOG = 0

Bayer GIDEON (E, W, S)

Global Investigation of therapeutic DEcisions in hepatocellular carcinoma and Of its treatment with sorafeNib

Eligibility:

- Outpatients with histologically/cytologically documented or radiographically diagnosed unresectable HCC who are candidates for systemic therapy and for whom a decision to treat with Nexavar[®] has been made. Radiographic diagnosis needs typical findings of HCC by radiographic method i.e. on multi-dimensional dynamic CT, CT hepatic arteriography (CTHA)/CT arterial portography (CTAP) or MRI.
- Life expectancy of at least 8 weeks.

Pancreatic

ACOSOG Z5041 (E, W, NW 22nd)

A Phase II Study of Preoperative Gemcitabine and Erlotinib Plus Pancreatectomy and Postoperative Gemcitabine and Erlotinib for Patients with Operable Pancreatic Adenocarcinoma

- Cytologic or histologic proof of adenocarcinoma of the pancreatic head or uncinate process. NOTE: Patients with tumors of the pancreatic neck, body or tail are not eligible. Patients with evidence of neuroendocrine tumors, duodenal adenocarcinoma, or ampullary adenocarcinoma are not eligible.
- Localized, potentially resectable tumors as defined below. All patients must be staged with a chest X-ray or CT, and abdominal CT (contrast-enhanced, helical thin-cut) or MRI. Radiological resectability is defined by the following criteria on abdominal imaging:
 - a) No evidence of tumor extension to the celiac axis, hepatic artery or superior mesenteric artery
 - b) No evidence of tumor encasement or occlusion of the superior mesenteric vein (SMV) or the SMV/portal vein confluence
 - c) No evidence of visceral or peritoneal metastasesNOTE: Patients with borderline resectable or marginally resectable pancreatic cancer are not eligible. Patients must meet all objective imaging criteria outlined above.
- No history of the following:
 - Prior EGFR targeted therapy or therapy for pancreatic cancer
 - Active infection requiring intravenous antibiotics at the time of registration.

Rectal (stage II/III) – Neoadjuvant/Adjuvant

ACOSOG Z6041 (W, NW 22nd)

A Phase II Trial of Neoadjuvant Chemoradiation and Local Excision for uT2uN0 Rectal Cancer (Capecitabine and Oxaliplatin, Five Week Regimen With Rest Week From Chemotherapy only on Week Three.)

Eligibility:

- Age 18 years or older; ECOG PS of 0 or 1
- Histologically confirmed invasive adenocarcinoma of the rectum.
- Distal border of the patient's tumor must be within 8 cm from the anal verge as measured on rigid protoscopic exam.
- No tumors fixed to adjacent structures on digital exam.
- No known, existing, uncontrolled coagulopathy
- No history of prior pelvic radiation
- No evidence of distant mets
- No extension of disease to anal canal
- No prior chemo for malignancies

ACOSOG Z6051 (NW 22nd)

A Phase III Prospective Randomized Trial Comparing Laparoscopic-assisted Resection Versus Open Resection for Rectal Cancer

Eligibility:

- Histological diagnosis of adenocarcinoma of the rectum (<12 cm from the anal verge).
- T3N0M0 disease as determined by pre-treatment CT scans and pelvic MRI or transrectal ultrasound. Patients with T4 disease extending to circumferential margin of rectum or invading adjacent organs are not eligible.
- Completion of pre-operative 5FU-based chemotherapy and/or radiation therapy. Capecitabine may be substituted for 5FU.
- ECOG <2
- BMI <34
- No systemic disease that would preclude surgery.
- No evidence of conditions that would preclude use of laparoscopic approach.

NSABP R-04

A Clinical Trial Comparing Preoperative Radiation Therapy and Capecitabine with or without Oxaliplatin with Preoperative Radiation Therapy and Continuous Intravenous Infusion of 5-Fluorouracil with or without Oxaliplatin in the Treatment of Patients with Operable Carcinoma of the Rectum.

Eligibility:

- Histologically confirmed invasive rectal adenocarcinoma
- Measurable tumor (>=10 mm) with distal border no greater than 12 cm from the anal verge < 43 days from diagnosis to date of randomization
- Clinical stage II or III disease (with positive node being > 5 mm)
- Zubrod PS of 0,1, or 2 with life expectancy > 10 years excluding current diagnosis of cancer
- No advanced disease (metastatic or inoperable locoregional disease)
- No prior RT or systemic therapy for current rectal cancer
- No prior invasive colon or rectal malignancy
- No synchronous primary rectal lesions
- No tumor extending to the colon
- No uncontrolled hypertension, inflammatory bowel disease, or uncontrolled coagulopathy

Duke PANVAC (E)

A Phase II Study of Active Immunotherapy with PANVAC or Autologous, Cultured Dendritic Cells Infected with PANVAC After Complete Resection of Hepatic or pulmonary Metastases of Colorectal Carcinoma.

Eligibility:

- Potential patients will be approached about enrollment prior to surgery if possible in order to request that we obtain tumor tissue to be used as targets for immunologic studies.
- Histologically confirmed hepatic metastases or pulmonary metastases of colorectal adenocarcinoma, resected with curative intent. Patients must have no evidence of disease at the time of study enrollment.
- Must have had a minimum of 2 months of peri-operative systemic chemotherapy (includes pre-operative, post-operative or both) chosen at the discretion of their physicians. Patients may be screened starting any time after their chemotherapy is completed, but may not start the TX related procedures until at least 1 month after completion of chemotherapy.
- Karnofsky PS of >70%
- Estimated life expectancy >6 months
- No prior radiotherapy for this cancer.
- More than 28 days since prior major surgery or open biopsy. More than 7 days since prior core biopsy or other minor procedure except, placement of a vascular access device.

CALGB 80405

A Phase III Trial 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.

Eligibility:

- Histologically or cytologically confirmed colorectal cancer. Metastatic disease: The site of the primary lesion must be or must have been confirmed endoscopically, surgically, or radiologically. Separate histological or cytological confirmation is not required from patients with a history of colorectal cancer (previously treated by surgical resection) who have now developed radiological or clinical evidence of metastatic disease, unless 1 of the following is true: An interval of > 5 years has elapsed between the primary surgery and the development of metastatic disease. The primary cancer was stage I.
- The intent of this treatment must be indicated as follows: Palliative or neoadjuvant treatment with the potential for resection of all sites of metastatic disease.
- At least 1 paraffin block of previously resected primary tumor or tumor deposit available.
- No known CNS metastases or carcinomatous meningitis.
- Biologic therapy: No prior agents that target vascular endothelial growth factor (VEGF) or EGF receptors including protein products, monoclonal antibodies, or antisense therapies. No prior bevacizumab or cetuximab. No concurrent prophylactic filgrastim (G-CSF), pegfilgrastim, or sargramostim (GM-CSF).
- Chemotherapy: See Radiotherapy, More than 12 months since prior adjuvant chemotherapy (≤ 6 months in duration) that included fluorouracil alone or in combination with oxaliplatin or irinotecan hydrochloride, No other concurrent chemotherapy. Endocrine therapy: No concurrent hormonal therapy except steroids for adrenal failure, hormones for noncancer-related conditions (e.g., insulin for diabetes), or intermittent dexamethasone as an antiemetic.
- Radiotherapy: Prior radiotherapy with radiosensitizing chemotherapy allowed. Prior standard adjuvant chemoradiotherapy for rectal cancer allowed. At least 4 weeks since prior radiotherapy. No prior radiotherapy to > 25% of bone marrow. No concurrent palliative radiotherapy except whole brain irradiation for documented CNS disease.
- Surgery: See Disease Characteristics, At least 4 weeks since prior major surgery, At least 2 weeks since prior minor surgery, Insertion of a vascular access device is not considered a prior surgery, Recovered from all prior surgery.
- Other: At least 4 weeks since prior itraconazole or ketoconazole. No prior tyrosine kinase inhibitor therapy. No prior treatment for metastatic colorectal cancer. No concurrent aprepitant. Concurrent full-dose anticoagulation (i.e., warfarin) allowed provided all of the following criteria are met: In-range INR (usually 2-3) on a stable dose of oral anticoagulant or stable dose of low molecular weight heparin. No active bleeding. No pathological condition with a high risk of bleeding (e.g., tumor involving major vessels or known varices). Concurrent antiplatelet agents allowed. Concurrent daily prophylactic aspirin or anticoagulation for atrial fibrillation allowed.

Amgen AMG 386 (E)

A Phase 2, Randomized, Double-Blind, Placebo Controlled Study of AMG 386 in Combination with FOLFIRI in Subjects with Previously Treated Metastatic Colorectal Carcinoma

Eligibility:

- Histologically confirmed adenocarcinoma of the colon or rectum in patients who are presenting with metastatic disease
- One and only one prior chemotherapy regimen for metastatic disease consisting of the combination of a fluoropyrimidine-based chemotherapy and an oxaliplatin-based chemotherapy. Prior adjuvant chemotherapy used prior to the onset of metastatic disease is permitted
- At least one uni-dimensionally measurable lesion per modified RECIST criteria. All sites of disease must be evaluated ≤ 28 days before randomization
- Radiographically documented disease progression per modified RECIST criteria either while receiving or ≤ 6 months after the last dose of prior chemotherapy regimen for metastatic disease
- ECOG performance status of 0 or 1
- No prior irinotecan therapy
- Experimental or approved proteins/antibodies (e.g., bevacizumab) must be > 30 days prior to randomization
- Ineligible if: currently or previously treated with AMG 386, or other molecules that inhibit the angiotensin II or Tie2 receptor including but not limited to: AZD-5180, XL-820, CEP 11981/SSR-106462, BSF-486,895, CGI-1842, LOC-590, XL-184, or CP-8681596
- Ineligible if: active inflammatory bowel disease or other bowel disease causing chronic diarrhea (defined as ≥ CTC Grade 2).

Prostate

SWOG S0421

Phase III Study of Docetaxel and Atrasentan Versus Docetaxel and Placebo for Patients with Advanced Hormone Refractory Prostate Cancer

Eligibility:

- Histologically confirmed adenocarcinoma of the prostate. Stage IV disease (any T, any N, M1b).
- Evidence of bone metastases by bone scan or MRI.
- Measurable or nonmeasurable disease
- Soft tissue disease that has been irradiated within the past 2 months is not assessable as measurable disease
- Hormone-refractory disease despite androgen deprivation and antiandrogen withdrawal
- Must have undergone surgical or medical ([LHRH] agonist [e.g., leuprolide or goserelin] or LHRH antagonist therapy) castration.
- No prior or concurrent brain metastases.
- More than 2 years since prior adjuvant therapy with a single non-taxane-containing cytotoxic regimen
- No concurrent prophylactic colony-stimulating factors.

BMS CA180227 (E)

A Randomized, Double-Blind, Phase 3 Trial Comparing Docetaxel Combined with Dasatinib to Docetaxel Combined with Placebo in Castration-Resistant Prostate Cancer

Eligibility:

- History of histologically diagnosed prostate cancer.
- Evidence of metastatic disease by any 1 of the following modalities: CT scan, MRI, bone scan, or skeletal survey.
- Evidence of progression, as defined by 1 of the following: rising PSA values at least 1 week apart with the final value being ≥ 2 ng/mL, or progression of measurable nodal or visceral disease (nodal lesions must be ≥ 20 mm, visceral lesions must be measurable per RECIST), or two or more new lesions appearing on a bone scan compared with a prior scan, or local recurrence in the prostate or prostate bed.
- Maintaining castrate status: Subjects who have not undergone surgical orchiectomy should have received and continue on medical therapies [e.g., gonadotropin releasing hormone analogs] to maintain castrate levels of serum testosterone ≤ 50 ng/dL (1.7 nmol/L).
- ECOG 0-2
- At least 4 weeks since major therapy, radiotherapy, and investigational agent.
- At least 8 weeks since radioisotope therapy.
- No brain mets or leptomeningeal mets
- No clinically significant cardiovascular disease.

Renal Stage IV First-Line

GSK VEG 108844 (E, W, S)

Study VEG108844, a Study of Pazopanib versus Sunitinib in the Treatment of Subjects with Locally Advanced and/or Metastatic Renal Cell Carcinoma

Eligibility:

- Diagnosis of renal cell carcinoma with clear-cell component histology
- Received no prior systemic therapy (interleukin-2, interferon- α , chemotherapy, bevacizumab, mTOR inhibitor, sunitinib, sorafenib or other VEGF TKI) for advanced or metastatic RCC
- Locally advanced (defined as disease not amenable to curative surgery or radiation therapy) or metastatic RCC (equivalent to Stage IV RCC according to AJCC staging).
- Must have measurable disease per RECIST. A measurable lesion is defined as a lesion that can be accurately measured in at least one dimension with the longest diameter ≥ 20 mm using conventional techniques, or ≥ 10 mm with spiral CT scan. **Note:** Subject should be excluded if all baseline measurable lesions are within previously irradiated areas.
- KPS of ≥ 70

Renal Stage IV Second-Line

Medarex MDX1411-01 (E)

A Phase 1, Open-label, Multicenter, Dose-escalation, Multidose Study of MDX-1411 Administered Every 14 Days in Subjects with Advanced or Recurrent Clear Cell Renal Cell Carcinoma

Eligibility:

- Subjects must have histologically confirmed diagnosis of RCC (clear cell component) with advanced or recurrent disease that is not amenable to cure by surgery or other means and must have failed at least 1 prior systemic therapy, including but not limited to treatment with Sunitinib, Temsirolimus, Sorafenib, IL-2, and/or chemotherapy
- Subjects must have measurable disease with at least 1 unidimensional measurable lesion per RECIST criteria with modifications
- Subjects may have been treated with up to 6 prior systemic therapies for advanced/recurrent disease or have become intolerant to a systemic therapy

ACRIN 6671/GOG 0223 (E)

Utility of Preoperative FDG-PET/CT and Ferumoxtran-10 MRI Scanning Prior to Primary Chemoradiation Therapy to Detect Retroperitoneal Lymph Node Metastasis in Patients with Locoregionally Advanced (IB2, IIA \geq 4 CM, IIB-IVA) Carcinoma of the Cervix

Eligibility:

- Primary, untreated, histologically confirmed, locoregionally advanced invasive carcinoma of the cervix.
- Must be able to undergo extra-peritoneal or laparoscopic lymph node sampling.
- No mets to lungs, scalene lymph nodes or organs outside of the pelvis or abdominal lymph nodes at the time of original clinical diagnosis.
- No prior pelvic radiation therapy.
- No pelvis or abdominal lymphadenectomy performed.

GOG 136 (E)

Acquisition of Human Gynecologic Specimens and Serum to be Used in Studying the Causes, Diagnosis, Prevention and Treatment of Cancer Cancer

Eligibility:

- Pts who have had ovarian tumor tissue removed including epithelial tumors, germ cell, and sex cord stromal.
- At least one gram of tumor tissue is required for patients with invasive malignant ovarian epithelial tissues.
- Pts who have had ovaries removed because of extra-ovarian peritoneal serous papillary carcinoma.
- Pts who have had ovaries removed prophylactically because of a first or second-degree family member with cancer.
- Pts who have had primary cervical or uterine corpus tumor tissue removed.
- Pts may have received prior hormonal, cytotoxic chemotherapy, irradiation or surgical therapy.

GOG 210 (E)

An Endometrial Study of Endometrial Carcinoma

Eligibility:

- Patients with endometrial carcinoma or carcinosarcoma diagnosed by an endometrial biopsy or dilation and curettage who will undergo full surgical staging; all stages, grades and histologic subtypes will be eligible.
- Patients must be suitable candidates for surgery. Patients may also be entered on GOG-2222 (LAP2).
- Patients who have met the pre-entry requirements specified in Section 7.1 of the protocol.

GOG 0212 (E)

GOG 0212, A Randomized Phase III Trial OF Maintenance Chemotherapy comparing 12, Monthly cycles of single agent Paclitaxel (Taxol®) or Xyotax™ Versus no treatment until documented relapse in women with advanced Ovarian or Primary peritoneal Cancer who Achieve a complete clinical response to primary Platinum/Taxane Chemotherapy

Eligibility:

- Patients with a histologic diagnosis of primary peritoneal carcinoma or epithelial
- Ovarian carcinoma, Stage III or IV, with either optimal or suboptimal residual disease following initial surgery.
- Pts must have had appropriate surgery for ovarian or peritoneal carcinoma with appropriate tissue available for histologic evaluation to confirm diagnosis and stage.
- Must have the following histologic epithelial cell types: Serous adenocarcinoma, endometrioid adenocarcinoma, mucinous adenocarcinoma, undifferentiated carcinoma, clear cell adenocarcinoma, mixed epithelial carcinoma, transitional cell carcinoma, malignant Brenner's Tumor, or adenocarcinoma N.O.S.
- Patients must have completed treatment within the past 6 weeks with at least 5 cycles and not more than 8 cycles of a platinum (IV or IP) and paclitaxel or docetaxel-based combination chemotherapy and have no symptoms suggestive of persistent cancer, normal CT scans of the abdomen/pelvis and normal CA-125 following this therapy.
- Patients must have adequate bone marrow function.
- Absolute neutrophil count (ANC) greater than or equal to 1,500/ul creatinine less than or equal to 1.5 x institutional upper limit normal

GOG 0213 (E)

A Phase III Randomized Controlled Trial of Carboplatin and Paclitaxel Alone or in Combination with Bevacizumab Followed by Bevacizumab and Secondary CytoReductive Surgery in Platinum Sensitive, Recurrent Ovarian, Peritoneal Primary and Fallopian Tube Cancer

Eligibility:

- Patients must have histologic diagnosis of epithelial ovarian carcinoma, peritoneal primary or fallopian tube carcinoma, which is now recurrent.
- Patients with the following histologic epithelial cell types are eligible: Serous adenocarcinoma, endometrioid adenocarcinoma, mucinous adenocarcinoma, undifferentiated carcinoma, clear cell adenocarcinoma, mixed epithelial carcinoma, transitional cell carcinoma, malignant Brenner's Tumor, or adenocarcinoma not otherwise specified
- Patients must have had a complete response to front-line platinum-taxane therapy (at least three cycles) and a treatment-free interval without clinical evidence of progressive disease lasting at least 6 months. Front-line therapy may have included a biologic agent (i.e. bevacizumab) but an interval of at least six months must have elapsed after completion of therapy.
- Patients must have clinically evident measurable or non-measurable disease.

Surgery Stage 1a

ACOSOG Z4033 (E)

A Pilot Study of Radiofrequency Ablation in High-Risk Patients with Stage IA Non-Small Cell Lung Cancer

Eligibility:

- Suspected or proven clinical stage Ia NSCLC
- Must have a mass \leq 3 cm maximum diameter by CT size estimate
- Evaluated by a thoracic surgeon and been deemed at high risk for a lung resection
- ECOG/Zubrod performance status of 0-2
- Must meet one of the following: FEV% \leq 50% or DLCO \leq 50% or Two minor: Age \geq 75, FEV1 51-60% predicted, DLCO 51-60% predicted, Pulmonary hypertension as estimated by echocardiography or right heart catheterization, poor LVF (ejection fraction of \leq 40%), Resting or Exercise Arterial pO₂ \leq 55 mmHg or SpO₂ \leq 88%, pCO₂ $>$ 45mmHg, or MMRC Dyspnea Scale \geq 3.

ACOSOG Z4032 (E)

A Randomized Phase III Study of Sublobar Resection versus Sublobar Resection plus Brachytherapy in High Risk Patients with NSCLC, 3cm or Smaller

Eligibility:

- Must have suspicious lung nodule for clinical stage I NSCLC.
- Must have a mass \leq 3cm maximum diameter by CT size estimate; clinical stage Ia or selected Ib
- ECOG/Zubrod performance status of 0-2
- Must not have had previous intra-thoracic radiation therapy.
- Must meet one of the following: FEV% \leq 50% or DLCO \leq 50%

CALGB 140503

A Phase III Randomized Trial of Lobectomy versus Sublobar Resection for Small (\leq 2 cm) Peripheral Non-Small Cell Lung Cancer

Eligibility:

- Suspected or proven NSCLC, meeting both preoperative and intraoperative criteria:
 - Preoperative criteria: peripheral lung nodule \leq 2 cm by CT scan; center of the tumor must be located in the outer third of the lung in either the transverse, coronal, or sagittal plan; tumor location must be suitable for either lobar or sublobar resection (wedge resection or segmentectomy); no pure ground opacities or pathologically confirmed N1 or N2 disease.
 - Intraoperative criteria: histologically confirmed NSCLC; confirmation of N0 status by frozen examination of nodal levels 4, 7, and 10 on the right side and 5, 6, 7, and 10 on the left side; levels 4 and 7 nodes may be sampled by mediastinoscopy or at the time of thoracotomy or video-assisted thoracoscopic surgery (VATS) exploration
- No evidence of locally advanced or metastatic disease.
- No prior chemotherapy or radiotherapy for this malignancy
- ECOG of 0-2

Adjuvant

OSI OSI-774-302 (E, W, S)

A Multi-center, Randomized, Double-blind, Placebo-controlled, Phase III Study of Single-agent Tarceva Following Complete Tumor Resection With or Without Adjuvant Chemotherapy in Patients with Stage IB-IIIa NSCLC who have EGFR-Positive Tumors

Eligibility:

- Histologically or cytologically confirmed non-small cell lung cancer.
- Measurable disease by plain radiographs, CT scan, or MRI within the past 28 days.
- At least 90 days since prior chemotherapy.
- At least 3 weeks since prior radiotherapy.
- No prior surgical procedures affecting absorption.
- No concurrent systemic corticosteroids.
- Must have disease outside the area of prior surgical resection OR a new lesion must be present

CTSU ECOG E1505

A Phase III Randomized Trial of Adjuvant Chemotherapy with or without Bevacizumab for Completely Resected Stage IB-IIIa NSCLC

Eligibility:

- patients must have undergone complete resection of their non-small cell lung cancer (NSCLC) [stage IB ($>$ 4 cm)] - [IIIA (T2-3N0, T1-3N1, T1-3N2)] prior to enrollment.
- Must have undergone complete resection of NSCLC within the past 6-12 weeks. Accepted types of resection include any of the following: Lobectomy, Sleeve lobectomy, Bilobectomy, Pneumonectomy, No resection by segmentectomy or wedge resection.

SWOG S0720

Phase II ERCC 1and RRM1-Based Adjuvant Therapy Trial in Patients with Stage I Non-Small Cell Lung Cancer (NSCLC)

Eligibility:

- Histologically confirmed non-small cell lung cancer. Stage IA (longest tumor diameter 2-3 cm) or stage IB disease.
- Must have undergone preoperative CT scan of the chest (including the entire liver and adrenals) with IV contrast AND a whole body PET scan or a combined PET/CT scan with no evidence of N1, N2, N3, or M1 disease within 42 days prior to surgery.
- Completely resected (R0) disease by lobectomy, bilobectomy, or pneumonectomy performed by open thoracotomy or video-assisted thoracoscopic surgery within the past 35 days.
- Completely excised primary lesion with negative gross and microscopic margins.
- At least two mediastinal lymph node stations sampled.
- Must have tumor tissue available from the surgical resection specimen AND agree to have treatment assignment determined by a gene expression analysis performed on that tissue.
- No prior systemic chemotherapy or biologic therapy for lung cancer. No prior thoracic radiation therapy (RT) (including RT to the chest wall). No other concurrent investigational agents, chemotherapeutic agents, RT, or hormonal therapy. Steroids administered for antiemesis, adrenal failure, or septic shock OR hormones administered for non-disease-related conditions (e.g., insulin for diabetes) allowed.

Unresectable Stage III NSCLC

Merck EMR 63325 (E)

A multi-center phase III randomized, double-blind placebo-controlled study of the cancer vaccine Stimuvax® (L-BLP25 or BLP25 liposome vaccine) in non-small cell lung cancer (NSCLC) subjects with unresectable stage III disease

Eligibility:

- Histologically or cytologically documented unresectable stage III NSCLC. All histological subtypes are acceptable, including bronchioalveolar carcinomas. Cancer stage must be confirmed and documented by CT, MRI or positron PET scan.
- Documented stable disease or objective response, according to RECIST, after primary chemoradiotherapy (either sequential or concomitant) for unresectable stage III disease, within 4 weeks (28 days) prior to randomization*.
- Receipt of concomitant or sequential chemoradiotherapy, consisting of a minimum of two cycles of platinum-based chemotherapy and a minimum radiation dose of ≥ 50 Gy. Subjects must have completed the primary thoracic chemo-radiotherapy at least four weeks (28 days) and no later than 12 weeks (84 days) prior to randomization. Subjects who received prophylactic brain irradiation as part of primary chemo-radiotherapy are eligible.
- An ECOG performance status of 0-1.
- A platelet count $\geq 100 \times 10^9/L$; WBC $\geq 2.5 \times 10^9/L$ and hemoglobin ≥ 90 g/L.
- ≥ 18 years of age.
- If imaging after primary chemo-radiotherapy was earlier than 4 weeks prior to randomization, it must be repeated within 4 weeks prior to randomization, and the results of the second restaging after end of primary chemo-radiotherapy must be compared with the first restaging after end of primary chemo-radiotherapy. Subjects that show progression between these two assessments are not eligible for this trial.

Stage IIIb-IV First-Line

EACRI DRibble (E)

A Pilot Study of Autologous Tumor DRibble Vaccine with Docetaxel in Stage IIIb and IV Non-Small Cell Lung Cancer

Eligibility:

Stage IIIb or IV NSCLC

Adequate pleural effusion (>600 cc) or subcutaneous metastases (>1 cc) for DRibble vaccine production.

Measurable or evaluable disease.

No or one prior chemotherapy regimen for advanced NSCLC.

ECOG performance status of 0, 1, or 2.

Stage Wet IIIb-IV Second Line

Tragara TP2001-201 APRiCOT-L (E, W)

APRiCOT-L: Apricoxib in Combination Oncology Treatment – Lung “A Randomized, Double-Blind, Placebo-Controlled Multicenter Phase 2 Study of the Efficacy and Safety of Apricoxib in Combination with Erlotinib in Non-Small Cell Lung Cancer Patients”

Eligibility:

- Pathologically determined stage IV non-small cell lung cancer (NSCLC), including stage IIIb (pleural effusion) (histology or cytology acceptable).
- Failed ≥ 1 prior platinum-based chemotherapy.
- Patients must have measurable disease by Response Evaluation Criteria in Solid Tumors at least 20mm for conventional computed tomography (CT) scan or at least 10mm for spiral CT scan.

CALGB 30607

A Randomized, Phase III, Placebo-Controlled Trial of Sunitinib 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

Eligibility:

- Histologically or cytologically confirmed primary NSCLC, Stage IIIB or IV disease.
- Not a candidate for combined modality therapy (chemoradiotherapy).
- No evidence of brain metastases, spinal cord compression, or carcinomatous meningitis.
- No cavitory lesions.
- Must have received one prior first-line chemotherapy regimen that included 4 courses of platinum-based doublet chemotherapy with or without bevacizumab.
- Must have achieved a complete response, partial response, or stable disease and have no evidence of disease progression.

NCCTG N0724

A Randomized Phase II Study of Oligometastatic Stage IV Non-Small Cell Lung Cancer (NSCLC) Treated with Systemic Therapy plus Either Radiotherapy to all Sites of Gross Disease or No Radiotherapy

Eligibility:

- Histologically or cytologically confirmed non-small cell lung cancer (NSCLC). Mixed histology allowed if all components are consistent with NSCLC.
- Squamous cell histology allowed
- Stage IV disease
- Oligometastatic disease (M1 with 1-3 metastases)
- Patients with M1 disease that involves intrapulmonary metastases are eligible provided $\leq 40\%$ of the total lung volume receives ≥ 20 Gy of radiotherapy.
- Achieved stable disease, partial response, or complete response within 8 weeks after completion of 2-6 courses of standard platinum-based chemotherapy (administered every 3-4 weeks).
- Pleural effusion allowed provided it is minimal.
- No history of or current brain metastases.

NSCLC – Case Study Comparison

SWOG S0424

Molecular Epidemiology Case-Series Study of Non-small Cell Cancer in Smoking and Non-Smoking Women and Men

Eligibility:

- Pts must have newly diagnosed, primary, histologically confirmed Stage I, II or IIIB (T4 or N3, excluding patients w/ malignant pleural effusion) NSCLC; Pts w/effusion are eligible if: a) fluid tapped is benign cytology and all physicians concur that it is from a benign etiology, b) fluid present after mediastinoscopy or thoracotomy, but not before, c) fluid deemed too small to tap under CT or U/S guidance;
- May be registered concurrently to a therapeutic study but not required to be on a therapeutic study;
- Must have tumor block/slides available and willing to provide tissue and blood sample for testing;
- Must have specific tissue specimens available as outlined in Section 4.2; A
- Must be identified and registered w/in 120 days of diagnosis;
- Must be willing to provide smoking history; Pts must not have diagnosis by cytology alone; Pts must not have malignant pleural effusion;
- Pts must not have other prior malignancy except for treated basal cell (or squamous cell) skin ca or in situ cervical ca
- Pts must not have prior systemic chemotherapy or RT for cancer

SCLC – First Line

HOG 113

A Randomized Double Blind Phase II Trial of Platinum Therapy plus Etoposide with/without Concurrent ZD6474 in Patients with Previously Untreated Extensive Stage Small Cell Lung Cancer

Eligibility:

- Histological or cytological proof of chemotherapy-naïve, extensive, small cell lung cancer or neuroendocrine cancers that are either high grade or poorly differentiated
- Measurable disease according to RECIST and obtained by imaging within 30 days prior to being registered for protocol therapy
- No prior EGFR inhibitor or antiangiogenic agent allowed
- No prior hormonal therapy
- No symptomatic brain metastasis

SWOG S0722

A Phase II Trial of mTOR Inhibitor, Everolimus, (RAD001) in Malignant Pleural Mesothelioma (MPM)

Eligibility:

- Histologically confirmed malignant pleural mesothelioma
- Unresectable disease
- Must have measurable or nonmeasurable disease by RECIST or modified RECIST criteria
- Must have received prior systemically administered platinum-based chemotherapy (no more than 2 prior systemic therapeutic regimens allowed – including biologics, targeted, and immunotherapies)

Lymphoma

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Large B-Cell Lymphoma

Seattle Genetics SG040-0005 (E, W)

Randomized, Phase IIB Placebo-Controlled Study of R-ICE Chemotherapy (Rituximab, Ifosfamide, Carboplatin, and Etoposide) With and Without SGN-40 (Anti-CD40 Humanized Monoclonal Antibody for Second-Line Treatment of Patients with Diffuse Large B-Cell Lymphoma

Eligibility:

- Pathologically confirmed diagnosis of DLBCL, including both de novo and transformed DLBCL and follicular lymphoma
- Pt has received at least four cycles of first-line therapy with R-CHOP or equivalent first-line therapy including rituximab, cyclophosphamide, anthracycline or anthracenedione, and steroid with or without additional chemotherapy agents
- Patient had a best clinical response to first-line therapy of stable disease, partial response, or complete response.
- Must have had: Autologous bone marrow transplant or Autologous peripheral blood stem cell transplant if eligible and did not refuse.
- Pt has complete first-line therapy at least four weeks prior to the first date of therapy
- ECOG PS of 0-2
- Measurable disease with the longest axis greater than or equal to 2 cm by radiographic imaging, Positive FDG-PET scans at baseline

ROCHE BO20603 (E, W)

A multi-center, randomized, double-blind, placebo-controlled phase III trial comparing the efficacy of Bevacizumab in combination with Rituximab and CHOP (RA-CHOP) versus Rituximab and CHOP (R-CHOP) in previously untreated patients with CD20-positive diffuse large B-cell lymphoma (DLBCL)

Eligibility:

- CD20 Positive diffuse large B cell lymphoma or histologic variants. Under WHO classification.
- Low-Intermediate, High-Intermediate or High risk disease by IPI score and/or bulky disease.
- Bi-Dimensional Disease
- ECOG PS of 0-2
- No prior therapy for DLBCL
- No CNS involvement, spinal cord compression, major blood vessel invasion or GI involvement by Lymphoma

BMT CTN 0401

Phase III Rituxan/BEAM vs. Bexxar/BEAM with Autologous Hematopoietic Stem Cell Transplantation (ASCT) for Persistent or Relapsed Chemotherapy Sensitive Diffuse Large B-cell Non-Hodgkin's Lymphoma

Eligibility:

- Persistent or recurrent REAL classification diffuse large B-cell, composite with >50% diffuse large B-Cell, mediastinal lymphoma
- Demonstration of CD20+ on at least one histologic specimen.
- 18-80 years old.
- Less than or equal to 20% bone marrow involvement
- Disease status of primary induction failure, first relapse or second complete remission.
- Three or fewer prior regimens of chemotherapy over the entire course of their disease treatment.
- Monoclonal antibody therapy and involved field radiation therapy will not be counted as prior therapies.
- No prior radiotherapy for lymphoma

NHL First-Line

RTOG 0227

Phase I/II Study of Pre-Irradiation Chemotherapy with Methotrexate, Rituximab, and Temozolomide and Post-Irradiation Temozolomide for primary Central Nervous System Lymphoma

Eligibility:

- Cytologically confirmed primary CNS lymphoma, Based on positive biopsy, cerebrospinal fluid, or vitreous cytology (in association with measurable intraparenchymal tumor) , B-cell type , CD20+ disease.
- Cytology must demonstrate lymphoma OR an immunohistochemical diagnosis of malignant lymphocytes with a monoclonal lymphocytic population.
- No evidence of systemic lymphoma.
- No prior chemotherapy.
- No prior radiotherapy to the brain, head, or neck. Surgery: No prior organ transplantation.
- Age: 18 and over.
- Performance status: Zubrod 0-2.
- Life expectancy: At least 8 weeks. -
- Absolute granulocyte count at least 1,500/mm³, Platelet count at least 100,000/mm³ Hepatic: Bilirubin no greater than 2 times upper limit of normal (ULN) , AST no greater than 2 times ULN , Alkaline phosphatase no greater than 2 times ULN. Renal:
- Not pregnant or nursing, Negative pregnancy test, Fertile patients must use effective contraception, HIV negative.
- No other malignancy within the past 5 years except nonmelanoma skin cancer or carcinoma in situ of the cervix.
- No history of idiopathic sensitivity to any of the drugs in this study, No active infection, No known anaphylaxis or IgE-mediated hypersensitivity to murine proteins or to any component of Rituximab.

NCCTG N0682

A Phase II Clinical Trial of Denileukin Diftitox in Combination with Rituximab in Previously Untreated Follicular B-cell Non-Hodgkin's Lymphoma

Eligibility:

- Pathologically confirmed follicular B-cell non-Hodgkin's lymphoma (NHL). Stage III or IV disease. Grade 1 or 2 disease.
- Previously untreated disease
- Measurable disease (defined as ≥ 1 unidimensionally measurable lesion ≥ 20 mm by conventional techniques, clearly defined bidimensional diameter $\Rightarrow 2 \times 2$ cm on physical examination, OR > 2.0 cm in 1 of the dimensions by CT scan, MRI, or plain radiograph imaging). Splenic enlargement may be used as a measurable parameter if the spleen is palpable $\Rightarrow 3$ cm below the left costal margin.
- Circulating tumor cells $< 5,000/\text{mm}^3$
- Must have paraffin-embedded tissue blocks/slides available.
- No CNS lymphoma.
- No prior chemotherapy, immunotherapy, vaccines, or radiotherapy for NHL.

NHL Second-Line

Genentech ACF4325g (E, W)

An Open-Label, Phase Ib study of the safety, pharmacokinetics, and activity of the Anti-CD40 Monoclonal Antibody SGN-40, administered in combination with Rituximab in patients with CD20-positive, follicular and marginal zone B-CELL Non-Hodgkin's Lymphoma who have relapsed following previous Rituximab therapy

Eligibility:

- Histologically confirmed CD20 Positive, follicular NHL or marginal zone NHL
- At least one prior treatment with a Rituximab-containing regimen
- Measurable disease with at least one site of bi-dimensionally measurable disease ≥ 2 cm.
- Fresh or Archived tumor specimen must be available for central diagnosis
- Ecog 0-1
- Life expectancy > 3 months
- No chemo or RT w/in 28 days
- No prior TX with Monoclonal Antibody directed against CD40
- No prior Radioimmunotherapy or Immunotherapy with a monoclonal antibody other than Rituximab within 3 months of day 1.
- No prior allogeneic bone marrow transplant.
- No prior autologous hematopoietic stem cell transplant with in 12 week of Day 1.

EACRI Lymphopenia (E)

A Pilot Trial of Therapeutic Vaccination with a Modified gp100 Melanoma Peptide (gp100:209-217(210M)), Montanide ISA 51, and KLH with Reconstitution After Chemotherapy to Induce Lymphopenia in Patients with Metastatic Melanoma

Eligibility:

Histologically or cytologically confirmed malignant melanoma which is metastatic or unresectable.

Measurable disease

HLA-A2 positive

First 6 patients must have received at least one prior chemo or immunotherapy regimen for metastatic disease.

ECOG PS \leq 2; life expectancy $>$ 3 months

No prior gp100 peptide immunization

No unstable brain mets

No hx of MS, systemic lupus erythmatosis, or myasthenia gravis

No concurrent corticosteroids other than replacement steroids.

SWOG ECOG E1697

Phase III Randomized Study of Four Weeks High Dose IFN-a2b in Stage T2b N0, T3a-bN0, T4a-b N0, and T1-4, N1a, 2a, 3 (microscopic) Melanoma

Eligibility:

- Pts. must have melanoma w/cutaneous origin; only pts. w/initial presentation of primary melanoma are eligible; pts. must not have clinically palpable lymphadenopathy; pts must meet one of the following criteria:
 - T3N0M0 - primary melanoma of 0-4 mm Breslow depth, clinically negative regional lymph nodes, pathologic status unknown
 - T3N0M0 - primary melanoma of 1.5-4 mm Breslow depth, histologically negative regional lymph nodes
 - T4N0M0 - primary melanoma $>$ 4 mm Breslow depth
 - T1-4N1 - primary melanoma, one lymph node positive microscopically;
- Pts. must complete all primary therapy (wide excision w/or w/o lymphadenectomy) and be randomized w/in 84 days of their wide excision.

GSK DERMA (E)

A double-blind, randomized, placebo-controlled Phase III study to assess the efficacy of recMAGE-A3 + AS15 ASCI as adjuvant therapy in patients with MAGE-A3 positive resected stage III melanoma

Eligibility:

- Male or female patient with histologically proven stage IIIB or IIIC cutaneous melanoma presenting with macroscopic lymph node involvement suitable for surgery. In terms of the AJCC classification, this means that patients with T1-4a N1-2b M0 (stage IIIB with macroscopic nodal involvement) and patients with T1-4b N1-2bM0 or any TN3 macroscopic M0 (\geq 4 macroscopic nodes or macroscopic matted nodes) may be enrolled. Macroscopic lymph-node involvement is defined as clinically detectable lymph node metastases confirmed by therapeutic lymphadenectomy.
- The patient must have been surgically rendered free of disease no more than 8 weeks before randomization.
- Patient's lymph node tumor shows expression of the MAGE-A3 gene, as determined by RT-PCR analysis on formalin-fixed paraffin-embedded (FFPE) tissue.
- ECOG = 0 or 1
- Patient must not have mucous membrane melanoma or ocular melanoma
- Patient must not have in-transit metastases.

ONCOVEX (E)

A Randomized Phase 3 Clinical Trial to Evaluate the Efficacy and Safety of Treatment with OncoVEX^{GM-CSF} Compared to Subcutaneously Administered GM-CSF in Previously Treated Melanoma Patients with Unresectable Stage IIIB, IIIC and IV Disease

- Histologically confirmed diagnosis of malignant melanoma
- Received at least 1 prior non-surgical therapy for active disease, e.g. chemotherapy, radiation, biologic, or investigational treatment given as part of a clinical trial.
- Stage IIIB, IIIC or stage IV disease that is not surgically respectable.
- Measurable and injectable disease (as defined in protocol)

EACRI SBRT/IL-2 (E)

Phase I Study of Stereotactic Body Radiation Therapy (SBRT) and Immunotherapy in the Treatment of Patients with Melanoma Metastases

- Histological confirmation of metastatic melanoma will be required by previous biopsy or cytology. Patients may have metastases in sites other than lung and liver. Brain metastases allowed if the patient is a radiosurgery candidate and it is treated prior to enrollment in this study or is planned to be treated within 4 weeks post SBRT.
- Tumors of interest in lungs or liver, 1-3 foci, 1-3 cm in maximum diameter. Patients may have other metastases but only a maximum of 3 will be treated.
- Must have metastatic site amenable to SBRT

CTSU CALGB C100104

A Phase III Randomized, Double-Blind Study of Maintenance Therapy with CC-5013 (NSC # 703813, IND # 70116) or Placebo Following Autologous Stem Cell Transplantation for Multiple Myeloma

Eligibility:

- Diagnosis of multiple myeloma.
- Active disease requiring treatment.
- Durie-Salmon Stage I, II, or III.
- Stable disease or responsive after \geq 2 months of induction therapy initiated within the past year
- No prior disease progression after initial therapy.
- Patients with smoldering myeloma are eligible provided disease has progressed to \geq stage I.
- Prior thalidomide or lenalidomide allowed provided treatment duration was \leq 12 months.
- No prior bone marrow or peripheral blood stem cell transplantation.
- No concurrent pegfilgrastim.

CTSU 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

Eligibility:

- Diagnosis of symptomatic multiple Myeloma
- Must meet the following criteria at one point in the course of the disease for the original diagnosis of myeloma: Bone marrow plasmacytosis with $>$ 10% plasma cells or sheets of plasma cells or biopsy proven plasmacytoma.
- Must have symptomatic disease that prompted the initiation of therapy (e.g., anemia, hypercalcemia, bone disease, or renal dysfunction).
- Must have completed a minimum of 4 and a maximum of 6 courses of a dexamethasone-based regimen within the past 8 weeks

CTSU ECOG E1A06

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

Eligibility:

- Newly diagnosed multiple myeloma (MM), meeting the following criteria:
- Bone marrow plasmacytosis with \geq 10% plasma cells or sheets of plasma cells or biopsy proven plasmacytoma.
- Symptomatic disease with evidence of end-organ damage at initial diagnosis that prompted the initiation of therapy, including \geq 1 of the following: Anemia, Hypercalcemia, Bone disease (lytic bone lesions or pathologic fracture), Renal dysfunction.
- No smoldering MM, defined by all of the following: Serum monoclonal protein \geq 3 g/dL, Bone marrow plasma cells \geq 10% or greater, Absence of anemia, hypercalcemia, lytic bone lesions, or renal dysfunction,
- No monoclonal gammopathy of undetermined significance, defined by all of the following: Serum monoclonal protein $<$ 3 g/dL, Bone marrow plasma cells \leq 10%, Absence of anemia, hypercalcemia, lytic bone lesions, or renal dysfunction,
- Previously untreated for MM, Patients 18 to 64 years old must not be a candidate for autologous stem cell transplantation or have declined transplantation or other alternative treatment.

SWOG S0115

A Phase II Trial Evaluating Modified High Dose Melphalan (100 mg/m²) and Autologous Peripheral Blood Stem Cell Supported Transplantation (SCT) for High Risk Patients With Multiple Myeloma And/Or Light Chain Amyloidosis (AL Amyloidosis) (A BMT Study).

Eligibility:

Diagnosis of stage II or III multiple myeloma $<$ 1 year prior to registration and/or histological diagnosis of primary systemic (AL) amyloidosis
 No pts with IgM peaks, MGUS, indolent or smoldering myeloma
 No severe cardiac involvement, preexertional syncope, ventricular arrhythmia, or symptomatic pleural effusions in association with cardiac involvement
 No senile, secondary, localized, dialysis-related or familial amyloidosis
 Prior treatment for MM or AL including VAD, dexamethasone alone, cyclophosphamide, or thalidomide (for $<$ 3 months) allowed
 Prior cumulative melphalan dose $<$ 200 mg allowed
 No prior thalidomide or dexamethasone if pt progressed or didn't respond while on these drugs
 Zubrod PS 0-2
 No hx of COPD or CRPD
 Systolic BP $>$ 90 in lying position

CTSU CALGB-10501

A Phase III Intergroup CLL Study of Asymptomatic Patients with Untreated Chronic Lymphocytic Leukemia Randomized to Early Intervention Versus Observation with Later Treatment in the High-Risk Genetic Subset with IGVH Unmutated Disease

Eligibility:

- Clinical and immunophenotypic evidence of B-cell chronic lymphocytic leukemia (CLL) diagnosed within the past 6 months AND meets the following criteria:
- An absolute lymphocytosis of $> 5,000/\mu\text{L}$.
- Morphologically, the lymphocytes must appear mature with $< 55\%$ prolymphocytes.
- Local institution lymphocyte phenotype must reveal a predominant B-cell monoclonal population sharing a B-cell marker (CD19, CD20, CD23) with the CD5 antigen, in the absence of other pan-T-cell markers.
- B-cells must be monoclonal with regard to expression of either κ or λ and have surface immunoglobulin expression of low density.
- Patients with bright surface immunoglobulin levels must have CD23 coexpression and absence of t(11;14) on interphase cytogenetics or have negative tumor protein staining for cyclin D1.
- Low-risk category (i.e., only stages 0 or I) of the modified three-stage Rai staging system.
- No evidence of active or progressive disease

SWOG S0777

A Randomized Phase III Trial of CC-5-13 (lenalidomide, NSD-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

Eligibility:

- Newly diagnosed multiple myeloma (MM). Stage I, II, or III disease by the New International Staging System.
- Measurable disease
- Nonsecretory MM based upon standard M-component criteria (i.e., measurable serum/urine M-component) is not allowed unless the baseline serum free light chain level (Freelite™) is elevated.
- Must be offered participation in the Myeloma Specimen Repository for banking and future research.
- Institutions must submit a local cytogenetics report and FISH analysis prior to study entry.
- No prior chemotherapy for this disease.
- No prior radiotherapy to a large area of the pelvis (i.e., more than half of the pelvis).
- No prior bortezomib or lenalidomide.
- Prior steroid treatment allowed provided treatment was no more than 2 weeks in duration.
- Must be able to take concurrent aspirin 325 mg daily (or enoxaparin 40 mg subcutaneously daily if allergic to aspirin) as prophylactic coagulation.

Testicular

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HOG QL05-37 (E)

A Phase III, Double-Blind, Placebo-Controlled, Crossover Study Evaluating the Oral Neurokinin-1 Antagonist Aprepitant in Combination with 5HT3 and Dexamethasone in Patients with Germ Cell Tumors Undergoing 5 day Cisplatin-Based Chemotherapy Regimens

Eligibility:

- No known history of anticipatory nausea or vomiting.
- Male patients 15 years of age or older at time of registration.
- Male pts 15 years of age or older at time of registration
- Histologic, serologic or clinical evidence of germ cell tumor.
- Pts scheduled to receive 5-day fractionated cisplatin-based combination chemotherapy.
- No known CNS mets.
- No use of another antiemetic agent within 72 hours prior to beginning chemotherapy.
- No concurrent participation in a clinical trial, which involves another investigational agent.
- No use of agents expected to induce the metabolism or aprepitant which include: Rifampin, Rifabutin, Phenytoin, Carbamazepine, and barbiturates.

Tissue Repository Studies

SWOG S0309

A Myeloma Repository Protocol, Ancillary (Multiple Myeloma)

SWOG S9808

Long Term Follow-Up Protocol: An Administrative Tool (Sentinel Node Resection)

SWOG S9910

Leukemia Centralized Reference Laboratories and Tissue Repositories, Ancillary (Leukemia)

SWOG S9925

Lung Cancer Specimen Repository Protocol-Ancillary (Lung Cancer)

SWOG S8819

Central Lymphoma Repository Tissue Procurement Protocol

SWOG S8947

Central Lymphoma Serum Repository Protocol

SWOG S9007

Cytogenetic Studies in Leukemia Patients

RTOG-0514

Establishment of a Head and Neck Tissue/Specimen Repository

EACRI OX40 (E)

Phase I Trial of a Monoclonal Antibody Anti-OX40 in Patients with Advanced Cancer

Eligibility:

- Patients with measurable or evaluable metastatic carcinoma, lymphoma or sarcoma not curable with standard surgery, chemotherapy, or radiation therapy. Either histologic or cytologic diagnosis is acceptable.
- (ECOG) performance status 0, 1, or 2
- Age 18 years or above.
- Laboratory values (performed within 28 days prior to enrollment) as follows:
 - WBC >2000/mL
 - Absolute lymphocyte count > 1000/mm³
 - BUN and serum creatinine <1.5 X upper limit of laboratory normal
 - Hgb >8g/dl (patients may be transfused to reach this level)
 - Hct > 24%
 - Platelets >100,000 cells/mm³
 - AST (SGOT)/ALT (SGPT) <2.5 X upper limit of laboratory normal
 - Alkaline phosphatase <2.5 X upper limit of laboratory normal
 - HIV: Negative
 - Hepatitis B surface antigen: Negative
 - Hepatitis C antibody: Negative
 - Rheumatoid Factor: Normal
 - Anti-nuclear Antibody: Normal
- No active bleeding or clinical coagulopathy (INR <1.5, PT <16 seconds, PTT < 38 seconds).