Chicago Market
Cancer Research Program

Active Protocols
by
Disease Site

Summer 2016
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Breast

**Adjuvant**
SI207 SWOG Stage II-III Weiss/WSMC

Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of EVEROLIMUS in Patients with High-Risk, Hormone Receptor Positive and HER2/neu Negative Breast Cancer

NCT01674140

- Histologically confirmed invasive breast carcinoma
- ER + and/or PR +; Her-2 negative
- PS 0-2
- Multifocal, multicentric, synchronous bilateral, and primary inflammatory breast cancers are allowed
- Completion of adjuvant chemotherapy and pathologically negative lymph nodes, and a tumor measuring ≥ 2 cm in greatest diameter, and an Oncotype DX® Recurrence Score > 25 (completed as SOC)
- Completion of adjuvant chemotherapy, and pathologically 1-3 positive lymph nodes, and an Oncotype DX® Recurrence Score > 25
- Completion of adjuvant chemotherapy and pathologically 4 or more positive lymph nodes independent of the Oncotype DX® Recurrence Score in the primary tumor
- Completion of neoadjuvant chemotherapy and ≥ 4 positive nodes pathologically determined prior to or after chemotherapy
- Patients who had breast-conserving surgery must have completed whole breast radiation; Pts with ≥ 4 positive lymph nodes must have completed breast/chest wall and nodal basin radiation therapy
- Must have undergone axillary staging by sentinel node biopsy or axillary lymph node dissection (ALND).
- Must have completed standard neoadjuvant or adjuvant taxane and/or anthracycline based chemotherapy prior to randomization.
- May have started endocrine therapy at any time after the diagnosis of the current breast cancer.

**NRG-BR003**

Weiss/WSMC

A Randomized Phase III Trial of Adjuvant Therapy Comparing Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel with or without Carboplatin for Node-Positive or High-Risk Node-Negative Triple-Negative Invasive Breast Cancer

NCT02488967

- The tumor must be unilateral invasive adenocarcinoma of the
breast on histological exam

- The tumor must have been determined to be HER2-negative based on study parameters
- The tumor must have been determined to be ER– and PgR Negative assessed by current ASCO/CAP guidelines. Patients with <1% ER and PgR staining by IHC are considered negative
- The patient must have undergone either a mastectomy or lumpectomy

**Locally Advanced/Metastatic**

E2112 A Randomized Phase III Trial of Endocrine Therapy plus Weiss/WSMC Etinostat /Placebo in Patients with Hormone Receptor Positive Advanced Breast Cancer NCT02115282

- Estrogen receptor (ER) and/or progesterone receptor (PR) positive histologically confirmed adenocarcinoma of the breast with staining of ≥ 1% cells will be considered positive.
- Patients whose tumors have HER2 IHC+ , ISH ≥ 2.0, or average HER2 copy number ≥ 6.0 signals per ell are not eligible.
- Patients must have measurable or non-measurable Stage III/locally advanced metastatic carcinoma of the breast, where local therapy with curative intent is not possible.
- Pre/peri- and postmenopausal women and all men are eligible
- Patients must not have known central nervous system metastasis or a history of DNS metastases
- Patients may have received one prior chemotherapy regimen for metastatic disease provided treatment was completed ≥ 3 weeks prior to randomization

**Quality of Life**

E1ZII A Cohort Study to Evaluate Genetic Predictors for Aromatase Inhibitor Musculoskeletal Symptoms (AIMSS) Weiss/WSMC NCT01824836

- Must be female and post-menopausal
- Must have ER + and/or PR + histologically confirmed Stage I-III adenocarcinoma of the breast
- Must have completed recommended local therapy & adjuvant chemo
- Must not have received prior AI therapy with exemestane, letrozole, or anastrozole as adjuvant therapy or for prevention of breast cancer. Prior tamoxifen as adjuvant therapy or for prevention is allowed.
- Plan to treat with anastrozole for at least 12 month
- PS0-2
- Must not be currently taking (or have taken in the past 6 months) ongoing, daily analgesic medication for active, chronic conditions
(Note: pts taking daily low dose aspirin are allowed to participate

- Must have worst pain rated as < 4 out of 10 within one week prior to

**Colon/Rectal**

*Prevention*

S0820  A Double Blind Placebo-Controlled Trial of Eflornithine and Sulfinac to Prevent Recurrence of High Risk Adenomas and Second Primary Colorectal Cancers in Patients with Stage 0-III Colon or Rectal Cancer Phase III-Preventing Adenomas of the Colon with PACES NCT01349881

- No synchronous contralateral breast cancer
- History of Stage 0, I, II or III colon cancer with primary resection one year previously
- Patients with rectosigmoid cancer eligible if no radiation therapy
- One year post-op colonoscopy and CT scans of chest abdomen & pelvis showing no evidence of disease
- At least 30 days from completion of adj chemo
- PS 0-1
- Must have a pure tone audiometry evaluation to document air conduction within 30 days prior to registration. No > 20dB uncorrectable hearing loss for age of any two continuous frequencies.
- Must not have documented hx of gastric/duodenal ulcer within 12 months

**Lung (NSCLC)**

*Supportive*

20070782  A Randomized, Double-blind, Placebo-controlled Study to Evaluate the Long-term Safety and Efficacy of Darbepoetin Alfa Administered at 500 μg Once-Every-3-Weeks in Anemic Subjects with Advanced Stage Non-small Cell Lung Cancer Receiving Multi-cycle Chemo NCT00858364

- Stage IV NSCLC Expected to receive at least 2 additional cycles (at least 6 total weeks) of first line myelosuppressive cyclic chemotherapy after randomization. Patients should not be expected to receive only maintenance chemo.
- PS 0-1
- Life expectancy > 6 months
- No known primary benign or malignant hematologic disorder which
can cause anemia

- No prior adjuvant or neoadjuvant therapy for NSCLC
- No history of brain metastasis
- No uncontrolled hypertension (systolic BP > 160 mmHg or diastolic BP > 100 mmHg)
- No hx of DVT or embolic event within 6 months prior to randomization

**Lymphoma**

_S1001_  
SWOG  
Weiss

- Biopsy-proven Diffuse Large B-cell Lymphoma
- Non-bulky Stage I or II disease by Ann Arbor classification. Patients who have Stage I or II non-bulky disease based on diagnostic CT scan, but are upstaged to Stage III or IV based on FDG-PET evaluation are also eligible
- Lymphoma must express the CD20 antigen by either flow cytometry or by immunoperoxidase staining of paraffin sections
- PS-02
- Must have completed 3 cycles of R-CHOP with no evidence of disease progression

**Multiple Myeloma**

_E1A11_  
ECOG  
Weiss/WSMC

- Must be diagnosed with symptomatic standard-risk multiple myeloma (SR-MM) within 90 days prior to registration as defined by the protocol.
- Patients must have measurable or evaluable disease as defined by having one or more the following, within 28 days prior to randomization;
  - 1 g/dl monoclonal protein (M-protein) or serum protein electrophoresis
  - >200 mg/24 hrs of monoclonal protein on a 24 hour urine protein electrophoresis
  - Involved free light chain >10 g/dL AND abnormal serum immunoglobulin kappa to lambda free light chain ratio (/<0.26 or >/1.65)
- Monoclonal bone marrow plasmacytosis ≥ 30% (evaluable disease)
- Patients must have received no more than one cycle of prior chemotherapy and no more than 160 mg of prior dexamethasone (or equivalent dose of prednisone) for treatment of symptomatic myeloma.
- No prior exposure to lenalidomide, bortezomib, or carfilzomib for treatment of symptomatic myeloma

Multiple Sites

**Non-Interventional**

**S1204**

Weiss/WMSC

A Sero-Epidemiologic Survey and Cost Effectiveness Study of Screening for Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Among Newly Diagnosed Cancer NCT019446516

- Patients must be presenting for evaluation of a new cancer (including hemalogic). Confirmed diagnosis must be within 120 days prior to the first clinic visit.
- Individuals are ineligible if they have been diagnosed with a malignancy other than the current one within the past 5 years

**Myelodysplastic Syndrome**

**Low/Intermediate Risk**

**E2905**

ECOG Weiss

Randomized Phase III Trial Comparing the Frequency of Major Erythroid Response (MER) to Tx w/Lenalidomide (Revlimid®) Alone and in Combination with Epoetin Alfa (Procrit®) in Subjects with Low or Intermediate-1 Risk MDS and Symptomatic Anemia NCT00843882

- Must have documented diagnosis of MDS lasting at least three months (MDS duration ≥ 3 months) according to WHO or non-proliferative CMML
- Must have IPSS categories of Low- or Intermediate-1-risk disease
- Must have IPSS score determined by cytogenetic analysis prior to randomization
- Must have symptomatic anemia un-transfused with hemoglobin < 9.5 g/dL < 8 wks prior to randomization or with RBC transfusion dependence (i.e., > 2 units/month) confirmed for < 8 wks before randomization
Prior erythropoietin failure requires a minimum of >40,000 Units epoetin alfa/week x 8 weeks or equivalent dose of darbepoetin alfa for 8 weeks with failure to achieve transfusion independence in dependent pts or a failure to achieve a >2g rise in hemoglobin sustained for >4 weeks in non-transfusion dependent patients.

- Must not have prior therapy with lenalidomide
- Must not have clinically significant anemia resulting from iron, B12 or folate deficiencies, autoimmune or hereditary hemolysis, or GI bleeds
- No prior chemo or experimental agents for the tx of MDS within 8 weeks
- Must not have a history of thromboembolic events within 3 years

**Polycythemia Vera**

*Non-Interventional*

**Reveal**

Prospective, Non-Interventional Study of Disease Progression and Treatment of Patients with Polycythemia Vera in United States Academic or Community Clinical Practices NCT02252159

- Age >18 years
- Diagnosis of PV
- Willing and able to complete patient assessment questionnaires either alone or with minimal assistance
- Under the supervision of a physician for current care of PV included but not limited to watchful waiting, ASA 81 mg or greater, antithrombotic therapy, PHL, HU, interferon (recombinant or pegylated), busulfan, anagrelide
- Must have life expectancy >6 months
- Must not have a diagnosis of myelofibrosis (MF) (including primary MF, Post-PV MF, or post-essential thrombocythemia MF
- Cannot have a diagnosis of secondary AML or MDS
- Must not have a history of active plan to proceed to hematopoietic stem cell transplant in next 3 month
- Must not have had a splenectomy
Prostate

Unfavorable Intermediate/Favorable High Risk

0924 Androgen Deprivation Therapy and High Dose Radiotherapy
RTOG With or Without Whole-Pelvic Radiotherapy in Unfavorable Intermediate or Favorable High Risk Prostate Cancer: A Phase III Randomized Trial NCT01368588

- Histological or cytological proven prostatic adenocarcinoma within 180 days of registration at moderate to high risk for recurrence as determined by one of the following combinations:
  - Gleason score 7-10 + T1c-T2b (palpation) + PSA < 50 ng/ml (includes intermediate and high risk patients)
  - Gleason score 6 + T2c-T4 (palpation) or > 50% (positive) biopsies + PSA < 50 ng/ml
  - Gleason score 6 + T1c-T2b (palpation) + PSA > 20 ng/ml
- Clinically negative lymph nodes as established by imaging (pelvic ± abdominal CT or MR within 90 days prior to registration) **PS 0-1
- Patients with lymph nodes equivocal or questionable by imaging are eligible if the nodes are ≤ 1.5 cm
- No evidence of bone mets (M0) on bone scan within 120 days
- No previous hormonal therapy, such as LHRH agonists
- Prior pharmacologic androgen ablation for prostate ca is allowed only if the onset of androgen ablation is ≤ 45 days prior to registration
- No finasteride within 30 days prior to registration
- No dutasteride or dutasteride/tamsulosin (Jalyn) within 90 days
- No previous or concurrent cytotoxic chemotherapy for prostate cancer.
- Note that prior chemotherapy for a different cancer is allowable
- No prior radiotherapy, including brachytherapy, to the region of the study cancer that would result in overlap of radiation therapy fields
- Patients status post a negative lymph node dissection are not eligible

Metastatic

A031201 Phase III trial of Enzalutamide (NSC # 766085) versus Enzalutamide, Abiraterone and Prednisone for Castration Resistant Metastatic Prostate Cancer NCT01949337

- Must not have a history of thrombo-embolic events within 3 years
- Progressive castration-resistant metastatic prostate cancer with histologically or cytologically confirmed adenocarcinoma of the prostate without neuroendocrine differentiation or small cell features
- Patients must have Measurable or Non-measurable Disease
- No treatment with prior taxane-based chemotherapy for metastatic disease
- No prior enzalutamide, abiraterone, or other novel antiandrogen or androgen synthesis inhibitor
- Asymptomatic or mildly symptomatic from prostate cancer.
- PS 0-1

**SI216**

**A Phase III Randomized Trial Comparing Androgen Deprivation Therapy + TAK-700 with Androgen Deprivation Therapy + Bicalutamide in Patients with Newly Diagnosed Metastatic Hormone Sensitive Prostate Cancer**  
_NCT 01809691_

- Must have histologically or cytologically proven diagnosis of adenocarcinoma of the prostate.
- Must have radiographic assessment (abdominal/pelvic CT or MRI) within 28 days of the first injection of LHRH agonist.
- Non-measurable disease must also be assessed (e.g., bone scan) in all patients within 42 days of the first injection of LHRH agonist.
- No known brain mets
- Patients may have received prior neoadjuvant and/or adjuvant hormonal therapy, but it must not have lasted for more than 36 months. Single or combination therapy allowed.
- Patients may have received palliative radiotherapy for symptomatic bone or visceral metastasis. Radiotherapy must have been completed at least 14 days prior to registration and pt must have recovered from all side effects.
- PS 0-2 (PS 3 will be allowed if from bone pain only).

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**Renal**

**Adjuvant**

**S0931**

**EVEREST: EVErolimus for Renal Cancer Ensuing Surgical Therapy, A Phase III Study**  
_NCT01120249_

- Histological or cytological confirmed renal carcinoma
- Must be considered pathologically either Intermediate High Risk or Very High Risk; Must not have a history of distant metastases
- Must have undergone a full surgical resection (radical nephrectomy or partial nephrectomy), including removal of all clinically positive nodes. Surgical margins must be negative. Pts with positive renal vein margins are eligible unless there is invasion of the renal vein wall at the margin (provided no other margins are positive)
- Patients with bilateral renal tumors are eligible provided both tumors have undergone full surgical resection and at least one of the tumors meets all eligibility criteria
Must not have received any prior anti-cancer therapy (except for radical or partial nephrectomy) for renal cell cancer including systemic therapy in the adjuvant or neoadjuvant setting, immunotherapy, investigational therapy, surgical metastastectomy, or RT.

Must not be taking, nor plan to take while on protocol tx, strong CYP3A4 inhibitors and/or CYP3A4 inducers within 14 days of random. PS 0-1

**Upcoming Trials**

- **A221102**: Randomized Double-Blind Placebo Controlled Study of Testosterone in the Adjuvant Treatment of Postmenopausal Women with Aromatase Inhibitor Induced Arthralgias (Weiss/WSMC)

- **E1412**: Randomized Phase II Open Label Study of LENalidomide R-CHOP (R2CHOP) vs RCHOP (Rituximab, Cyclophosphamide, Doxorubicin, Vincristine and Prednisone) in Patients with Newly Diagnosed Diffuse Large B Cell Lymphoma (Weiss)

*S1207 and NRG-BR003 will be added to MacNeal in the coming months*