

**FRONT RANGE CANCER SPECIALISTS
OPEN STUDIES LIST
December, 2009**

BREAST

EMILIA BREAST STUDY (GENENTECH): a randomized, multicenter, Phase III open label study of the efficacy and safety of trastuzumab-MCC-DM1 vs. capecitabine + lapatinib in patients with HER2 positive locally advanced or metastatic breast cancer who have received prior trastuzumab-based therapy. (0 patients)

Inclusion:

HER2 status must be prospectively, centrally tested and HER2+.

Histologically or cytologically confirmed invasive breast cancer (incurable locally advanced or metastatic disease).

Prior treatment for breast cancer must include both: a taxane alone or in combo with another agent and trastuzumab in the adjuvant, locally advanced, or metastatic setting.

Documented progression of incurable locally advanced or metastatic breast cancer, defined by the investigator.

Cardiac ejection fraction greater than 50% by ECHO.

ECOG 0 – 1

Adequate labs

Exclusions:

History of treatment with T-DM1

Prior treatment with lapatinib or capecitabine

Peripheral neuropathy great than or equal to 2

History of other malignancy in last 5 years

Chemotherapy within 21 days of randomization to study

History of radiation therapy within 14 days of randomization

Brain mets untreated and symptomatic

No history of symptomatic CHF, ventricular arrhythmia requiring treatment. No MI within 6 months of starting study.

ACORN BREAST STUDY: a double blinded, randomized phase 2b study of sorafenib compared to placebo when administered in combination with chemotherapy for patients with locally advanced or metastatic breast cancer that has progressed during or after bevacizumab therapy. (0 Patients)

Inclusion: (See study for complete list)

Histologically or cytologically confirmed adenocarcinoma of the breast.
Measurable or evaluable locally advanced or metastatic disease.
Must have experienced disease progression during or after treatment with a bevacizumab containing regimen in the adjuvant or first line metastatic setting
No more than one prior chemo regimen
Prior hormonal therapy is allowed but this must have been discontinued before randomization
ECOG 0 or 1

Exclusion:

Brain Mets
Prior use of gemcitabine or sorafenib
Use of cytochrome P450 enzyme inducing anti epileptic drugs
No cardiac disease
Bleeding events
Prior treatment with any agent that targets vascular endothelial growth factor or VEGF receptors

CML

TASIGNA CAMN1107AUS09: a multi center, open label exploratory study of Bcr-Abl kinetics in adult patients on nilotinib with Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia in chronic phase (CML-CP) and a suboptimal molecular response to imatinib. (0 Patients)

Inclusion: (See study for complete list)

ECOG 0 – 2
Diagnosis of CML-CP and CCyR defined by:
< 15% blasts in peripheral blood and bone marrow
<30% blasts plus promyelocytes in peripheral blood and bone marrow
<20% basophils in the peripheral blood
>100,000/mm³ platelets
Imatinib washout period of at least 3 days and to exceed 7 days prior to first dose of nilotinib.

Exclusions:

Prior accelerated phase or blast phase CML
Previously documented T3152 mutation
Achieved prior CCYR on imatinib and lost cytogenetic response prior to entering study
Patients that have had any other treatment for CML (interferon, transplant) except hydroxyurea and/or anagrelide
Impaired cardiac function

WORLD CML REGISTRY: a worldwide, observational registry collecting longitudinal data on the management of Chronic Myelogenous Leukemia (CML) on patients in routine practice. (1 patient)

Inclusion/Exclusion (See study for complete list)

Histologically confirmed metastatic CRC with disease measurable by RECIST
ECOG 0 -1
Acceptable labs
No prior chemotherapy for metastatic CRC or adjuvant chemo for CRC in prior 6 months
No suspected or confirmed CNS mets
No major surgery within 4 weeks of start of treatment. (Standard Avastin precautions)
No MI, CV within previous 6 months

COLON

A phase 1B study of the safety and pharmacokinetics of Apo2L/TRAIL administered in combination with the FOLFOX regimen and bevacizumab in patients with previously untreated, locally advanced recurrent, or metastatic colorectal cancer. (0 patients)

Inclusion Criteria:

Histologically confirmed CRC with evidence of locally advanced recurrent or metastatic disease and measurable tumor lesions per RECIST.
Prior 5FU, capecitabine, and/or oxaliplatin adjuvant therapy is allowed if disease progression occurred ≥ 6 months following the last dose of therapy.
ECOG of 0-2.
Life expectancy > 3 months

Exclusion Criteria:

Prior 5FU, capecitabine, and/or oxaliplatin treatment with exception of the following:
Patients who received prior Oxaliplatin treatment for < 6 weeks in advanced or metastatic setting will not be excluded.

Patients who received prior 5FU, capecitabine and or oxaliplatin in the adjuvant Setting (defined by relapse occurring >6 months after conclusion of adjuvant therapy).

Prior death-receptor agonist therapy.

Peripheral neuropathy grade ≥ 2

Prior radiotherapy to a measurable metastatic lesion to be used for response assessment, unless the lesion has progressed subsequent to therapy.

Radiotherapy to a peripheral lesion within 14 days prior to Cycle 1 Day 1 or radiotherapy to a thoracic, abdominal, or pelvic field within 28 days prior to cycle 1 day 1.

Chemotherapy, Hormonal therapy, or immunotherapy within 4 weeks (6 weeks for nitrosoureas or mitomycin) prior to Cycle 1 Day 1.

Evidence of clinically detectable ascites on Cycle 1 Day 1.

Other invasive malignancies within 5 years prior to Cycle 1 Day 1

History or evidence upon physical examination of active central nervous system (CNS) disease (e.g. primary brain tumor, seizures not controlled with standard medical therapy, any active brain mets or history of stroke in the past year.

HEAD AND NECK

HEAD AND NECK REGISTRY: LORHAN An observational study for head and neck cancer. (1 patient)

Inclusions/Exclusions (See study for complete list)

New diagnosis head and neck CA: oral, oropharynx, nasopharynx, hypopharynx, larynx or neck node mets from unknown origin.

Scheduled to receive XRT and/or drug therapy including chemo, biologic therapy, and targeted therapy. Pts can be on clinical trials. Patients can't be only surgical patients.

LUNG

NSCLC – PO5146: A randomized phase 2 study of maintenance temozolomide versus observation in stable or responding stage IIIB/IV non small cell lung cancer patients. (3 patients)

Inclusions/exclusions (see study for complete list)

Must have stage IV or IIIb with pleural and/or pericardial effusion histologically confirmed NSCLC

Must have completed 4-6 cycles of a standard systemic therapy consisting of at least 2 antitumor agents as first line treatment and have document complete response, partial response or stable disease.

Free of any clinically relevant disease

No brain mets documented on post chemo MRI

Can not have received more than one prior antitumor regimen. Bevacizumab as part of a planned sequence of therapy after first line platinum containing double regimen is not considered a second regimen.

Can not be receiving immunotherapy or chemo cytotoxic or targeted therapy as treatment for active systemic disease.

Uncontrolled diabetes

ACORN NSCLC : A multicenter randomized Phase 2b study of cetuximab (erbitux) in combination with platinum-based chemotherapy as first line treatment of patients with recurrent or advanced non small cell lung cancer. (3 patient)

Inclusion/Exclusion Criteria (see study for complete list)

Histologically or cytologically confirmed Stage IIIb with cytologically documented malignant pleural or pericardial effusion, Stage IV, or recurrent NSCLC after resection or radiation for earlier stage disease.

Measurable or evaluable disease (per modified RECIST)

ECOG performance of 0-1 at study entry.

Recovering from prior surgery or radiation to grade 1 or better.

No pregnant or breastfeeding women.

Must use adequate birth control if patient or spouse of child bearing potential.

No prior chemo for advanced NSCLC; neoadjuvant and/or post operative adjuvant chemo allowed if completed at 12 months before study entry.

No previous exposure to targeted EGFR therapy. Prior treatments with monoclonal antibodies targeting receptors other than EGFR such as bevacizumab is ok if been off 30 days prior to randomization.

No symptomatic or uncontrolled metastases in the central nervous system.

No peripheral neuropathy greater than grade 2.

LYMPHOMA

CEPHALON C18083/3064/NL//MN : An open label, randomized, parallel group study of bendamustine hydrochloride and Rituximab compared with Rituximab, cyclophosphamide, vincristine, and prednisone (R-CVP) or Rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone (R-CHOP) in the first line treatment of patients with advanced indolent non hodgkins lymphoma or mantle cell lymphoma. (1 patient)

Inclusions/Exclusions – see study for complete list

Histopathologic confirmation of 1 of the following C20+B-cell non Hodgkins lymphomas with a lymph node biopsy performed within 6 months of study entry:

- Follicular Lymphoma (Grade 1 or 2)
- immunoplasmacytoma/immunocytoma (Waldenstrom's macroglobulinemia)
- splenic marginal zone B-cell lymphoma
- Extra-nodal marginal zone lymphoma of mucosa associated lymphoid tumor (MALT) Type
- nodal marginal zone B-cell lymphoma
- mantle cell lymphoma

Patient not previously treated

ECOG performance of 2 or less

Life Expectancy of at least 6 months

No CLL or small lymphocytic lymphoma or grade 3 follicular lymphoma

No presence or history central nervous system involvement or leptomeningeal lymphoma.

No prior treatment for NHL except for a single course of locally delimited radiation

Can not have received corticosteroids for treatment of lymphoma within 28 days of study entry.

MYELOFIBROSIS

INCYTE STUDY : A randomized, double blind, placebo controlled study of the JAK inhibitor INCB01824 tablets administered orally to subjects with primary myelofibrosis (PMF), Post Polycythemia Vera-Myelofibrosis (PPV-MF) or post essential thrombocythemia Myelofibrosis. (1 patient)

Inclusion criteria:

Must be diagnosed with PMF, PPV-MF or PET-MF according to 2008 World Health Organization criteria irrespective of JAK2 mutation status.

Subjects requiring therapy must be classified as high risk (3 or more prognostic factors)
OR intermediate risk level 2 (2 prognostic factors).

Prognostic factors are:

- Age > 65
- Presence of constitutional symptoms (weight loss, fever, night sweats)
- Marked anemia (Hb < 10.0)
- Leukocytosis (History of WBC > 25 X10/L)
- Circulating Blasts $\geq 1\%$

Subjects must have one or more of the following:

- Early Satiety
- Abdominal discomfort
- Abdominal pain
- Inactivity
- Night Sweats
- Pruritis
- Bone Pain

Subjects who are refractory, resistant, or intolerant to available therapy or in the investigator's judgment, are not candidates for available therapy.

ECOG 0 – 3

Palpable spleen measuring 5cm or greater below costal margin

Peripheral blood blast count of <10%

Absolute cell count of >20X10/L CD34+

Exclusion criteria:

Life expectancy less than 6 months

MF disease that is well controlled with current therapy

Platelets of <50,000 or ANC <500

Inadequate liver function

Cardiac Disease

Patients that have had splenic irradiation within 12 months prior to randomization

OVARIAN

GENENTECH “OCEANS” AVF4095G :A phase III, multicenter, randomized, blinded, placebo-controlled trial of carboplatin and gemcitabine plus bevacizumab in patients with platinum sensitive recurrent ovary, primary peritoneal or fallopian tube carcinoma. (1 patient)

Inclusion/Exclusion Criteria (See study for complete list)

Histologically documented ovarian, primary peritoneal or fallopian tube carcinoma that has recurred > 6 months after platinum based chemo.

First recurrence of epithelial ovarian, primary peritoneal, or fallopian tube carcinoma.

No prior chemo in the recurrent setting.

Measurable disease per RECIST

ECOG 0-1

Bevacizumab specific exclusions

PANCREATIC

TRAGERA TP2001-203: A randomized placebo controlled multicenter Phase II study of the efficacy and safety of Apricoxib in combination with gemcitabine and erlotinib in the treatment of patients with advanced pancreatic cancer.(1 patient)

Inclusions: (See study for complete list)

Pathologically determined locally advanced or metastatic pancreatic cancer.

Patients could have received prior 5FU or gemcitabine as a radiosensitizer

ECOG 0-2

Exclusions:

Radiation therapy less than or equal 2 weeks, chemo, non cytotoxic investigational agents or high dose corticosteroids within 3 weeks of initiating therapy.

No history of MI, stroke, ventricular arrhythmia within the last 12 months

Symptomatic central nervous system mets

Concurrent use of COX-2 inhibitors or other non steroidal anti inflammatory drugs for 2 days and ASA for seven days prior to first dose and during study

PHASE 1 – SOLID TUMORS

CYLENE C4-08-001: A phase I, multi-center, open label, dose escalation, safety, pharmacokinetic, and pharmacodynamic study of CX-4945 administered orally to patients with advanced solid tumors, Castleman's Disease, or Multiple Myeloma.

Inclusion Criteria:

Histologically or cytologically confirmed malignancy or lymphoproliferative disorder known to over express CK2 which has failed standard therapies or for which effective therapy is not available.

One or more measurable tumors measurable by CT or evaluable disease defined as non measurable lesions per RECIST or detection of protein M in serum and/or urine of patients with Multiple Myeloma.

Acceptable labs.

Karnofsky Performance Status >70%

Exclusion Criteria:

Seizure disorders requiring anticonvulsant therapy.

Known brain metastases unless previously treated and controlled > 3 months

Major surgery within 4 weeks before first dose of study drug.

Treatment with radiation within 1 month of starting study drug.

Treatment with chemotherapy within 21 days of starting study drug.

Concurrent severe or uncontrolled medical disease

Chronic diarrhea

Gastrointestinal disease

History of gastric or small bowel surgery

See protocol for complete list of inclusion/exclusion criteria.