



CANCER RESEARCH  
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## LUNG PROTOCOLS

### NON-SMALL CELL LUNG CANCER

#### CHEMOPREVENTION

- E5597      Selenium supplementation vs placebo for 4 yrs
- Resected Stage IA/IB NSCLC
  - Eligible between 6 to 36 mos postop
  - Must have at least one mediastinal lymph node sample
  - No previous chemo/RT
  - PS 0-1
- RTOG 0235/  
ACRIN 6668      Pre-treatment FDG-PET scan then 12-16 wks after completion of definitive chemoradiation, follow-up FDG-PET scan
- Stage IIB/III NSCLC
  - Patients being treated for definitive concurrent chemo-radiotherapy
  - PET Pre and Post treatment assessment for locally advanced NSCLC
  - Must have pathologically confirmed NSCLC
  - Must be inoperable Stage IIB or III NSCLC being treated with chemoradiation
  - May concurrently participate in other Clinical Trials
  - Must be able to tolerate PET
  - CT chest/upper abdomen required within 4 weeks prior to study
  - Head CT or MRI required within 6 weeks prior to study
  - Bone scan required within 6 weeks prior to study if pt. has skeletal symptoms suspicious for mets and/or elevated alk phos.

#### LOCALLY ADVANCED

- U of C 14576A      Concurrent chemoradiotherapy (Carboplatin/Paclitaxel/Bevacizumab/Radiation Therapy) followed by consolidation chemotherapy (Carboplatin/Paclitaxel/Bevacizumab) at two different dose levels of Bevacizumab (10 mg/kg vs 5 mg/kg)
- NSCLC (including Adenocarcinoma and bronchoalveolar) or large cell (including giant and clear cell carcinomas), or poorly differentiated
  - Squamous cell excluded
  - Unresectable stage II or III

- Measurable or evaluable
- No prior therapy
- PS  $\leq$ 1
- No history of hemoptysis
- No full-dose anticoagulation

RTOG 0214      Prophylactic cranial irradiation vs observation with locally advanced NSCLC

- Stage IIIA or IIIB with complete, partial or stable disease after therapy
- No progressive disease, extra cranial mets or suspicion for CNS mets
- Must be restaged and enrolled within 16 wks of completing therapy
- Must not be on any other Phase III studies

### **ADVANCED METASTATIC**

U of C 13744B      Tarceva + Avastin q 21d x 4 cycles followed by Avastin + Carboplatin  
1<sup>st</sup> Line      + Taxol q 21d x 4 cycles for previously untreated Stage IIIB with pleural  
TACTIC      effusion or Stage IV NSCLC. Pts that did not progress during pre-chemo  
Tarceva + Avastin will receive Tarceva + Avastin q 21d until progression.

- Prior palliative RT allowed but must be 2 wks out prior to study entry
- PS 0-1
- Baseline evaluations need to be within 7d of study entry
- Pre-tx tumor specimen is required
- No brain mets

CP02-0452      Randomized 4 arm study of Erbitux +Taxotere vs Erbitux + Alimta vs  
ImClone      Taxotere vs Alimta in recurrent or progressive NSCLC after platinum-  
2<sup>nd</sup> Line      based therapy

- Metastatic unresectable or locally advanced NSCLC
- Disease progression during or following one prior platinum-based chemotherapy regimen
- Bidimensionally measurable disease with at least one lesion with both perpendicular diameters  $\geq$  1.5 cm
- 4 wks out of surgery, chemo or RT

U of C 13722A      Comparing Cetuximab with concurrent Pemetrexed/Cetuximab  
2<sup>nd</sup> Line      ▪Locally advanced or metastatic (Stage III or IV at entry) NSCLC not amenable to curative therapy

- Previous treatment with 1 platinum or taxane-containing regimen
- No more than 2 prior systemic anti-cancer therapies allowed
- No prior RT allowed to whole pelvis

	<ul style="list-style-type: none"> <li>▪No prior therapy with pemetrexed or therapy targeted to EGF pathway</li> </ul>
E2501 3 <sup>rd</sup> Line	<p>Double blind study of BAY 43-9006</p> <ul style="list-style-type: none"> <li>▪Must have had at least 2 prior chemotherapy regimens for NSCLC</li> <li>▪Must have progressing disease</li> <li>▪Stage IIIB with pleural effusion, Stage IV, or recurrent</li> <li>▪Measurable or non-measurable</li> <li>▪May have a history of brain mets; off tx. <math>\geq 2</math> months and stable</li> </ul>
AVF3996g Genentech ARIES	<p>Phase II Study of the Safety and Efficacy of Sunitinib in Combination with Bevacizumab, Carboplatin, and Paclitaxel in Previously Untreated Patients with Advanced Non-Small Cell Lung Cancer</p> <ul style="list-style-type: none"> <li>▪Advanced histologically or cytologically confirmed NSCLC (Stage IIIb with malignant pleural effusion, Stage IV, or recurrent)</li> <li>▪Measurable or non-measurable disease</li> <li>▪PS 0 or 1</li> <li>▪No prior systemic chemo for metastatic disease</li> <li>▪No active malignancy other than lung ca</li> <li>▪No prior tx with anti-VEGF agent or agents targeting similar pathways as sunitinib</li> </ul>
ARD6123 Sanofi-Aventis 3 <sup>rd</sup> Line	<p>Phase II study of AVE0005 (VEGF Trap) IV q 2 wks in pts with platinum and erlotinib-resistant locally advanced or metastatic non-small cell lung ca</p> <ul style="list-style-type: none"> <li>▪Histologically confirmed NSCLC that is locally advanced or metastatic</li> <li>▪Prior tx with at least 2 cancer drug regimens in the adv setting</li> <li>▪Platinum and erlotinib resistant disease defined by relapse or progression of disease during or after tx, or drug intolerance</li> <li>▪Must have at least one measurable lesion by CT or MRI that has not been treated with surgery or RT</li> <li>▪No squamous cell lung ca</li> <li>▪No prior tx with a VEGF inhibitor except Avastin</li> <li>▪Must be 3 wks out from prior therapy (6 wks for nitrosoureas, cytokine tx)</li> </ul>
RTOG 0320	<p>Arm 1 --Whole Brain RT (WBRT)+Stereotactic Radiosurgery (SRS)          Arm 2 --WBRT + SRS + Temozolomide          Arm 3 --WBRT + SRS + Ertotinib (Tarceva)</p> <ul style="list-style-type: none"> <li>▪NSCLC with 1-3 intra parenchymal brain mets</li> <li>▪Max tumor diameter &lt; 4.0 cm/lesion</li> </ul>

- If multiple lesions, one can be at max diameter, the others must not exceed 3.0 cm
- Patients may have undergone subtotal resection

**REGISTRY**

AVF3991n  
Genentech  
ARIES

Observational, registry study of tx with Avastin for metastatic or locally advanced and unresectable colorectal ca, locally advanced or metastatic non-small cell lung ca. Any chemotherapy or monoclonal antibody regimen.

**SMALL CELL LUNG CANCER****LIMITED**

RTOG 0212

Randomized 3 arm study of two doses (standard vs. high) and two dose schedules (once vs twice daily) for delivering prophylactic cranial irradiation (PCI) for limited small cell lung ca

- Limited disease SCLC, clinical stages I-IIIb
- Completion of all chemo  $\geq$  1 wk prior study entry
- Must have achieved a complete response to induction chemo +/- thoracic RT
- PCI should begin no more than 240d from the start of induction chemo
- Normal brain CT or MRI <1 mo prior to study entry