

## Center for Oncology Research & Treatment Contacts

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Center for Oncology Research & Treatment, PA



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## September 2009 CORT Clinical Trials

### **Breast Cancer: Adjuvant Studies:**

#### **NCCTG N063D (BIG 2-06) - Phase III Intergroup**

Adjuvant Lapatinib and/or Trastuzumab Treatment Optimization (ALTO) study: A Randomized, Multi-Center, Open-Label, Phase III Study of Adjuvant Lapatinib, Trastuzumab, Their Sequence and Their Combination in Patients with HER2/ErbB2 Positive Primary Breast Cancer

**S0307:** Phase III Trial of Addition of Bisphosphonates to Adjuvant therapy of Primary Breast Cancer

#### **IBCSG 24-02 (SOFT):**

Phase III Trial Evaluating the Role of Ovarian Function Suppression in Adjuvant Therapy of Premenopausal Breast Cancer

#### **TAILORx (PACCT-1):**

Trial Assessing the Use of a Tissue Genetic Microarray in Treatment Selection Adjuvant Therapy Hormone-Responsive Breast Cancer

#### **E5103:**

Phase III Study of the Addition of Bevacizumab (Avastin) to Standard Adjuvant Chemotherapy (AC>T)

#### **NSABP B42:**

Phase III Randomized Comparison of Placebo versus Letrozole (Femara) for Extended Endocrine Adjuvant Therapy in Patients who have Completed 5 years of Tamoxifen-Aromatase Inhibitor Therapy

#### **3144A2 3004 WW: Neratinib**

Randomized Double Blind Study of Neratinib (HKI-272) versus Placebo in Women with Early Stage Her-2+ Breast Cancer After Completion of Herceptin-Based Adjuvant Therapy

### **Breast Cancer: Neoadjuvant (Preoperative) Study:**

None Current

### **Breast Cancer: Metastatic Studies (Her-2 Negative):**

#### **EMR 200038-010 (ER+, Her-2-): Stimuvax**

A Study of Stimuvax® in Combination With Hormonal Treatment Versus Hormonal Treatment Alone for First-line Therapy of Endocrine-sensitive Advanced Breast Cancer (STRIDE)

#### **Pfizer A6181077: (Triple Negative): Sutent**

Phase II Randomized Comparison of Sutent versus Standard Chemotherapy for Second-Line Treatment of Her-2-negative, ER-negative, PR-negative Metastatic Breast Cancer

**Pending Site Selection: Survivin Inhibitor + Docetaxel for First-Line Treatment of Her-2 Negative Metastatic Breast Cancer**

### **Breast Cancer: Metastatic Studies (Her-2 Positive):**

#### **NCCTG N0733 - Phase II Intergroup**

Randomized Phase II Trial of Capecitabine and Lapatinib with or without IMC-A12 in Patients with HER2 Positive Breast Cancer Previously Treated with Trastuzumab and an Anthracycline and/or a Taxane

### **3144A2 3005 WW: Neratinib**

Randomized Comparison of Neratinib (HKI-272) + Paclitaxel versus Trastuzumab + Paclitaxel in First-Line Treatment of Her-2+ Metastatic Breast Cancer

#### **Genentech TDM4370g: T-DM1**

Phase III comparison of T-DM1 (Trastuzumab-Maytansine) versus Lapatinib/Capecitabine for Metastatic Her-2+ Breast Cancer that has progressed on Trastuzumab (Herceptin)

### **Colon Cancer: Adjuvant Studies**

#### **E5202:**

Phase III Study of FOLFOX versus FOLFOX-Avastin in Stage II Patients with High Risk for Recurrence as Defined by Genetic and Molecular Markers

#### **N0147 - Phase III**

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

### **Colon Cancer: Metastatic Studies:**

**Pending: Panitumumab + mFOLFOX6 versus Bevacizumab + mFOLFOX6 for First-line Treatment of Metastatic Colorectal Cancer with Wild-type k-ras Gene Status**

### **Solid Tumors:**

**Pending: Study to Evaluate Effect of Cetuximab on Corrected QT Interval in Patients with Advanced Solid Tumors**

**Pending: TES10887: Study to Evaluate Effect of Taxotere on Corrected QT Interval in Patients with Solid Tumors Receiving 3rd Line Therapy**

### **Gastric Cancer Studies:**

None Current

### **Lung Cancer (Non-Small Cell) NSCLC: Adjuvant Studies:**

#### **EMR 63325-001: Stimuvax**

Phase III Study of Stimuvax Vaccine versus Placebo for Stage III NSCLC Patients After Completion of Definitive Chemoradiotherapy

### **Lung Cancer (Non-Small Cell) NSCLC: Metastatic Studies:**

**Pending: AC01208: A Multicenter Randomized Phase IIB Study of Erbitux in Combination with Platinum-Based Chemotherapy in Patients with Recurrent or Locally-Advanced NSCLC**

#### **ImClone CP02-0452:**

Phase III Study of Erbitux + Taxotere versus Taxotere for Second-Line Treatment of Recurrent or Progressive NSCLC

#### **CYC682-08**

Phase II protocol "A Phase II Study of Oral Sapacitabine in Patients with Previously Treated Non-Small Cell Lung Cancer".

### **Lymphoma Studies:**

#### **Biogen IDEC 114-NH-301:**

Phase III Study of Rituximab +/- Galiximab Therapy for Relapsed B-cell Lymphoma

### **Melanoma Studies:**

#### **CA184-029, EORTC 18071: Adjuvant Therapy after Resection**

Adjuvant Immunotherapy With Anti-CTLA-4 Monoclonal Antibody (Ipilimumab) Versus Placebo After Complete Resection of High Risk Stage III Melanoma: A Randomized, Double-Blind Phase 3 Trial of the EORTC Melanoma Group

#### **S0438 - Phase II Intergroup**

A Randomized Phase II Trial of BAY 43-9006 (Sorafenib; NSC-724772) with Either CCI-779 (Temsirrolimus; NSC-683864) or R115777 (Tipifarnib; NSC-702818) in Metastatic Melanoma

**Pending Site Selection: Survivin Inhibitor + Docetaxel for First-Line Treatment of Metastatic Melanoma**

**Pending Site Selection:**

### **Pancreatic Cancer Studies:**

None Current

### **Prostate Cancer Studies:**

#### **Hormone-Resistant Stage IV:**

**S0421:** Phase III Study of Docetaxel and Atrasentan Versus Docetaxel and Placebo for Patients with Advanced Hormone Refractory Prostate Cancer

#### **BMS C184-043:**

Second-Line Treatment with Ipilimumab (Anti-CTLA-4) versus placebo

### **Renal Cell Carcinoma (non-study):**

#### **Proleukin (IL-2)**

Interleukin-2 Therapy for Patients with Appropriate Disease Criteria and Adequate Performance Status and Organ Function

### **Multiple Myeloma:**

None Current

