

## ACTIVE PROTOCOLS as of 11/5/2007

### **BREAST – Adjuvant**

**NSABP B36:** A Clinical Trial of Adjuvant Therapy Comparing Six Cycles of 5-Fluorouracil, Epirubicin and Cyclophosphamide (FEC) to Four Cycles of Adriamycin and Cyclophosphamide (AC) in Patients With Node-Negative Breast Cancer

**NSABP B39:** 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

**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

**NSABP B42 REG:** [OPTIONAL NSABP PROTOCOL B-42 REGISTRATION PROGRAM] Registration Program to Provide Up to Three Years of Letrozole to Postmenopausal Women with Hormone Receptor Positive Breast Cancer Who Have Received at Least Two Years of Initial Adjuvant Hormonal Therapy

**TAILOR Rx / PACCT 1:** Program for the Assessment of Clinical Cancer Tests (PACCT-1): Trial Assigning Individualized Options for Treatment: “The TAILORx Trial” .

### **LSU - CCOP Studies:**

**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

**CALGB/CTSU 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

**S0307:** Phase III Trial of Bisphosphonates as Adjuvant Therapy for Primary Breast Cancer"

### **BREAST –Metastatic**

**(EMBRACE) E7389-G000-305:** A Phase III Open Label, Randomized Parallel Two-Arm Multi Center Study of E7389 versus ‘Treatment of Physician’s Choice’ in Patients with Locally Recurrent or Metastatic Breast Cancer, Previously Treated with At Least Two and a Maximum of Five Prior Chemotherapy Regimens, Including an Anthracycline and a Taxane

**BRE 77:** A Phase II Trial of Trastuzumab and Oxaliplatin in Patients with Metastatic Breast Cancer

**BRE 86:** A Phase II Trial of Open Label Bevacizumab Administered with Anastrozole or Fulvestrant as First-Line Therapy in Postmenopausal Hormone Receptor Positive Metastatic Breast Cancer

**BRE 74:** Phase II Trial of Docetaxel Plus Imatinib Mesylate (Gleevec®) in Metastatic Breast Cancer

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### **BREAST –Metastatic (cont.)**

#### **LSU - CCOP Studies:**

**E4101**, A Randomized Phase II Trial of Combination Anastrozole (NSC #719344) plus ZD1839 (Iressa, NSC #715055, IND #61187) and of Combination Fulvestrant (NSC #719276) plus ZD1839 in the Treatment of Postmenopausal Women with Hormone Receptor-Positive Metastatic Breast Cancer

**S0226**: Phase III Randomized Trial of Anastrozole versus Anastrozole and Fulvestrant as First Line Therapy for Post Menopausal Women with Metastatic Breast Cancer

### **LUNG – 1st line: N/A**

### **LUNG - 2<sup>nd</sup> line**

**BETA LUNG OSI3364g**: A Phase III, Placebo Controlled, Double Blind Clinical Trial to Evaluate the Efficacy of Bevacizumab in Combination with Tarceva compared with Tarceva alone For Advanced NSCLC after Failure of Standard First Line Therapy

### **GI - Adjuvant Colon/Rectal**

**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-FU with or without Oxaliplatin in the Treatment of Patients with Operable Carcinoma of the Rectum

**E5202**: A Randomized Phase III Study Comparing 5-FU, Leucovorin and Oxaliplatin versus 5-FU, Leucovorin, Oxaliplatin and Bevacizumab in Patients with Stage II Colon Cancer at High Risk for Recurrence to Determine Prospectively the Prognostic Value of Molecular Markers

#### **LSU CCOP Studies:**

**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

### **GI - Metastatic Colon/Rectal**

**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.

### **RENAL**

**GU 32**: PHASE II TRIAL OF BEVACIZUMAB AND RAD001 (EVEROLIMUS) IN THE TREATMENT OF PATIENTS WITH ADVANCED CLEAR CELL RENAL CARCINOMA

#### **LSU – CCOP Studies:**

**E2805 ASSURE**: Adjuvant Sorafenib or Sunitinib for Unfavorable Renal Carcinoma

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### PROSTATE

**EFC6193 (TROPIC):** A Randomized, Open Label Multi-Center Study of XRP6258 At 25 mg/m<sup>2</sup> in Combination With Prednisone Every 3 Weeks Compared To Mitoxantrone in Combination With Prednisone For the Treatment of Hormone Refractory Metastatic Prostate Cancer Previously Treated With A Taxotere®-Containing Regimen.

#### **LSU - CCOP Studies**

**R0232:** A PHASE III STUDY COMPARING COMBINED EXTERNAL BEAM RADIATION AND TRANSPERINEAL INTERSTITIAL PERMANENT BRACHYTHERAPY WITH BRACHYTHERAPY ALONE FOR SELECTED PATIENTS WITH INTERMEDIATE RISK PROSTATIC CARCINOMA

**S0354:** A Phase II Study of CNTO 328, A Monoclonal Antibody Against Interleukin-6 (IL-6), in Patients with Hormone Refractory Prostate Cancer.

**S9346:** Intermittent Androgen Deprivation in Patients with Stage D2 Prostate Cancer, Phase III

### LEUKEMIA

#### **LSU - CCOP Studies**

**S0106:** A Phase III Study of the Addition of Gemtuzumab Ozogamicin (Mylotarg®) During Induction Therapy Versus Standard Induction with Daunomycin and Cytosine Arabinoside Followed by Consolidation and Subsequent Randomization to Post-Consolidation Therapy with Gemtuzumab Ozogamicin (Mylotarg®) or No Additional Therapy for Patients Under Age 61 with Previously Untreated De Novo Acute Myeloid Leukemia (AML)

### LYMPHOMA

**LYM 37:** Rituximab ± Bevacizumab in the Treatment of Patients with Follicular Non-Hodgkin's Lymphoma: A Randomized, Phase II Trial

**PIX 203 "RAPID":** Cyclophosphamide, Doxorubicin, Vincristine, Prednisone plus Rituximab (CHOP-R) and Cyclophosphamide, Pixantrone, Vincristine, Prednisone plus Rituximab (CPOP-R) in Patients with Diffuse Large B-cell Lymphoma; a Phase II, Randomized, Multicenter, Comparative Trial.

#### **LSU - CCOP Studies:**

**E4402:** Randomized Phase III Trial Comparing Two Different Rituximab Dosing Regimens for Low Tumor Burden Patients with Indolent non-Hodgkin's Lymphoma

**S0520** "Phase II Study of PDX101 (NSC-726630) in Relapsed and Refractory Aggressive B-Cell Lymphomas"

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### **METASTATIC MELANOMA**

**(BEAM) AVF4096g:** A Phase II, multicenter, randomized, Double-Blind, placebo-controlled trial evaluating the efficacy and safety of bevacizumab in combination with Carboplatin and Paclitaxel chemotherapy for the First-line treatment of patients with Metastatic Melanoma

### **Multiple Myeloma**

**C05009 (UPFRONT):** Randomized Phase 3b Study of Three Treatment Regimens in Subjects with Previously Untreated Multiple Myeloma Who Are Not Considered Candidates for High-Dose Chemotherapy and Autologous Stem Cell Transplantation: VELCADE ® (Bortezomib), Thalidomide, and Dexamethasone (VTD) versus VELCADE ®, Melphalan, and Prednisone (VMP).

### **UNKNOWN PRIMARY**

**UNK PRI 14:** A Phase II Trial of Oxaliplatin and Capecitabine in the Treatment of Patients with Relapsed or Refractory Carcinoma of Unknown Primary Site.

**UNKPRI 19:** A Phase II study of Paclitaxel/ Carboplatin + Bevacizumab/ Erlotinib in the first-line treatment of patient with carcinoma of unknown primary site.

### **Anal**

**E3205:** Phase II Trial of Cetuximab Plus Cisplatin, 5-Fluorouracil and Radiation in Immunocompetent Patients with Anal Carcinoma.