

CLINICAL TRIAL REVIEW

SCRI Strategic Site Trials...September 2010



STUDY #	TITLE	CONTACT
SOLID TUMORS		
BREAST		
Adjuvant Triple Negative		
BRE 145 OPEN-TIER II	A Randomized Trial of Ixempra vs. Taxol in Adjuvant Therapy of Triple-Negative Breast Cancer (TITAN)	Research Hotline 803-461-3708
Adjuvant-HER2-		
BRE 163 OPEN-IST	Phase III Clinical Trial Comparing the Combination of TC Plus Bevacizumab to TC Alone and to TAC for Women with Node-Positive or High-Risk Negative, HER2-Negative Breast Cancer	Research Hotline 803-461-3708
Neoadjuvant-HER2+		
BRE 139 OPEN-IIT	Phase II Study of Neoadjuvant Ixabepilone/Carboplatin/Trastuzumab in HER2-Positive Locally Advanced Breast Cancer	Research Hotline 803-461-3708
Neoadjuvant-HER2-		
BRE 133 OPEN-IIT	Phase II Study of Ixabepilone and Cyclophosphamide as Neoadjuvant Therapy in HER2-Negative Breast Cancer	Research Hotline 803-461-3708
Metastatic, First-Line, HER2-		
BRE 154 OPEN-TIER II	A Randomized, Double-Blind, Placebo-Controlled Phase II Trial of Weekly Paclitaxel/Bevacizumab +/- Everolimus as First-Line Chemotherapy for Patients with HER2-Negative Metastatic Breast Cancer (MBC)	Research Hotline 803-461-3708
Metastatic, Refractory, HER2+		
BRE 157 OPEN-IST	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	Research Hotline 803-461-3708
BRE 167 OPEN-IST	BOLERO 3: A Randomized Phase III, Double-Blind, Placebo-Controlled Multicenter Trial of Daily Everolimus in Combination with Trastuzumab and Vinorelbine, in Pretreated Women her HER2/neu Over-expressing Locally Advanced or Metastatic Breast Cancer	Research Hotline 803-461-3708
Metastatic, Refractory, HER2-		
BRE 179 OPEN-IST	A Phase II, Randomized, Multicenter Study of CDX-011 (CRO11-vcMMAE) in Patients with Advanced, Refractory, GPNMB-expressing Breast Cancer	Research Hotline 803-461-3708
Metastatic, Refractory, Triple Negative		
BRE 156 OPEN-IST	A Phase II Study of NK012 in Locally Advanced Non-Resectable Metastatic Breast Cancer Patients with Triple Negative Phenotype	Research Hotline 803-461-3708
BRE 174 OPEN-IST	An Open-Label, Expanded Access Protocol of BSI-201 in Combination with Gemcitabine/Carboplatin in Patients with ER-, PR-, and HER2 Negative Metastatic Breast Cancer	Research Hotline 803-461-3708

STUDY #	TITLE	CONTACT
COLORECTAL		
Metastatic, Relapsed/Refractory		
GI 141 OPEN-IST	An Open-label, Multicenter, Randomized Phase 2 Study Evaluating the Safety and Efficacy of 5-FU/FA and Oxaliplatin (Modified FOLFOX-6) in Combination With IMC-1121B or IMC-18F1 or Without Investigational Therapy as Second-line Therapy in Patients With Metastatic Colorectal Cancer following Disease Progression on First-line Irinotecan-based Therapy	Research Hotline 803-461-3708
GI 142 OPEN-IST	A Phase III Randomized DoubleBlind Study to Assess the Efficacy and Safety of Perifosine Plus Capecitabine Versus Placebo Plus Capecitabine in Patients with Refractory Advanced Colorectal Cancer.	Research Hotline 803-461-3708
OUTCOMES 04 OPEN-IIT	A Retrospective Cohort Study of Infusion Reactions Due to Vectibix (Panitumumab)	Research Hotline 803-461-3708
KIDNEY		
Metastatic, First-Line		
GU 44 OPEN-IIT	A Phase I/II Trial of Sorafenib (Nexavar) and RAD001 (Everolimus) in the Treatment of Patients with Advanced Clear Cell Renal Carcinoma	Research Hotline 803-461-3708
Metastatic, Relapsed/Refractory		
GU 56 OPEN-IIT	A Phase II Trial of Pazopanib in Patients with Metastatic Renal Cell Carcinoma Previously Treated with Sunitinib or Bevacizumab	Research Hotline 803-461-3708
LUNG – NON-SMALL CELL		
Neoadjuvant		
LUN 186 OPEN-IIT	Phase II trial of Preoperative Pemetrexed and Carboplatin in Patients with Select Stage IB, II, and III Non-Squamous Non-Small-Cell Lung Cancer	Research Hotline 803-461-3708
Stage IIIB/IV, First-Line		
LUN 192 OPEN-IST	Open-Label, Phase 3 Study of Pemetrexed plus Carboplatin and Bevacizumab Followed by Maintenance Pemetrexed and Bevacizumab versus Paclitaxel plus Carboplatin and Bevacizumab Followed by Maintenance Bevacizumab	Research Hotline 803-461-3708
LUN 196 OPEN-TIER II	TOPPS (Trial Of Poor Performance Status patients): Randomized Phase II Trial of Pemetrexed vs. Pemetrexed/Bevacizumab vs. Pemetrexed/Carboplatin/Bevacizumab in Patients with Stage III/IV Non Small-Cell Lung Cancer and ECOG Performance Status 2	Research Hotline 803-461-3708
LUN 201 OPEN-IST	Randomized Phase 3 Trial of Gemcitabine/Carboplatin With or Without BSI-201 (a PARP1 Inhibitor) in Patients with Previously Untreated Advanced Squamous Cell Lung Cancer (Squamous Only)	Research Hotline 803-461-3708
LUN 205 OPEN-IST	A Randomized, Double-blind, Placebo-controlled Study to Evaluate the Long-term Safety and Efficacy of Darbeoetin Alfa Administered at 500 mg Once-Every-3-Weeks (Q3W) to a Hemoglobin Ceiling of 12.0 g/dL in Anemic Subjects with Advanced Stage Non-small Cell Lung Cancer Receiving Multi-cycle Chemotherapy	Research Hotline 803-461-3708
LUN 206 OPEN-IST	A Randomized Phase II Study of Imetelstat as Maintenance Therapy After Initial Induction Chemotherapy for Advanced Non-Small Cell Lung Cancer (NSCLC)	Research Hotline 803-461-3708
Relapsed/Refractory		
LUN 195 OPEN-IST	A Randomized, Phase II, Multi-Center, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Activity of MetMAB, A Monovalent Antagonist Antibody to the Receptor Met, Administered to Patients with Advanced Non-Small Cell Lung Cancer in Combination with Tarceva®	Research Hotline 803-461-3708
LUN 200 OPEN-TIER II	A Randomized, Phase II, Double-Blinded, trial of Erlotinib and Pazopanib or Erlotinib and Placebo in Patients with previously Treated Advanced Non-Small-Cell Lung Cancer	Research Hotline 803-461-3708
LUNG – SMALL CELL		
First Line		
LUN 199 OPEN-IIT	A Phase II Trial of Amrubicin and Carboplatin with Pegfilgrastim in Patients with Extensive-Stage Small Cell Lung Cancer	Research Hotline 803-461-3708



STUDY #	TITLE	CONTACT
MELANOMA		
Metastatic, Relapsed/Refractory		
MEL 20 OPEN-IST	A Randomized Phase III Study of Tasisulam Administered as an Intravenous Infusion on Day 1 of a 28-day Cycle vs. Paclitaxel as Second-Line Treatment in Patients with Unresectable or Metastatic Melanoma	Research Hotline 803-461-3708
OVARY		
Stage III/IV, First-Line		
GYN 19 OPEN-IIT	A Randomized Phase II Study of Paclitaxel/Carboplatin with or without Sorafenib in the First-Line Treatment of Patients with Stage III/IV Epithelial Ovarian Cancer	Research Hotline 803-461-3708
Relapsed/Refractory		
GYN 26 ON HOLD-IIT	A Phase I/II Study of the Combination of Pazopanib and Liposomal Doxorubicin (Doxil) in Patients with Advanced Relapsed Platinum-Sensitive or Platinum-Resistant Ovarian, Fallopian Tube or Primary Peritoneal Adenocarcinoma	Research Hotline 803-461-3708
PANCREAS		
Metastatic, First-Line		
GI 130 OPEN-IST	A Randomized Phase III Study of Weekly ABI-007 plus Gemcitabine versus Gemcitabine Alone in Patients with Metastatic Adenocarcinoma of the Pancreas	Research Hotline 803-461-3708
PROSTATE		
Metastatic, First-Line		
GU 64 OPEN-IST	A Phase 3 Study to Evaluate the Efficacy and Safety of Docetaxel and Prednisone with or without Lenalidomide in Subjects with Castrate-Resistant Prostate Cancer	Research Hotline 803-461-3708
UNKNOWN PRIMARY		
First-Line		
UNKPRI 21 OPEN-IST	An Open-Label Randomized Phase II Trial of Belinostat (PXD101) in Combination with Carboplatin and Paclitaxel (BeICaP) Compared to Carboplatin and Paclitaxel in Patients with Previously Untreated Carcinoma of Unknown Primary.	Research Hotline 803-461-3708



STUDY #	TITLE	CONTACT
HEMATOLOGIC MALIGNANCIES		
CHRONIC LYMPHOCYTIC LEUKEMIA (CLL)		
First-Line		
CLL 02 OPEN-IIT	A Phase I/II Study of Fludarabine, Rituximab, and Lenalidomide in Minimally Treated and Untreated Patients with Chronic Lymphocytic Leukemia	Research Hotline 803-461-3708
CLL 11 OPEN-IIT	A Phase II Trial of Ofatumumab for Older Patients and Patients who Refuse Fludarabine-Based Regimens with Previously Untreated Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma	Research Hotline 803-461-3708
Registry		
OBS 03 OPEN-IIT	Connect CLL Registry Protocol	Research Hotline 803-461-3708
NON-HODGKIN'S LYMPHOMA (NHL) - FOLLICULAR		
First-Line		
LYM 64 OPEN-IST	An Open-Label, Randomized, Parallel-Group Study of Bendamustine Hydrochloride and Rituximab (BR) Compared with Rituximab, Cyclophosphamide, Doxorubicin, Vincristine, and Prednisone (R-CHOP) in the First-Line Treatment of Patients with Advanced Indolent Non-	Research Hotline 803-461-3708
LYM 64 OPEN-IST	An Open-Label, Randomized, Parallel-Group Study of Bendamustine Hydrochloride and Rituximab (BR) Compared with Rituximab, Cyclophosphamide, Doxorubicin, Vincristine, and Prednisone (R-CHOP) in the First-Line Treatment of Patients with Advanced Indolent Non-Hodgkin's Lymphoma (NHL) or Mantle cell Lymphoma (MCL)	Research Hotline 803-461-3708
NON-HODGKIN'S LYMPHOMA - DIFFUSE LARGE CELL		
First-Line		
LYM 67 OPEN-IST	An Open-Label, Randomized, Phase 2 Study to Assess the Effectiveness of RCHOP With or Without VELCADE in Previously Untreated patients with Non-Germinal Center B-Cell like Diffuse Large B-Cell Lymphoma	Research Hotline 803-461-3708
MULTIPLE MYELOMA		
First-Line		
MM 23 OPEN-IIT	Phase II Study for the Evaluation of Bendamustine, Bortezomib and Dexamethasone (BBD) in the First-Line Treatment of patients with Multiple Myeloma Who are not Candidates for High Dose Chemotherapy.	Research Hotline 803-461-3708