

Clinical Trial Review

January 2012



STUDY #	TITLE	CONTACT
SOLID TUMORS		
BREAST		
Adjuvant		
BRE 177 OPEN-IST	A Randomized, Double-Blind, Placebo-Controlled, Multi-Center Phase 3 Study of Denosumab as Adjuvant Treatment for Women with Early-Stage Breast Cancer	Research Hotline 803-461-3708
Adjuvant-HER2+		
BRE 193 OPEN-IST	A randomized multicenter, double-blind, placebo-controlled comparison of chemotherapy plus trastuzumab plus placebo versus chemotherapy plus trastuzumab plus pertuzumab as adjuvant therapy in patients with operable HER2-positive primary breast cancer	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 Node-Negative, HER2-Negative Breast Cancer.	Research Hotline 803-461-3708
Neoadjuvant		
BRE 186 OPEN-IIT	Phase 2 Trial of Eribulin in Patients Who Do Not Achieve Pathologic Complete Response (pCR) Following Neoadjuvant Chemotherapy	Research Hotline 803-461-3708
Metastatic, First-Line, HER2+		
BRE 171 OPEN-IST	A Randomized, 3 Arm, Multicentre, Phase III Study to Evaluate the Efficacy and the Safety of T-DM1 Combined with Pertuzumab or T-DM1 Combined with Pertuzumab-Placebo, Versus the Combination of Herceptin plus Taxane, as 1st Line Treatment in HER2 Positive Progressive or Recurrent Locally Advanced or Metastatic Breast Cancer	Research Hotline 803-461-3708
Metastatic, First-Line, HER2-		
BRE 138 Phase 2 OPEN-IIT	Phase I/II Trial of Sorafenib Plus Ixabepilone as First-Line Treatment for Patients with HER2-Negative Metastatic Breast Cancer	Research Hotline 803-461-3708
Metastatic, First-Line, Triple Negative		
BRE 178 OPEN-IST	A Randomized, Phase II, Multi-Center, Double-Blind, Placebo-Controlled Study Evaluating The Safety and Efficacy of Metmab and/or Bevacizumab in Combination with Paclitaxel in Subjects with Metastatic, Triple Negative Breast Cancer	Research Hotline 803-461-3708
Metastatic, Refractory, HER2+		
BRE 185 OPEN-IST	A Randomized Phase 2 Study of LY2523355 versus Ixabepilone in Patients with Metastatic Breast Cancer Who Have Received Prior Taxane Therapy	Research Hotline 803-461-3708
Metastatic, Refractory, HER2-		
BRE 185 OPEN-IST	A Randomized Phase 2 Study of LY2523355 versus Ixabepilone in Patients with Metastatic Breast Cancer Who Have Received Prior Taxane Therapy	Research Hotline 803-461-3708



STUDY #	TITLE	CONTACT
BREAST Cont.		
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 178 OPEN-IST	A Randomized, Phase II, Multi-Center, Double-Blind, Placebo-Controlled Study Evaluating The Safety and Efficacy of Metmab and/or Bevacizumab in Combination with Paclitaxel in Subjects with Metastatic, Triple Negative Breast Cancer	Research Hotline 803-461-3708
BRE 185 OPEN-IST	A Randomized Phase 2 Study of LY2523355 versus Ixabepilone in Patients with Metastatic Breast Cancer Who Have Received Prior Taxane Therapy	Research Hotline 803-461-3708
COLORECTAL		
Metastatic, First-Line		
GI 155 OPEN-IST	Randomized Double-Blind, Placebo Controlled, Phase II Study of FOLFOX/ Bevacizumab with or without Met MAb as First-Line Treatment for Patients with Metastatic Colorectal Cancer	Research Hotline 803-461-3708
Metastatic, Relapsed/Refractory		
GI 138 Phase 2 OPEN-IST	A Randomized, Placebo-Controlled, Phase 1/2 Study of ARQ 197 in Combination with Irinotecan and Cetuximab in Subjects with Metastatic Colorectal Cancer with Wild-Type KRAS who have Received Front-Line Systemic Therapy	Research Hotline 803-461-3708
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
OUTCOMES 04 OPEN-IIT	A Retrospective Cohort Study of Infusion Reactions Due to Vectibix (Panitumumab)	Research Hotline 803-461-3708
ESOPHAGEAL; GASTRIC		
Metastatic, First-Line		
GI 152 OPEN-IST	Randomized, Placebo-Controlled, Double-Blind Phase 2 Study of mFOLFOX6 Chemotherapy Plus Ramucirumab Drug Product (IMC-1121B) versus mFOLFOX6 Plus Placebo for Advanced Adenocarcinoma of the Esophagus, Gastroesophageal Junction, or Stomach	Research Hotline 803-461-3708
HEAD AND NECK		
Metastatic, First-Line		
HN 12 OPEN-IST	Phase II Study of Pemetrexed in Combination with Carboplatin or Cisplatin and Cetuximab in Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck	Research Hotline 803-461-3708
KIDNEY		
Metastatic, First-Line		
GU 75 OPEN-IST	Randomized, Multicenter, Open-label, Active-Controlled, Phase 2 Study of LY2510924 and Sunitinib versus Sunitinib in Patients with Metastatic Renal Cell Carcinoma	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



STUDY #	TITLE	CONTACT
LUNG – NON- SMALL CELL (CONT.)		
Stage IIIB/IV, First-Line		
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 Darbepoetin 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
LUN 210 OPEN-IST	Randomized, Open-Label, Phase 3 Study of Pemetrexed plus Carboplatin Followed by Maintenance Pemetrexed versus Paclitaxel plus Carboplatin and Bevacizumab Followed by Maintenance Bevacizumab in Patients with Advanced Non-Small Cell Lung Cancer of Nonsquamous Histology	Research Hotline 803-461-3708
Relapsed/Refractory		
LUN 212 OPEN-IST	A Phase 3, Randomized, Double-Blinded, Placebo-Controlled Study of ARQ 197 Plus Erlotinib Versus Erlotinib Plus Placebo in Previously Treated Subjects with Locally Advanced or Metastatic, Non-Squamous Non-Small-Cell Lung Cancer (NSCLC)	Research Hotline 803-461-3708
OVARY		
Stage III/IV, Relapsed/Refractory		
GYN 26 OPEN-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
PROSTATE		
Metastatic, First-Line		
GU 69 OPEN-IST	A Phase 3, Randomized, Double-Blind, Multicenter Trial Comparing TAK-700 Plus Prednisone With Placebo Plus Prednisone in Patients With Chemotherapy-Naïve Metastatic Castration-Resistant Prostate Cancer	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
Registry		
OBS 03 OPEN-IIT	Connect CLL Registry Protocol	Research Hotline 803-461-3708
NON-HODGKIN'S LYMPHOMA (NHL) - FOLLICULAR		
Relapsed/Refractory		
LYM 71 OPEN-IST	A Phase 2 Study to Assess the Efficacy and Safety of CAL-101 in Patients with Indolent B-Cell Non-Hodgkin Lymphoma Refractory to Rituximab and Alkylating Agents	Research Hotline 803-461-3708
NON-HODGKIN'S LYMPHOMA (NHL) - 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
LYM 74 OPEN-IST	A Phase III, Multicenter, Randomized Trial Comparing the Efficacy of GA101 in Combination with CHOP (G-CHOP) Versus Rituximab and CHOP (R-CHOP) in Previously Untreated Patients with CD20-Positive Diffuse Large B-Cell Lymphoma (DLBCL)	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