

Breast Center Therapeutic Trials

Ductal Carcinoma In Situ Pre-Operative

CALGB-40903 (P.I. Isabelle Bedrosian, M.D.) Phase II Study of Neoadjuvant Letrozole for Postmenopausal Women with Estrogen Receptor Positive Ductal Carcinoma In Situ.

2013-0849 (P.I. Henry Kuerer, M.D.) Impact of the Oncotype DX® DCIS Score on Treatment Decision Making in Patients with Ductal Carcinoma in Situ

Neoadjuvant Therapy-Untreated

Alliance-A011106 (P.I. Abigail Caudle, M.D.) Alternate Approaches for Clinical Stage II or III Estrogen Receptor Positive Breast Cancer NeoAdjuvant Treatment (ALTERNATE) in postmenopausal women: A Phase III Study

2010-0145 (P.I. Stacy Moulder, M.D.): Investigation of Serial Studies to Predict Therapeutic Response with Imaging and Molecular Analysis.

2013-0137 (P.I. Banu Arun, M.D.): Randomized Phase II trial of Neoadjuvant Cisplatin vs. Doxorubicin/Cyclophosphamide ("AC") in Women with Newly Diagnosed Breast Cancer and Germline BRCA Mutations

Adjuvant Therapy

2013-0139 (P.I. Elizabeth Mittendorf, M.D.) Phase Ib Trial of Two Folate Binding Protein (FBP) Peptide Vaccines (E39 and J65) in Breast and Ovarian Cancer Patients

2013-0436 (P.I. Elizabeth Mittendorf, M.D.) Combination immunotherapy with Herceptin and the HER2 vaccine E75 in low and intermediate HER2-expressing breast cancer patients to prevent recurrence

2009-0818 (P.I. Eric A. Strom, M.D.) Assessing the Cosmesis and Toxicity of Partial Breast Irradiation Using Proton Beam Irradiation.

SWOGS1007 (P.I. Gabriel Hortobagyi, M.D.) Phase III Randomized Clinical Trial of Standard Adjuvant Endocrine Therapy +/- Chemotherapy in Patients with 1-3 Positive Nodes, Hormone Receptor-Positive and HER2-Negative Breast Cancer with Recurrence Score (RS) of 25 or Less.

SWOG S1207 (P.I. Mariana Chavez, M.D.) Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients with High-Risk, Hormone Receptor-Positive and HER2/neu Negative Breast Cancer. e³ Breast Cancer Study-evaluating everolimus with Endocrine Therapy

2011-0595 (P.I. Elizabeth A. Mittendorf, M.D.) Prevention of Recurrence in Early-Stage, Node-Positive Breast Cancer with Low to Intermediate HER2 Expression with NeuVax Treatment.

Local Regional Therapy

ACOSOG Z11102 (P.I. Elizabeth Mittendorf, M.D.) Impact of Breast Conservation Surgery on Surgical Outcomes and Cosmesis in Patients with Multiple Ipsilateral Breast Cancers (MIBC)

Alliance A011202 (P.I. : Elizabeth Mittendorf, M.D.) A Randomized Phase III Trial Evaluating The Role of Axillary Lymph Node Dissection In Breast Cancer Patients (cT1-3 N1) Who Have Positive Sentinel Lymph Node Disease After Neoadjuvant Chemotherapy

Alliance A011104 (P.I. Gildy Babiera, M.D.) Effect of Preoperative Breast MRI on Surgical Outcomes, Costs and Quality of Life of Women with Breast Cancer



Breast Center Therapeutic Trials
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To refer online: <https://my.mdanderson.org>

To refer a patient, call the Breast Center: **713-792-2360**

To discuss breast cancer clinical trials, call Jie Willey, administrative director, Protocol Research: **713-792-3965** or Carolyn McKinney, Research Nurse Manager: **713-792-6045**

THE UNIVERSITY OF TEXAS
MD Anderson
Cancer Center

Making Cancer History®

Breast Center Therapeutic Trials

Inflammatory Breast Cancer (IBC) - Neoadjuvant-Untreated

2008-0372 (P.I. Naoto Ueno, M.D.): Phase II Study of Panitumumab, Nab-Paclitaxel and Carboplatin for Patients with Primary Inflammatory Breast Cancer (IBC) without HER2 Overexpression.

2006-1072 (P.I. Naoto Ueno, M.D.): Inflammatory Breast Cancer (IBC) Registry.

2010-0842 (P.I. Naoto Ueno, M.D.): Phase I/II Study of Entinostat and Lapatinib in Patients with HER2-Positive Metastatic Breast Cancer in Whom Trastuzumab Has Failed.

Metastatic Breast Cancer

2012-0930 (P.I. Wendy Woodward, M.D.) Randomized phase II double blind study of VPA vs. placebo to shorten time of indwelling pleural catheter

First or Second Line Therapy

2012-0408 (P.I. James Murray, M.D.) A Double-Blind, Randomized Phase II Trial of Active Immunotherapy with Globo H-KLH (OPT 822) in Subjects with Metastatic Breast Cancer

Third or Any Line

2010-0842 (P.I. Naoto Ueno, M.D.) Phase I/II Study of Entinostat and Lapatinib in Patients with HER2-Positive Metastatic Breast Cancer in Whom Trastuzumab Has Failed.

2013-0468 (P.I. Mariana Chavez, M.D.) A Phase 1b/11 Trial of LEE011 in Combination Everolimus (RAD001) and Exemestane in the Treatment of Postmenopausal Women with Estrogen Receptor Positive Her2 negative Locally Advanced or Metastatic Breast Cancer

2013-0776 (P.I. Ricardo Alvarez, M.D.) A Phase 1b/2 Study of Safety and Efficacy of MLN0128 (Dual TORC 1/2 Inhibitor) in Combination With Exemestane or Fulvestrant Therapy in Postmenopausal Women With ER+/HER2-Advanced or Metastatic Breast Cancer That Has Progressed on Treatment With Everolimus in Combination With Exemestane or Fulvestrant

2011-1009 (P.I. George Blumenschein, M.D.) Phase I Open-Label, Dose Escalation Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Maximum Tolerated Dose of the Anti-Mesothelin Antibody Drug Conjugate BAY 94-9343 in Subjects with Advanced Solid Tumors.

2011-0327 (P.I. George Blumenschein, M.D.) Phase Ib Trial of the Combination of PI3K Inhibitor BAY 80-6946 and Allosteric-MEK Inhibitor BAY 86-9766 in Subjects with Advanced Cancer.

2013-0728 (P.I. Jennifer Litton, M.D.) A Phase 3, Open-Label, Randomized, Parallel, 2-Arm, Multi-Center Study of BMN 673 versus Physician's Choice in Germline BRCA Mutation Subjects with Locally Advanced and/or Metastatic Breast Cancer, Who Have Received No More than 2 Prior Chemotherapy Regimens for Metastatic Disease

2013-0375 (P.I. Stacy Moulder, M.D.) An Open-Label, Phase I/II, Dose Escalation Study Evaluating the Safety and Tolerability of GDC-0032 in Patients with Locally Advanced or Metastatic Solid Tumors and in Combination with Endocrine Therapy in Patients with Locally Advanced or Metastatic Hormone Receptor-Positive Breast Cancer

2013-0814 (P.I. Wen-Jen Hwu, M.D.) A Phase I Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of MEDI4736 in Subjects With Advanced Solid Tumors (2012-0513)

2010-0794 (P.I. Banu Arun, M.D.) Phase II Short-term Adjuvant Therapy and Biomarker studies with targeted agents in Women with Estrogen Receptor Negative Breast Cancer

Bone Metastasis

2008-0319 (P.I. Eric Strom, M.D.) Aggressive Local Therapy for Limited Bone-Only Metastasis to Improve Progression-Free Survival in Breast Cancer Patient

Brain Metastasis

2010-0198 (P.I. Nuhaad K. Ibrahim, M.D.) A Phase 1/2 Open-Label Study of TPI 287 in Patients with Breast Cancer Metastatic to the Brain

Breast Radiation Clinical Trials

NSABP B-51/RTOG1304 (P.I. Simona F. Shaitelman, M.D.) A Randomized Phase III Clinical Trial Evaluating Post-Mastectomy Chestwall and Regional Nodal XRT and Post-Lumpectomy Regional Nodal XRT in Patients with Positive Axillary Nodes Before Neoadjuvant Chemotherapy Who Convert to Pathologically Negative Axillary Nodes After Neoadjuvant Chemotherapy

2008-0319 (P.I. Eric A. Strom, M.D.) Aggressive Local Therapy for Limited Bone-only Metastasis to Improve Progression-Free Survival in Breast Cancer Patients

2009-0818 (P.I. Eric A. Strom, M.D.) Assessing the cosmesis and toxicity of partial breast irradiation using proton beam irradiation