

CLINICAL TRIALS UPDATE

February 2011



Cancer Care Centers of South Texas (CCCST)

is affiliated with US Oncology, one of the nation's largest healthcare networks dedicated to cancer treatment and clinical research. The US Oncology Research Network has played a role in the development of 43 anticancer drugs approved by the Food and Drug Administration. Cancer Care Centers of South Texas, as a member of the US Oncology Research Network, provides access to clinical trials and new investigational drugs, for eligible patients, in San Antonio, New Braunfels, Kerrville and Boerne.

CCCST Research Office Locations

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Dear Colleague,

At Cancer Care Centers of South Texas, we are very excited to inform you of our continued efforts in research, and of additional clinical trial opportunities now open to patients with recurrent breast cancer. As always, CCCST strives to provide the most options to patients with cancer. With the many different types of breast cancer, we are making progress in understanding the factors that lead to cancer development and metastasis. Accordingly, we have identified similar interventions that appear to have promising activity in treating the many forms of breast cancer.

We are very proud to offer two new treatment options for eligible patients with difficult to treat and potentially deadly forms of breast cancer, HER2 Negative and Positive breast cancer:

A Phase 2, Multicenter, Single-Arm Study of Eribulin Mesylate with Trastuzumab as First-Line Therapy for Locally Recurrent or Metastatic Human Epidermal Growth Factor Receptor Two (HER2) Positive Breast Cancer

A Phase 2, Multicenter, Single-Arm Study of Single-Agent Eribulin Mesylate as First-Line Therapy for Locally Recurrent or Metastatic Human Epidermal Growth Factor Receptor Two (HER2) Negative Breast Cancer.

Eribulin is a known cytotoxic agent that leads to inhibition of the microtubular elements, and was recently FDA approved for advanced, recurrent breast cancer in patients who have already received anthracycline or taxane-based therapy. Due to the success of eribulin in this challenging phase of treatment, we are studying the role of this relatively well-tolerated treatment in the earlier phases of treatment for breast cancer. This drug reduces the risk for nausea and alopecia, with a slightly increased risk, with its use, of neuropathy and leucopenia, which are both completely reversible.


We are honored to be affiliated with the US Oncology Research program and to have the opportunity to offer these unique treatment options to patients with breast cancer in our communities. If you have questions about these two trials for breast cancer, or any of the many research treatment options that are available through our extensive research program, please feel free to contact any one the CCCST physicians.

Sincerely,

Sharon T. Wilks, MD, FACP
Lead Principal Investigator



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TRIALS FOR MALIGNANT DISEASES

Breast

A Prospective, Randomized Double-Blind, Stratified, Placebo-Controlled, Multi-Center, Two-Arm Trial of the Continued Efficacy and Safety of Zometa in Patients With Documented Bone Metastases from Breast Cancer

Randomized Phase II Trial of Letrozole with or without Dasatinib as First-Line Treatment for Hormone Receptor-Positive, HER2-Negative Post-Menopausal Breast Cancer that is Unresectable, Locally Recurrent or Metastatic

Phase II Randomized Trial of Fulvestrant with or without Dasatinib in Men and Postmenopausal Women who have Hormone Receptor-Positive Advanced Breast Cancer Previously Treated with an Aromatase Inhibitor

A 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

A Randomized, Double-Blind, Placebo-Controlled Trial of Neratinib (HKI-272) Following Trastuzumab in Women with Early-Stage HER-2/neu Overexpressed/Amplified Breast Cancer

A Randomized, Multi-Center, Open-Label, Phase III Study of Adjuvant Lapatinib, Trastuzumab, Their Sequence and Their Combination in Patients with HER/2ErbB2 Positive Primary Breast Cancer

A Randomized, Phase III, Double-Blind, Placebo-Controlled Multicenter Trial of Daily Everolimus in Combination with Trastuzumab and Vinorelbine, in Pretreated Women with HER2/neu Over-Expressing Locally Advanced or Metastatic Breast Cancer

Phase II Trial of Ixabepilone plus Carboplatin in Patients with Metastatic Breast Cancer

An Open-Label, Expanded Access Protocol of BSI-201 in Combination with Gemcitabine/Carboplatin in Patients with ER-negative, PR-negative and HER2-negative Metastatic Breast Cancer

Randomized, Double-Blind, Placebo-Controlled, Multi-Center Phase 3 Study of Denosumab as Adjuvant Treatment for Women with Early Stage Breast Cancer at High Risk of Recurrence

A Randomized, 3 Arm, Multicenter, Phase III Study to Evaluate the Efficacy and the Safety of TDM-1 Combined with Pertuzumab or TDM-1 Combined with Pertuzumab-placebo versus the Combination of Trastuzumab plus Taxane, as First Line Treatment of HER2-Positive Progressive or Recurrent Locally Advanced or Metastatic Breast Cancer

A Multicenter, Multinational Phase II Study to Assess the Clinical Safety and Feasibility of T-DM1 Sequential with Anthracycline-based Chemotherapy, as Adjuvant or Neoadjuvant Therapy for Patients with Early Stage HER2-Positive Breast Cancer

A Phase 2, Multicenter, Single-Arm Study of Eribulin Mesylate with Trastuzumab as First-Line Therapy for Locally Recurrent or Metastatic Human Epidermal Growth Factor Receptor Two (HER2) Positive Breast Cancer

A Phase 2, Multicenter, Single-Arm Study of Single-Agent Eribulin Mesylate as First-Line Therapy for Locally Recurrent or Metastatic Human Epidermal Growth Factor Two (HER2) Negative Breast Cancer

A Two-Part, Adaptive, Randomized Trial of Radaforolimus in Combination with Monotherapy in Estrogen Receptor Positive Breast Cancer Patients

Gastrointestinal

A Randomized, Multi-Center Phase III Study to Evaluate the Efficacy and Safety of Nilotinib versus Imatinib in Adult Patients with Unresectable or Metastatic Gastrointestinal Stromal Tumors

A Randomized, Double-Blind, Multicenter Phase 3 Study of Irinotecan, Folinic Acid, and 5-Fluorouracil (FOLFIRI) plus Ramucirumab or Placebo in Patients with Metastatic Colorectal Carcinoma Progressive During or Following First-Line Combination Therapy with Bevacizumab, Oxiplatin, and a Fluoropyrimidine

Genitourinary

Phase II Trial of Gemcitabine, Cisplatin and Sunitinib in Patients with Advanced/Metastatic Urothelial Carcinoma

AG-013736 (axitinib) vs. A4061051 (sorafenib) for the Treatment of Metastatic Renal Cell Cancer

A Randomized, Double-Blind, Placebo-Controlled Phase III Study to Evaluate the Efficacy and Safety of Pazopanib as Adjuvant Therapy for Subjects with Localized or Locally Advanced Renal Cell Carcinoma Following Nephrectomy

Leukemia

A Phase III, Open Label, Randomized, Multicenter Trial of Ofatumumab Added to Chlorambucil Monotherapy in Previously Untreated Patients with Chronic Lymphocytic Leukemia

The Chronic Lymphocytic Leukemia Disease Registry

A Multi-Center, Single-Arm Study of Nilotinib in Philadelphia Chromosome Positive (Ph+) Chronic Myelogenous Leukemia in Chronic Phase Patients with Low Imatinib Trough Plasma Concentrations

An Exploratory Trial to Assess the Improvement of Chronic Low-Grade Non-Hematologic Adverse Events Experienced by Patients with Philadelphia Chromosome Positive (Ph+) Chronic Myelogenous Leukemia in Chronic Phase Treated with Imatinib When Switched to Nilotinib Treatment

Liver

A Randomized, Phase III, Double-Blind, Placebo-Controlled, Multi-Center Study to Evaluate the Efficacy and Safety of Everolimus in Adult Patients with Advanced Hepatocellular Carcinoma After Failure of Sorafenib Treatment

Lung

Randomized, Open-Label, Phase 3 Study of Pemetrexed plus Carboplatin and Bevacizumab Followed by Maintenance Pemetrexed and Bevacizumab vs. Paclitaxel plus Carboplatin and Bevacizumab Followed by Maintenance Bevacizumab in Patients with Stage IIIB or IV Nonsquamous Non-Small Cell Lung Cancer

Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Long-Term Safety and Efficacy of Darbepoetin Alfa Administered at 500 ig Once-Every-3-Weeks to a Hemoglobin Ceiling of 12.0 g/dl in Anemic Subjects with Advanced Stage Non-Small Cell Lung Cancer Receiving Multi-Cycle Chemotherapy



Lung, cont.

An Open-Label, Multicenter, Randomized, Phase 2 Study of a Recombinant Human Anti-VEGFR-2 Monoclonal Antibody, IMC-1121B in Combination with Platinum-based Chemotherapy versus Platinum-based Chemotherapy Alone as First-Line Treatment of Patients with Recurrent or Advanced Non-Small Cell Lung Cancer

A Randomized, Double-Blind, Phase 3 Study of Docetaxel and Ramucirumab versus Docetaxel and Placebo in the Treatment of Stage IV Non-Small Cell Lung Cancer Following Disease Progression after One Prior Platinum-Based Therapy

Lymphoma

An Open-Label, Single-Arm Phase II Study of RAD001 in Patients with Refractory Mantle Cell Lymphoma

Single-Arm, Open-Label, Multi-Center Phase II Study to Evaluate the Efficacy and Safety of P276-00 in Patients with Relapsed and/or Refractory Mantle Cell Lymphoma

Malignant Melanoma

Expanded Access Use of Ipilimumab (BMS-734016) Monotherapy in Patients with Unresectable Stage III or IV Melanoma

Multiple Myeloma

The Multiple Myeloma Disease Registry--Registry Protocol

Myelodysplastic Syndrome (MDS)

A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Clinical Trial of Deferasirox in Patients with Myelodysplastic Syndromes (low/int-1 risk) and Transfusional Iron Overload

A Phase I/II Study of Eltrombopag in Thrombocytopenic Subjects with Advanced MDS or Secondary AML after MDS

Phase I Dose-Ranging Study of Ezatiostat Hydrochloride (tablets) in Combination with Revlimid in Patients with Non-Deletion (5q) Low to Intermediate-1 Risk MDS

MDS, CMML, AML, Lymphoma and Multiple Myeloma

A Phase I, Open-Label, Dose Ranging Study to Evaluate the Pharmacokinetics and Safety of Azacitidine Administered Subcutaneously and as Different Oral Formulations in Subjects with Myelodysplastic Syndromes (MDS), Chronic Myelomonocytic Leukemia (CMML), Acute Myelogenous Leukemia (AML), Lymphoma and Multiple Myeloma

Pancreatic

A Randomized, Double-Blind, Placebo-Controlled Phase II Study of the MEK Inhibitor GSK1120212 plus Gemcitabine vs. Placebo plus Gemcitabine in Subjects with Metastatic Pancreatic Cancer

Thymic

Phase II Study of Oral PHA-848125AC in Patients with Thymic Carcinoma Previously Treated with Chemotherapy (CDKO-125a-006)

For more information, please call any of our research offices listed on page one.

TRIALS FOR NON-MALIGNANT HEMATOLOGICAL DISEASES

DVT

A Safety and Efficacy Trial Evaluating the Use of Apixaban in the Treatment of Symptomatic Deep Vein Thrombosis and Pulmonary Embolism

A Phase 3, Randomized, Double-Blind, Double-Dummy, Parallel-Group, Multicenter Study for the Evaluation of Efficacy and Safety of (LMW) Heparin/Edoxaban Versus (LMW) Heparin/Warfarin in Subjects with Symptomatic Deep-Vein Thrombosis and/or Pulmonary Embolism

Severe Chronic Neutropenia

Phase II Randomized Study of Ezatiostat Hydrochloride (Tablets) for Treatment of Severe Chronic Neutropenia

RADIATION TRIALS

Breast

A Phase III Clinical Trial Comparing Trastuzumab Given Concurrently with Radiation Therapy Alone for Women with HER2-Positive Ductal Carcinoma In Situ Resected by Lumpectomy

Head and Neck

Phase III Study of Postoperative Radiation Therapy (IMRT) +/- Cetuximab for Locally-Advanced Resected Head and Neck Cancer

Lung

A Randomized Phase III Comparison of Standard-Dose (60 Gy) vs. High Dose (74 Gy) Conformal Radiotherapy with Concurrent and Consolidation Carboplatin/Paclitaxel in Patients with Stage IIIA/IIIB Non-Small Cell Lung Cancer

Prostate

A Phase III Trial of Short Term Androgen Deprivation with Pelvic Lymph Node or Prostate Bed only Radiotherapy in Prostate Cancer patients with a Rising PSA after Radical Prostatectomy

UPCOMING TRIALS

CCCST's research program will soon be opening new clinical trials for the following:

- Renal cell carcinoma
- Soft tissue sarcoma
- Esophageal
- CML
- Chronic ITP
- CLL
- Met. Her2 (-) breast cancer
- Polycythemia vera
- MDS, CMML or AML
- B-cell lymphoma



CANCER CARE CENTERS of South Texas

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A MEMBER OF THE US ONCOLOGY RESEARCH NETWORK

February 2011

MEDICAL SERVICES

- Medical Oncology, Hematology
- Radiation Oncology
- Gynecologic Oncology
- Out-patient Chemotherapy
- Out-patient Radiation Therapy
- Minimally Invasive Robot-Assisted Surgery
- PET Imaging, CT Imaging
- Ultrasound
- Bone Densitometry
- Clinical Trials
- Dietary Counseling
- Genetic Testing/Counseling
- Retail Pharmacy
- In-house Laboratory
- Treatment and Management of Hematological Disorders
- Thrombosis and Anticoagulation Center
- LDL Lipidpheresis, Plasmapheresis

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Cancer Care Centers of South Texas (CCCST) is a comprehensive cancer care practice with 17 locations in the San Antonio area including, New Braunfels, Seguin, Kerrville, Fredericksburg, Marble Falls, Boerne, Uvalde, Jourdanton, Hondo, Schertz and Floresville. The physicians and staff provide state-of-the-art treatment for cancer and disorders of the blood as well as clinical trials. The highly-qualified physician staff is comprised of 27 board-certified physicians, specializing in medical oncology, hematology, radiation oncology, and gynecologic oncology, and a skilled and compassionate team made up of RN's, nurse practitioners, and physician assistants specializing in the care of patients with cancer and blood disorders.