

# CLINICAL TRIALS UPDATE

September 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 Colleagues,

At Cancer Care Centers of South Texas we continue to provide more treatment options for patients with breast cancer. One of our newest clinical trials, "A 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 [D-CARE]", addresses a novel approach in prevention of breast cancer relapse. Depending upon the breast cancer type, many women may be at increased risk of relapse despite use of appropriate adjuncts to breast cancer management. There have been a number of reports emerging that suggest that certain medicines, such as Zometa® (zoledronic acid) and Evista® (raloxifene), used for improvement in bone health and bone density may have a role in breast cancer prevention.

Denosumab is a new drug that has shown promise in many solid cancers including prostate cancer for improvements in bone density and survival in the metastatic setting. Denosumab is a fully-human monoclonal IgG2 antibody to RANK ligand that binds with high affinity and specificity, functioning as a RANK ligand inhibitor. This binding is felt to prevent activation of RANK ligand (involved with several functions of the osteoclasts), leading to reduction of bone resorption and less bone loss. Denosumab has also shown activity in preventing tumor growth, and the use of it may lead to a less chance of breast cancer relapse. In this trial, open to patients with newly-diagnosed breast cancer, one important goal is to determine if the use of denosumab influences breast cancer relapse when compared with placebo-treated patients. Fortunately, this new drug has few side effects and is a potentially novel therapy to improve bone density in a high risk group of patients who tend to be prone to bone loss, as well as an agent that may prevent breast cancer relapse.

We are delighted to continue to provide state-of-the-art clinical trials that address current areas of interest in cancer research through our active affiliation with the US Oncology Research Network. Through this affiliation, we provide these prominent national clinical trials on a local level for patients who live in San Antonio and the surrounding South Texas and Hill Country communities. Please consider this trial, or possibly one of our other breast cancer trials for your patients. We truly believe that clinical trials should be considered as a best-of-therapy option for patients, and not thought of and only reserved as a last line of therapy.


Thank you for your continued support and patient referrals. If you have questions about this trial or about any of our other clinical trials, please feel free to contact me at 210-656-7177, or call any of our research offices. As always we remain committed to providing the best care available along with more treatment options for your patients.

Sincerely,

Sharon T. Wilks, MD, FACP  
Lead Principal Investigator



CANCER CARE CENTERS  
of South Texas

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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

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, 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

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 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

A Randomized, Phase II Study of AFP464 +/- Faslodex in ER-Positive Breast Cancer Patients Who Have Progressed on Aromatase Inhibitor Therapy

Prediction of Response to Neoadjuvant Chemotherapy in Women with Operable Breast Cancer

## Gastrointestinal

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

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

An Open-Label, Randomized, Multi-Center Phase III Study to Compare the Safety and Efficacy of TK1258 Versus Sorafenib in Patients with Metastatic Renal Cell Carcinoma After Failure of Anti-Angiogenic (VEGF-targeted and mTOR inhibitor therapies)

## Leukemia

The Chronic Lymphocytic Leukemia Disease Registry

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

A Pilot Phase II Study of Bafetinib as Treatment for Patients With Relapsed or Refractory B-CLL

A Phase III, Randomized, Controlled, Double-Blind, Multinational Clinical Study of the Efficacy and Safety of Vosaroxin and Cytarabine Versus Placebo and Cytarabine in Patients with First Relapsed or Refractory Acute Myeloid Leukemia

## 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

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

A Randomized, Multicenter Study Comparing Pixastrone plus Rituximab with Gemcitabine plus Rituximab in Patients with Aggressive B-Cell Non-Hodgkin's Lymphoma Who Have Relapsed After Therapy with CHOP-R or an Equivalent Regimen and are Ineligible for Stem Cell Transplant

A Phase II Open-Label Study of Ofatumumab and Bendamustine Followed by Maintenance Ofatumumab for Indolent B-Cell Non-Hodgkin's Lymphoma (B-NHL) Which Has Relapsed After Rituximab Therapy

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

## 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

A Phase III Multicenter, Randomized, Controlled Study to Assess the Efficacy and Safety of ONO1919/Na Administered as a 72 Hour Continuous Intravenous Infusion Every Other Week in MDS Patients with Excess Blasts Relapsing After, or Refractory to, or Intolerant to Azacitidine or Decitabine

A Phase I, Open-Label, Dose Escalation Study to Evaluate the Safety, PK and PD of Oral Azacitidine in Subjects with MDS, CMML, or AML (currently open for MDS only)

## **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

## **Primary Myelofibrosis Post-Essential Myelofibrosis Post-Polycythemia Vera Myelofibrosis**

Randomized, Open-Label, Multicenter, Phase III Study of Efficacy and Safety in Polycythemia Vera Subjects Who Are Resistant to or Intolerant of Hydroxyurea: JAK INH424 tablets Versus Best Available Care

Open Label Assessment of Safety and Efficacy of Ruxolitinib in Patients with Primary Myelofibrosis, Post-Essential Thrombocythemia Myelofibrosis and Post-Polycythemia Vera-Myelofibrosis Who Have Platelet Counts of 50 to 100

## **Sarcoma**

A Phase III Multicenter, International, Randomized, Double-Blind, Placebo-Controlled Study of Doxorubicin plus Palifosfamide-tris vs. Doxorubicin Plus Placebo in Patients with Front-Line Metastatic Soft Tissue Sarcoma

## **Supportive Care**

An Assessment of Chemotherapy-Induced Nausea and Vomiting from a Patient-Centered Outcomes Research Perspective

Registry of Caris Target Now Test Results (Biomarker Expression Patterns) and Hematopoietic Diagnostics for Evaluation of Correlation with Clinical Outcomes for Cancer and Other Patients

## **Tissue Sample Collection**

Collection of Patients' Tumor Tissue for Analysis of Molecular Markers that Predict for Benefit from Cancer Therapies

## **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

### **ITP**

Phase I/II Study of Immunotherapy with Humanized Anti-CD-20 Antibody, IMMU-106 (hA20) in Adults with Chronic ITP

### **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

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

### **Head and Neck**

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

A Phase III Trial Evaluating the Addition of Cetuximab to Paclitaxel, Cisplatin, and Radiation for Patients with Esophageal Cancer Who are Treated Without Surgery

### **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



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

- Acute Myeloid Leukemia
- Early-Stage Breast cancer
- Acquired Thrombotic Thrombocytopenic Purpura
- Metastatic Breast Cancer
- Pancreatic Cancer



# CANCER CARE CENTERS of South Texas

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September 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

## PRACTICE LOCATIONS - San Antonio

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 4411 Medical Dr., Ste 100, 210-595-5300  
 2130 NE Loop 410, Ste 100, 210-656-7177  
 4025 E. Southcross, Bldg 5, Ste 30, 210-337-4494  
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 11212 State Hwy. 151, Ste 190, 210-242-6506

### Kerrville

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### Fredericksburg

204 W. Schubert, 830-990-0255

### New Braunfels

1448 E. Common St., 830-643-1762

### Seguin

1348 E. Walnut St., Ste 1348, 830-379-8688

### Hondo

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### Uvalde

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### Jourdanton

1901 Hwy 97E, Ste 200, 830-769-5259

### Boerne

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### Marble Falls

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### Floresville

497 10th St., Suite 102, 210-242-6506

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# CANCER CARE CENTERS of South Texas



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Cancer Care Centers of South Texas (CCCST) is a comprehensive cancer care practice with 16 locations in the San Antonio area including, New Braunfels, Seguin, Kerrville, Fredericksburg, Marble Falls, Boerne, Uvalde, Jourdanton, Hondo 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.