

CLINICAL TRIALS UPDATE

May 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.

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Dear Colleagues,

At Cancer Care Centers of South Texas our goal is to continually provide more treatment options for patients with cancer and disorders of the blood, through our active clinical trials research program. We are very excited to inform you about a new clinical trial, that we now have open to enrollment, for patients with Idiopathic Thrombocytopenic Purpura (ITP).

"A Phase III Study of Immunotherapy with Humanized Anti-CD20 Antibody, Immu-106 (hA20), in Adult Patients with Chronic Immune Thrombocytopenic Purpura (ITP)"

The goal of current treatment guidelines for adult patients with ITP is to maintain a platelet level above $30 \times 10^9/L$. Conventional first-line therapy for ITP is corticosteroids with or without IV immunoglobulins, although many patients relapse when the steroids are tapered. The next standard therapy is splenectomy, but patients with refractory ITP who do not respond, will require further therapy. Other treatments such as immunosuppressive agents typically only produce short-term responses.

In patients with ITP, the effectiveness of anti-CD20 immunotherapy has been demonstrated in several previous clinical trials using rituximab, a chimeric monoclonal antibody. The use of IMMU-6, a humanized anti-CD20 monoclonal antibody, may be more effective, with a better safety and pharmacokinetic profile, while being less immunogenic. Previous clinical trials studying the use of IMMU-6 in patients with ITP have shown encouraging response rates even at the lower dosage levels, as reported at the American Society of Hematology Annual Meeting in December 2009.

The target population for this study, using IMMU-6, is adult patients with chronic ITP who have failed at least one standard ITP therapy and have a platelet count below $30 \times 10^9/L$. Patients in this study will receive IMMU-6 twice, two weeks apart, administered either IV at one of three dose levels (80, 120, or 200 mg), or by subcutaneous injection at one of three dose levels (80, 160, or 320 mg).


For eligibility criteria or more information about this trial, please call the CCCST research office at 210-595-5683. For more information about the other clinical trials that we currently have open please feel free to call any of our research offices. As always you may call any of the CCCST physicians for more information about our extensive clinical trial program.

Sincerely,

Roger M. Lyons, MD, FACP



CANCER CARE CENTERS
of South Texas

 United in Healing with US Oncology

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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, Multi-Center, Open-Label, Phase III Study of Adjuvant Lapatinib, Trastuzumab, Their Sequence and Their Combination in Patients with HER2/ErbB2 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

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

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

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

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

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

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, Randomized, Parallel-Group Study of Bendamustine Hydrochloride and Rituximab (BR) Compared with Rituximab, Cyclophosphamide, Vincristine, and Prednisone (R-CVP) or Rituximab, Cyclophosphamide, Doxorubicin, Vincristine, and Prednisone (R-CHOP) in the First-Line Treatment of Patients with Advanced Indolent Non-Hodgkin's Lymphoma or Mantle Cell Lymphoma

A Randomized, Multicenter Study Comparing Pixantrone 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

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

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 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
**trial currently 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

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

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

UPCOMING TRIALS

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

- Indolent B-Cell Non-Hodgkin's Lymphoma
- Acute Myeloid Leukemia
- Primary Myelofibrosis
- Post-Essential Thrombocythemia Myelofibrosis
- Post-Polycythemia Vera Myelofibrosis



CANCER CARE CENTERS of South Texas

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A MEMBER OF THE US ONCOLOGY RESEARCH NETWORK

May 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
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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.