Clinical Trial: MDA 3410 Study Summary

The following clinical trial Study Summary should be used for consultation with your healthcare provider

Additional questions should be directed to Shi-Ming Tu, MD at 713-563-7268 or by email stu@mdanderson.org
Protocol:

MDA 3410

Title:

A Prospective Randomized Phase III, Trial Comparing Consolidation Therapy With or Without Strontium-89 Following Induction Chemotherapy in Androgen-Independent Prostate Cancer

Sponsors:

M.D. Anderson Cancer Center, National Cancer Institute (NCI)

Participating Study Sites:

This clinical trial is recruiting at study sites throughout the United States. Please see the attached list of participating sites for a complete listing

Purpose:

This randomized phase III trial studies giving chemotherapy together with strontium-89 to see how well it works compared to chemotherapy alone in treating patients with prostate cancer that has spread to the bone

Objectives:

Primary:

- Compare the effectiveness, in terms of overall survival, of consolidation therapy with or without strontium chloride (Sr89) after induction chemotherapy in patients with androgen-independent prostate cancer.

Eligibility:

- Diagnosis of adenocarcinoma of the prostate (no small cell carcinoma)
- Androgen-independent with no evidence of response after either of the following anti-androgen withdrawal periods:
  - Within 4 weeks for flutamide
  - Within 6 weeks for bicalutamide or nilutamide
- Rising prostate-specific antigen (PSA) (at least 5 ng/mL) on at least 2 occasions at least 1 week apart AND bone pain OR worsening bone scan with new lesions in less than 6 months
- Castrate testosterone level no greater than 50 ng/mL (must continue treatment to maintain castrate levels)
- No symptomatic lymphadenopathy (scrotal or pedal edema) or significant local invasive disease (hematuria)
- Osteoblastic metastases on bone scan or CT scan
- No predominant visceral metastases to liver, lungs, or brain
**Patient Characteristics:**

- Zubrod performance status 0-3
- Life expectancy at least 12 weeks
- Hematopoietic:
  - WBC greater than 3,000/mm^3
  - Absolute neutrophil count greater than 1,500/mm^3
  - Platelet count greater than 100,000/mm^3
- Hepatic:
  - Bilirubin no greater than 2 times upper limit of normal (ULN)
  - AST and ALT no greater than 2 times ULN
- Cardiovascular:
  - No transient ischemic attack or myocardial infarction within the past 12 months
  - No active angina or claudication sufficient to limit activity
  - No symptomatic congestive heart failure
  - No unstable angina pectoris
  - No cardiac arrhythmia
- Other:
  - Fertile patients must use effective contraception
  - No prior allergic reaction to compounds of similar biologic or chemical composition to study drugs
  - No other conditions (e.g., pernicious anemia) associated with achlorhydria
  - No other active malignancy or malignancy that is likely to become active except non-melanoma skin cancer
  - No ongoing or active infection
  - No psychiatric illness or social situation that would preclude study participation
  - No other uncontrolled concurrent illness that would preclude study participation
Prior/Concurrent Therapy:

- At least 4 weeks since prior immunotherapy and recovered
- Prior angiogenesis inhibitors and gene therapy allowed
- At least 4 weeks since prior chemotherapy (6 weeks for nitrosoureas or mitomycin) and recovered
- No prior doxorubicin or vinblastine for patients receiving induction chemotherapy with KAVE (ketoconazole, doxorubicin, vinblastine, estramustine)
- No prior docetaxel for patients receiving induction chemotherapy with prednisone plus docetaxel
- Prior secondary hormonal agents (e.g., aminogluthethimide, diethylstilbestrol, or estramustine) allowed
- Prior steroid therapy (e.g., dexamethasone, prednisone, or hydrocortisone) allowed
- At least 4 weeks since prior radiotherapy and recovered
- No prior strontium chloride (Sr89) or samarium (Sm153) lexicronam pentasodium
- No prior vagotomy
- No more than 1 prior cytotoxic regimen

Contact:

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M.D. Anderson Cancer Center
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stu@mdanderson.org
Clinical Trial MDA 3410 – Participating Study Sites

For site specific contact information, please refer to www.clinicaltrials.gov and search MDA 3410
OR call Shi-Ming Tu, MD at 713-563-7268 OR email stu@mdanderson.org

California
Akron City Hospital, Akron

Florida
Halifax Medical Center, Daytona Beach
M.D. Anderson Cancer Center – Orlando, Orlando

Georgia
Northeast Georgia Medical Center, Gainesville

Iowa
Hematology Oncology Associates/Quad Cities, Bettendorf
Genesis Medical Center - East Campus, Davenport
Finley Hospital, Dubuque

Illinois
Crossroads Cancer Center, Effingham
Sherman Hospital, Elgin
Decatur Memorial Hospital, Decatur
Medical & Surgical Specialists, Galesburg
Hines Veteran's Administration Hospital, Hines
Memorial Medical Center, Springfield
Southern Illinois University, Springfield

Indiana
Saint Francis Hospital and Health Centers, Beech Grove
Reid Hospital and Health Care Services, Richmond

Kansas
Cancer Center of Kansas – Chanute, Chanute
Cancer Center of Kansas – Dodge, Dodge City
Cancer Center of Kansas – El Dorado, El Dorado
Providence Medical Center, Kansas City
Kansas (Continued)

Cancer Center of Kansas – Kingman, Kingman
Lawrence Cancer Center, Lawrence
Lawrence Memorial Hospital, Lawrence
Southwest Medical Center, Liberal
Shawnee Mission Medical Center, Mission
Cancer Center of Kansas – Newton, Newton
Radiation Oncology Center of Olathe, Olathe
Menorah Medical Center, Overland Parks
Mid-American Sarcoma Institute, Overland Park
South Kansas City Surgical Center, Overland Park
Cancer Center of Kansas – Parsons, Parsons
Cancer Center of Kansas – Pratt, Pratt
Cancer Center of Kansas – Salina, Salina
Georgetown Medical Building, Shawnee
Cancer Center of Kansas – Wellington, Wellington
Cancer Center of Kansas – Main, Wichita
Cancer Center of Kansas – Medical Art Tower, Wichita
Harry Hines Memorial Hospice, Wichita
University of Kansas – Wichita, Wichita
Veteran’s Administration Medical Center, Wichita
Via Christi Regional Medical Center, Wichita
Wesley Medical Center, Wichita
Wichita State University, Wichita
Cancer Center of Kansas – Winfield, Winfield

Michigan

Battle Creek Health System, Battle Creek
Mecosta County Medical Center, Big Rapids
Spectrum Health – Blodgett Campus, East Grand Rapids
Metro Health Hospital, Grand Rapids
Saint Mary’s Healthcare, Grand Rapids
Spectrum Health – Butterworth Campus, Grand Rapids
Holland Community Hospital, Holland
Kalamazoo Center for Medical Studies, Kalamazoo
Hackley Hospital, Muskegon
Michigan (Continued)

Northern Michigan Hospital, Petoskey
Munson Medical Center, Traverse City

Missouri

Independence Regional Health Center, Independence
Freeman Health System, Joplin
Saint John’s Regional Medical Center, Joplin
Heartland Surgical Associates, Kansas City
Kansas City Surgical Group, Kansas City
Liberty Radiation Oncology Clinic, Kansas City
North Kansas City Hospital, North Kansas City
Resource Center for Gynecologic Oncology, Kansas City
Saint Joseph Health Center, Kansas City
Saint Luke’s Hospital of Kansas City, Kansas City
Specialists in Cancer Care, Kansas City
Phelps County Regional Medical Center, Rolla
Springfield Bonds Clinic, Rolla
Cancer and Hematology Center, Springfield
Cox Medical Center, Springfield
Oncology – Hematology Associates of Springfield, Springfield
Saint John’s Hospital, Springfield
Heartland Regional Medical Center, St. Joseph

Montana

Billings Clinic, Billings
Saint Vincent Hospital, Billings
Northern Rockies Radiation Oncology Center, Billings
Deaconess Medical Center Billings MT
Montana Cancer Consortium CCOP, Billings
Hematology-Oncology Centers of the Northern Rockies, P.C., Billings
Bozeman Deaconess Hospital, Bozeman
Bozeman Deaconess Cancer Center, Bozeman
Saint James Community Hospital and Cancer Treatment Center, Butte
Benefis Healthcare - Sletten Regional Cancer Institute, Great Falls
Great Falls Clinic, Great Falls

Updated June 8, 2007
Montana (Continued)

Berdeaux, Donald, M.D., Great Falls
Saint Peter's Community Hospital, Helena
Kalispell Regional Medical Center, Kalispell
Glacier Oncology, PLLC, Kalispell
Kalispell Medical Oncology, Kalispell
Community Medical Hospital, Missoula
Saint Patrick Hospital - Community Hospital, Missoula
Montana Cancer Specialists, Missoula
Guardian Oncology and Center for Wellness, Missoula

North Carolina

Mission Hospitals, Inc, Asheville
Wayne Memorial Hospital, Goldsboro
Wayne Radiation Oncology, Goldsboro
Wilson Medical Center, Wilson

Ohio

Grandview Hospital, Dayton
Good Samaritan Hospital – Dayton, Dayton
Miami Valley Hospital, Dayton
Veteran Affairs Medical Center, Dayton
Samaritan North Health Center, Dayton
Dayton CCOP, Dayton
Kettering Medical Center, Kettering
Middletown Regional Hospital, Middletown
Cancer Care Center, Incorporated, Salem
Upper Valley Medical Center, Troy
Cancer Treatment Center, Wooster
Greene Memorial Hospital, Xenia

Pennsylvania

Albert Einstein Medical Center, Philadelphia
South Carolina

Cancer Centers of the Carolinas – Easley, Easley
Cancer Centers of the Carolinas – Self Memorial Hospital, Greenwood
Self Memorial Hospital, Greenwood
Cancer Centers of the Carolinas – Grove Commons, Greenville
Greenville Memorial Hospital, Greenville
Saint Francis Hospital, Greenville
Cancer Centers of the Carolinas – Seneca, Seneca
Cancer Centers of the Carolinas – Spartanburg, Spartanburg

Tennessee

University of Tennessee – Memphis, Memphis

Texas

Medical City Dallas Hospital, Dallas
M D Anderson Cancer Center, Houston

Washington

Saint Joseph Hospital, Bellingham
Swedish Hospital Medical Center, Seattle
University of Washington Medical Center, Seattle
Group Health Cooperative, Seattle
Cancer Care Northwest - Spokane South, Spokane

Wisconsin

Marshfield Clinic – Chippewa Center, Chippewa Falls
Marshfield Clinic Cancer Care at Regional Cancer Center, Eau Claire
Sacred Heart Hospital, Eau Claire
Marshfield Clinic – Ladysmith Center, Ladysmith
Marshfield Clinic, Marshfield
Saint Joseph’s Hospital, Marshfield
Marshfield Clinic – Lakeland Center, Minocqua
Marshfield Clinic Indian Head Center, Rice Lake
Saint Michael’s Hospital, Stevens Point
Marshfield Clinic – Wausau Center, Wausau
Marshfield Clinic – Wisconsin Rapids Center, Wisconsin Rapids

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Wyoming

Welch Cancer Center, Sheridan