

## RESEARCH

WILLIAM B. WEBSTER, Jr., Pharm.D., FCCP, BCPS

### GRANTS and APPROVED PROTOCOLS CLINICAL RESEARCH

- 2000 to 2001 Phase I/II Radioimmunotherapy of Non-Hodgkin's Lymphoma with Radiolabeled Humanized Immu-LL2: Treatment with 90Y-hLL2 IgG (#02340) Harwood SJ - Principal Investigator, **Webster W, Co-Investigator**. Immunomedics, Inc.
- 2000 to 2001 Pharmacokinetics and Biodistribution of Multiple Administrations of CEA-Scan (Arcitumomab) Following Complete Resection of Primary Colorectal Carcinoma Harwood SJ - Principal Investigator, **Webster W, Co-Investigator**. Immunomedics, Inc.
- 2000 to 2001 A Multicenter, Open Label Trial to Evaluate the Efficacy and Safety of IDEC-Y2B8 Radioimmunotherapy of Relapsed or Refractory Low-Grade or Follicular Transformed B-Cell Non-Hodgkin's Lymphoma Harwood SJ - Principal Investigator, **Webster W, Co-Investigator**. IDEC Pharmaceuticals
- 2000 to 2001 **Webster, W.B.**, Hakki, Sam I., **Principal Investigators**, Camblin JG, Nasser A, Morrissey M, Hoeldtke J. Clinical Protocol for a Double-blind, Placebo-Controlled, Randomized Study of the Efficacy of Parecoxib 20 mg IV and Parecoxib 40 mg IV Given Postoperatively to Determine Narcotic-Sparing Effectiveness in a Post-Orthopedic Surgery Pain Model, IND # 52,613. SIREX/G.D. Searle.
- 2000 to 2001 A Randomized, DB, Comparative Study of H376/95 and Enoxaparin for Prevention of Venous Thromboembolism following Total Hip Arthroplasty (BP#2300) Hakki, Sam I., Principal Investigator, **Webster, W.B. Co-Investigator**, Camblin JG, Nasser A, Morrissey M, Hoeldtke J. Astra Zeneca
- 2000 to 2001 Clinical Protocol for a Double-Blind, Placebo-Controlled Comparison of the Narcotic Sparing Activities of Valdecoxib 20 mg, Valdecoxib 40 mg, and Placebo in Post-Orthopedic Surgical Patients. Hakki, Sam I., Principal Investigator, **Webster, W.B. Co-Investigator**, Camblin JG, Nasser A, Morrissey M, Hoeldtke J. SIREX/Searle
- 1998 to 2001 Clinical Protocol For a Double-Blind, Placebo Controlled Evaluation of the Analgesic Activity of Parecoxib 20 mg IV and Parecoxib 40 mg IV Administered Pre-Operatively in a Postsurgical Orthopedic Pain Model. Protocol N93-99-02-037 US IND #52,613. Hakki, Sam I., Principal Investigator, **Webster, W.B. Co-Investigator**, Camblin JG, Nasser A, Morrissey M, Hoeldtke J. SIREX/Searle
- 1998 to 2001 CP-98-020 Expanded Access Study of Iodine-131 Anti-B1 Antibody for Relapsed/Refractory Low-Grade and Transformed Low-Grade Non-Hodgkin's Lymphoma. BB-IND 3323 Harwood SJ - Principal Investigator, **Webster W, Co-Investigator** Coulter Pharmaceutical, Palo Alto, Ca \$56,000 to date
- 1998 to 2001 A prospective Study of the AcuTect Imaging Characteristics of Patients with Acute Deep Vein Thrombosis and Patients with Post Phlebitic Syndrome. (Phase IV). **Principal Investigators Webster, W.B.**, and Harwood, SJ. Diatide, Inc., Londonberry NH.
- 1997 to 1998 A Multicenter Open-label Study Evaluating the Safety of Technetium (Tc-99m) P280 in Patients at Risk for Venous Thrombosis. (Phase III) ,

- Principal Investigators Webster, W.B.**, and Harwood, SJ, Co-Investigators: Camblin J, Hakki S, Webster T, Carroll R. Diatide, Inc., Londonberry NH.
- 1997 to 1999 A Multicenter, Double-Blind, Four-Arm, Parallel-Group, Comparative Study to Evaluate the Safety and Efficacy of Sn-117m DTPA and Metastron for Palliation of Bone Pain from Osseous Metastases in Prostate Cancer Patients. (Phase III) Harwood SJ - Principal Investigator, **Webster W**, Sochet A, Hakki S, Tantranond P, Hudson P, Morrissey M, Gibbons, L. Diatide, Inc., Londonberry NH.
- 1997 to 2001 A Multi-Center Study Evaluating the Safety and Efficacy of Technetium (Tc99m) P829 for the Detection and Localization of Cancer in the Lung.(Phase III) Harwood SJ - Principal Investigator, **Webster W**, Carroll R, Parikh SL, Bonilla-Santiago J, Tannenbaum M, Riveron E, Morrissey M. Diatide, Inc., Londonberry NH.
- 1997 to 2001 Utility of LymphoScan Imaging in the Detection of Residual Tumor after Chemo and/or Radiotherapy in Patients with Non-Hodgkin's Lymphoma (Protocol IM-D-LL2-05). (Phase III) **Webster, W.B.** and Harwood, SJ Co-Principal Investigators. Immunomedics Corp., Newark, NJ.
- 1997 to 2001 The Utility of LymphoScan Imaging in the Localization and Staging of Patients with Non-Hodgkin's Lymphoma (Protocol IM-D-LL2-05).(Phase III) **Webster, W.B.** and Harwood, SJ Co-Principal Investigators. Immunomedics Corp., Newark, NJ.
- 1997 to 1999 Pilot Study Evaluating the Safety and Efficacy of Technetium Tc99m P280 In the Detection of Carotid Artery Thrombi. (Phase II/III) **Webster, W.B.** and Harwood, SJ Co-Principal Investigators. Diatide, Inc., Londonberry NH.
- 1996 to 1997 Protocol Number: 280-11, A Multi-Center, Open Label Study evaluating the Pharmacokinetics and Radiation Dosimetry of Technetium Tc99m P280 in Patients at Risk for Venous Thrombosis.(Phase III) Harwood, SJ, and **Webster, W.B. Principal Investigators.** Diatide, Inc., Londonberry NH.
- 1994 to 1997 Protocol Number IM-D-MN3-15, Comparative Pharmacokinetics, Dosimetry and In-Vivo Stability of Two Formulations of 99mTc-Labeled Anti-Granulocyte Antibody Fab' Fragment (IMMU-MN3, LeukoScan™) in Patients Undergoing Arthroscopic Procedures. (Phase II/III - Bioequivalence of commercial scale-up) Harwood, SJ and **Webster, WB, Principal Investigators.** Immunomedics Corp., Newark, NJ.
- 1994 to 1998 Protocol Number 1033-PK Pharmacokinetics of Tc-99m-Labeled Anti-CEA Antibody IMMU-4 Lot (Phase II/III)Commercial scale up) #304121 in Patients with Known Colorectal Carcinoma. **Webster, WB, Principal Investigator.** Immunomedics Corp., Newark, NJ.
- 1992 to 1998 Safety and Efficacy of Tc-99m-Labeled Anti-Granulocyte Antibody Fab' Fragment (IMMU-MN3) in the Detection of Infected Prosthetic Joints.(Phase III) Harwood, SJ and **Webster, WB, Principal Investigators.** Immunomedics Corp., Newark, NJ.

- 1992 to 1998 Safety and Efficacy of Tc-99m-Labeled Anti-Granulocyte Antibody Fab' Fragment (IMMU-MN3) for the Diagnosis of Long Bone Osteomyelitis. (Phase III) Harwood, SJ and **Webster, WB, Principal Investigators.** Immunomedics Corp., Newark, NJ.
- 1992 to 1998 Safety and Efficacy of Tc-99m-Labeled Anti-Granulocyte Antibody Fab' Fragment (IMMU-MN3) for the Diagnosis of Osteomyelitis in Patients with Diabetic Foot Ulcers.(Phase III) Harwood, SJ and **Webster, WB, Principal Investigators.** Immunomedics Corp., Newark, NJ.
- 1993 to 1994 Pharmacokinetics, Dosimetry, and Detection of Lung Carcinoma by Diagnostic Imaging of FAB' Fragment of the Anti-CEA Antibody Labeled with Tc-99m. (Phase III) Harwood, SJ and **Webster, WB, Principal Investigators.** Immunomedics Corp., Newark, NJ.
- 1993 to 1994 Pharmacokinetics, Dosimetry and Imaging of Tc-99m-labelled Anti-CEA Antibody IMMU-4 Lot (Commercial Scale Up) #304121 in Patients with Known Colorectal Carcinoma. (Phase III) Harwood, SJ and **Webster, WB, Principal Investigators.** Immunomedics Corp., Newark, NJ..
- 1992 to 1993 Detection of Lung Carcinoma by Diagnostic Imaging of FAB' Fragment of the Anti-CEA Antibody Labeled with Tc-99m. (Phase III) Harwood, SJ and **Webster, WB, Principal Investigators.** Immunomedics Corp., Newark, NJ.
- 1992 Evaluation of Safety and Efficacy in Detection of Non-Hodgkin's B-Cell Lymphoma by Diagnostic Imaging of FAB' Fragment of the Anti-Lymphoma (B-Cell) Antibody IMMU-LL-2 Labeled with Tc-99m. (Phase III) Harwood, SJ and **Webster, WB, Principal Investigators.** Immunomedics Corp., Newark, NJ.
- 1992 Detection of Breast Carcinoma by Diagnostic Imaging of FAB' Fragment of the Anti-CEA Antibody IMMU-4 Labeled with Tc-99m. (Phase III) Harwood, SJ and **Webster, WB, Principal Investigators.** Immunomedics Corp., Newark, NJ.
- 1992 Detection of Hepatocellular Carcinoma by Diagnostic Imaging of FAB' Fragment of the Anti-AFP Antibody IMMU-31 Labeled with Tc-99m. (Phase III) Harwood, SJ and **Webster, WB, Principal Investigators.** Immunomedics Corp., Newark, NJ.
- 1992 Radioimmunodetection of Residual Recurrent or Metastatic Trophoblastic and Germinal Cell Tumors using <sup>99m</sup>Tc-Anti-hCG or Anti-AFP Antibody fab' Fragment. (Phase III) Harwood, SJ and **Webster, WB, Principal Investigators.** Immunomedics Corp., Newark, NJ.
- 1992 to 1993 Radioimmunoscintigraphy of Recurrent of Metastatic Colorectal Cancer with <sup>99</sup>Tc-88BV59H21-2V67-66, A Totally Human Antibody. Phase III Multi-center Study. (Phase III) Carroll RG, Principal Investigator, **Webster WB, Co-Investigator.** Organon Teknika/Biotechnology Research Institute, 1330A Piccard Drive, Rockville, MD.
- 1992 to 1993 Preoperative Immunoscintigraphy and Intraoperative Oncoprobe Assisted Detection of Colorectal Carcinoma after Intravenous Administration of <sup>99</sup>Tc-88BV59H21-2. (Phase III) Carroll RG, Principal

- Investigator, **Webster WB, Co-Investigator.** Organon  
Tekinika/Biotechnology Research Institute, 1330A Piccard Drive,  
Rockville, MD.
- 1991 to 1994 Post-Doctoral Fellowship (2 years) - Biotechnology: Antibody  
Immunoconjugates and Immunotherapeutics. **Webster WB, Principal  
Preceptor,** Glaxo Pharmaceutical, Research Triangle, N.C., \$ 81,000
- 1990 to 1993 Safety and Preliminary Efficacy of Intravenous Administration of <sup>111</sup>In-  
CYT-356 in the imaging of Prostate Cancer: Pre-surgical Staging,  
Dosimetry. (Phase III) Harwood SJ and **Webster WB, Principal  
Investigators.** Cytogen Corporation, Princeton, NJ.
- 1990 to 1993 Phase I/II Clinical Study: Detection of Colorectal Carcinoma Using IVP  
ZCE025, an <sup>111</sup>In-Labeled Anti-CEA MoAb (Dose Ranging Protocol).  
(Phase III) Carroll RG, Principal Investigator, **Webster WB, Co-  
Investigator.** Hybritech, La Jolla, Ca.
- 1989 to 1993 Repeat Intravenous Infusions of <sup>111</sup>In-CYT-103 in the Imaging and  
Detection of Recurrent Colorectal Carcinoma. (Phase III) Harwood SJ  
and **Webster WB, Principal Investigators.** Cytogen Corporation,  
Princeton, NJ.
- 1989 to 1990 <sup>111</sup>In-CYT-103 in the Imaging of Occult Colorectal Carcinoma:  
Dosimetry. (Phase III) Harwood and **Webster WB, Principal  
Investigators.** Cytogen Corporation, Princeton, NJ 1989.
- 1988 to 1989 Phase III Study of CYT-103 <sup>111</sup>In in the Imaging of Colorectal  
Carcinoma: Pre-surgical Staging. Harwood SJ and **Webster WB,  
Principal Investigators.** Cytogen Corporation, Princeton, NJ.
- 1988 to 1989 Phase III Study of CYT-103 <sup>111</sup>In in the Imaging of Occult Colorectal  
Carcinoma. (Phase III) Harwood SJ and **Webster WB, Principal  
Investigators.** Cytogen Corporation, Princeton, NJ.
- 1988 Phase I/II Study of <sup>111</sup>In-CYT-103 in the Imaging of Colorectal  
Carcinoma. Harwood SJ and **Webster WB, Co-Principal  
Investigators.** Cytogen Corporation, Princeton, NJ.
- 1987 Specificity of ZCE 025 (Fab)<sup>2</sup> Localization In Human Colorectal  
Cancer, VA Merit Review Board, Robert G. Carroll, Principal  
Investigator and **W. B. Webster, Co-Investigator,**

#### **GRANTS and APPROVED PROTOCOLS- CLINICAL PRACTICE**

- 1998 to 2001 The Role of TPF1 Levels with Enoxaparin Use in DVT Prophylaxis of Major  
Surgery (VA Career Development - Type I). Sam I. Hakki, MD, Principal  
Investigator, Robson, MC and **Webster, W.B.** Co-investigators.
- 1997 to 2001 Incidence of Nocturia and Relationship of Time of Administration in Veteran  
Population taking Alpha-Adrenergic Blocking Agents for the Treatment of  
Benign Prostatic Hyperplasia. Shaw B, Principal Investigator **Webster,  
W.B.** Co-investigator. Resident Project Bay Pines VAMC.
- 1997 to 2001 Evaluation of Metered Dose Inhaler Delivery Above Specified Number of  
Inhalations. Roman L, Principal Investigator **Webster W,** Co-investigator.  
Resident Project Bay Pines VAMC

- 1997 to 2001 Evaluation of Increased Serum Glucose Levels in Patients receiving Protease Inhibitors. Holloway FD Principal Investigator, **Webster, W.B.** Co-investigator. Resident Project Bay Pines VAMC.
- 1997 to 2001 Therapeutic Drug Monitoring in Patients Treated for Hyperlipidemia. Jackson N, **Webster W**, Resident Research Bay Pines VAMC
- 1997 to 2001 A survey of Patient's Perception of an Ambulatory Care Pharmacist in a Home Based Primary Care Setting. Calara R, Principal Investigator **Webster WB**, Laucka P, Co-investigators. Resident Project, Bay Pines VAMC.
- 1997 to 2001 Effects of Enoxaparin on TFPI and Anti-Xa Release in Prophylaxis of VTED in Hip of Knee Arthroplasty Surgery. Hakki S, Camblin J, **Webster WB**, Hill K, Fareed T. Bay Pines VAMC, Extramural funding pending.
- 1995 to 1997 Weight-Based Dosing of Heparin in Coronary Care. Nowacki, Gail, Rozance, Victor, **Webster, WB**. Unfunded Resident Research.
- 1988 Impact of a Pharmacy Based Phlebotomy service Integrated Into Aminoglycoside Clinical Pharmacokinetics Team. Lewis MJ, Principal Investigator, **Webster WB**, Co-Investigator. Bristol Laboratories.

## PROCEDURES and RESEARCH ACTIVITIES

- 1997 Procedure: Reverse phase gradient HPLC for: Protocol Number: 280-11, A Multi-Center, Open Label Study evaluating the Pharmacokinetics and Radiation Dosimetry of Technetium Tc99m P280 in Patients at Risk for Venous Thrombosis.(Phase III)
- 1995 Supporting authority for hearing before FDA/CBER Rockville, Md for protocol below
- 1994 Procedure: Size exclusion HPLC with radio detection for protocol below
- 1994 Authored pharmacokinetic and bioequivalence portions of the protocol accepted by FDA: Protocol Number IM-D-MN3-15, Comparative Pharmacokinetics, Dosimetry and In-Vivo Stability of Two Formulations of 99mTc-Labeled Anti-Granulocyte Antibody Fab' Fragment (IMMU-MN3, LeukoScan™) in Patients Undergoing Arthroscopic Procedures. (Phase II/III - Bioequivalence of commercial scale-up)
- 1994 Designed a retrospective cohort pharmacokinetic study for bioequivalence of investigational and commercial scale-up products -- Analysis accepted by FDA/CBER and product accepted: Protocol Number 1033-PK Pharmacokinetics of Tc-99m-Labelled Anti-CEA Antibody IMMU-4 Lot (Phase II/III) Commercial scale up) #304121 in Patients with Known Colorectal Carcinoma.
- 1990 Co-Authored pharmacokinetic portion of FDA accepted protocol: Safety and Preliminary Efficacy of Intravenous Administration of <sup>111</sup>In-CYT-356 in the imaging of Prostate Cancer: Pre-surgical Staging, Dosimetry. (Phase III)
- 1988 Co-Authored pharmacokinetic portion of FDA accepted protocol: Phase I/II Study of <sup>111</sup>In-CYT-103 in the Imaging of Colorectal Carcinoma.

- 1987                    Authored pharmacokinetic and statistical analysis portion of approved  
VA Merit grant: Specificity of ZCE 025 (Fab')<sub>2</sub> Localization In Human  
Colorectal Cancer
- 1986 to 2001    Pharmacokinetics and Tissue Distribution of Radiolabeled Monoclonal  
Antibodies and other Radioimmunodiagnostics and  
Radioimmunotherapeutics  
                          In association with: Steven J. Harwood, M.D., Ph.D., Robert G.  
                          Carroll, M.D.
- 1982 to 1984            Stereospecific Binding of Propranolol to Serum Proteins  
                          In association with: John A. Pieper, Pharm.D.
- 1980 to 1982            Determination of Pancreatic Alpha Subtype Receptors by Radioligand  
Binding Technique  
                          In association with: Mona M. McConnaughey, Ph.D.