

Gary L. Schroeder, MD

Office Address: University Medical Center
HIV Wellness Center
2300 S. Rancho Drive, Suite #205
Las Vegas, NV 89102
Office: (702) 383-2691
Fax: (702) 388-4114

Hospital Affiliation: University Medical Center of Southern Nevada
1800 W. Charleston Boulevard
Las Vegas, NV 89102
(702) 383-2606

EDUCATION AND TRAINING

1991 Residency Program, Shadyside Hospital, Pittsburgh, PA
Specialty - Family Practice

1988 Doctorate in Medicine, Ohio State College of Medicine,
Columbus, Ohio

1984 Bachelor of Arts in Zoology, Minor in Gerontology,
Miami University, Oxford, Ohio

PROFESSIONAL CERTIFICATION AND LICENSURE

1992 Licensed Medical Doctor, State of Nevada

1992 Certified in Family Practice, State of Virginia

1989 Completed and passed National Boards
Recertified 1998

PROFESSIONAL EXPERIENCE

June 1992 - Present Staff Physician, University Medical Center HIV
Wellness Center, 1112 Shadow Lane, Las Vegas,
NV

June 1992 - Present Community Health Centers of Southern Nevada,
235 N. Eastern Avenue, Suite #102, Las Vegas, NV

PROFESSIONAL EXPERIENCE

July 1991-July 1992 Staff Physician, Kaiser-Permanente Capital Area,
Permanente Medical Group of Washington, D.C.,
Woodbridge, VA

PROFESSIONAL AFFILIATIONS

2000 - Present American Academy of HIV Medicine (AAHIVM)
1991 - Present American Association of Family Practice

RESEARCH

Azithromycin. Oral/Intravenous Azithromycin Treatment of Cryptosporidiosis in Patients Whose Disease has not been Controlled by Conventional Therapy (066-167S). Investigator, Premier Research.

Vistide (Cidofovir). IV Treatment IND Protocol for Relapsing Cytomegalovirus Retinitis in Patients with AIDS (GS 95120). Investigator, Gilead Sciences.

Saquinavir. HIV Proteinase Inhibitor Saquinavir Ro 31-8959 (SV14604). Investigator, F. Hoffman LaRoche Limited.

Saquinavir Ro 31-8959 A Continuation Protocol with Open Label Saquinavir for HIV-Infected Patients Who Have Completed a Clinical Trial with Saquinavir Treatment (SV 14788). Investigator, F. Hoffman LaRoche Limited.

Lamivudine. 3TC (Lamivudine) Open Label Program (NUCA 3004). Investigator, Glaxo, Inc.

Indinavir (Crixivan). A Noncomparative, Multisite, Open-Label, 48 week Study to Monitor the Safety and Tolerability of MK-0639 (Indinavir Sulfate) 800mg q8h Administered as Monotherapy or in Combination with Reverse Transcriptase Inhibitor Therapy for the Treatment of HIV-1 Infection in Advanced AIDS Patients (Patients with CD4 Counts $50\text{cells}/\text{mm}^3$ (99-00). Investigator, Merck and Co., Inc.

Mycobutin (Rifabutin). An Open-Label Randomized Pharmacological/ Pharmacodynamic study of mycobutin (Rifabutin) monotherapy, and in combination with myambutal (Ethambutal), for prophylactic use in prevention of Mycobacterium-Avium Complex (MAC) bacteria in AIDS patients with CD4 count $\leq 100\text{mm}^3$. Investigator, Pharmacia.

Viracept. Viracept Expanded Access Program (Ind# 48.124). Investigator, Auguron.

RESEARCH

Nevirapine (Viramune). An Open Label Non-Randomized Trial to Evaluate the Tolerability and safety of Viramune (Nevirapine) in Adult and Pediatric Patients with Progressive, Symptomatic HIV Disease. Protocol 1100.859. Investigator, Roxanne.

An Open-Label Multicenter Study to Assess the Safety and Antiviral Activity of a Twice-Daily Dosing Regimen of Viracept Combined with Two Reverse Transcriptase Inhibitors in HIV-Infected, Treatment Naive Patients (AG13543-1022), Investigator, Auguron

A Multicenter Open Label Randomized 24-Week Study to Compare the Safety and activity of Indinavir Sulfate 800mg Q8H Versus 1200mg Q12H in HIV-Infected Individuals Having Plasma Viral RNA Less Than 400 copies/ml on Concomitant Therapy with Two Nucleoside Analogue Reverse Transcriptase Inhibitors (NRTI) 076-00. Investigator, Merck & Company.

Preveon Expanded Access Program for the Treatment of Patients with AIDS Who Have Failed Other Antiretroviral Therapy and have Limited Treatment Options (GS-52-427). Investigator, Gilead Sciences.

Sustiva (efavirenz). Expanded Access Program DMP266-903 (IND# 49,465). Investigator, DuPont Merck.

Saquinavir. A Randomized Phase IIIB Comparative Study to Evaluate Saquinavir Soft Gel Capsules (SGC) TID Regimen in Combination with two NRTI's Versus Saquinavir Soft Gel Capsules (SGC) BID Regimen in Combination with two NRTI's Versus Saquinavir Soft Gel Capsules (SGC) BID plus Nelfinavir BID plus an NRTI in HIV-1 Infected Patients (NR5520B/M51018). Investigator, F. Hoffmann-La Roche LTD.

A 1592U89 Open Label Protocol of Adult Patients with HIV-1 Infection (CNA/3008). Investigator, Glaxo Wellcome Research & Development.

The Thalidomide Compassionate Use Program. Compassionate Use of Thalidomide in Adults with HIV-Associated Wasting (W-002), Investigator, Celgene Corp (1998).

Amprenavir (141W94). Open label protocol for patients with HIV-1 infection who have experienced treatment failure or are intolerant to protease therapy, (PR030010), Investigator, Glaxo Wellcome, Dec., 1998.

A Phase III trial to determine efficacy of bivalent AIDSVAX™ B/B vaccine in adults at risk for sexually transmitted HIV-1 infection in North America (VAX004), Investigator, Vaxgen Inc., March, 1999.

RESEARCH

Evaluation of the safety and antiviral activity of stavudine extended release formulation as compared to stavudine immediate release formulation, each as part of potent antiretroviral combination therapy. (AI455-096), Investigator, Bristol-Myers Squibb, Oct 1999.

Protocol M99-046. ABT-378/r (ABT-378/ritonavir) Early Access Program. Investigator, Abbott Laboratories, Jan 2000.

Protocol ESS 40001 A Phase IV, open-label, randomized study to compare the efficacy and safety of Epivir/Ziagen/Zerit versus Epivir/Ziagen/Sustiva versus Epivir/Ziagen/Agenerase/Norvir for 96 weeks in the treatment of HIV-1 infected subjects who are Antiretroviral therapy naive. Glaxo Wellcome. Investigator, Aug 2000.

Protocol ESS 40009 Ziagen Optimal Regimen and Resistance Observational Study. A Phase IV, Open-label study to assess the safety and tolerability of abacavir (Ziagen), in HIV-1 infected individuals and to investigate the effect of baseline genotype with virtual phenotype on the response to abacavir (Ziagen) in therapy experienced subjects in the clinical setting. GlaxoWellcome Research and Development. Principle Investigator, Aug 2000.

AI455-110. A Study to Compare Stavudine (D4T) Extended Release (ER) versus Conventional (Immediate Release, IR) Formulations, Each in Combination with Lamivudine (3TC) and Efavirenz (EFV) in Subjects who have Completed BMS Studies AI455-096 and AI455-099. Bristol-Myers Squibb. Investigator Jan 2001.

ESS40013. A Phase IV Multicenter Study of the Efficacy and Safety Of 48-Week Induction Treatment with Trizivir + Efavirenz Followed by 48-Week Randomized, Open-Label Maintenance Treatment with Trizivir ± Efavirenz in HIV-1 Infected ART Naïve Subjects. GlaxoSmithKline, Investigator Mar 2001.

HIV-TE-Evaluation Project 101. An Evaluation of the Use of the HIV-Therapy Edge (HIV-TE) Service in the Management of HIV-Positive Patients Currently Failing Antiretroviral Drug Therapy. Intelligent Therapeutic Solutions, Inc. Investigator May 2001.

CNA30021. A phase III, 48 week, randomised, double-blind, multicentre study to evaluate the safety and efficacy of abacavir (ABC) 600mg once-daily(QD) vs abacavir 300mg BID in combination with lamivudine (3TC) (300mg QD) and efavirenz (EFV) (600mg QD) in antiretroviral therapy Naive HIV-1 infected subjects. GlaxoSmithKline. Investigator November 2001.

RESEARCH

AI424-045. A randomized, open label study of the antiviral efficacy and safety of atazanavir, in combination with ritonavir or saquinavir, and the combination of lopinavir each with tenofovir and a nucleoside in subjects who have experienced virologic failure. Bristol-Myers Squibb. Investigator April 2002.

BI1182.52. Double-blind, randomized, dose optimization trial of three doses of tipranavir boosted with low dose ritonavir (TPV/RTV) in multiple antiretroviral drug-experienced subjects. Boehringer Ingelheim Pharmaceuticals, Inc. Investigator May 2002.

AI424900. Atazanavir (BMS-232632) for HIV infected individuals: An early access program. Bristol-Myers Squibb. Investigator July 2002.

BI1182.17. A long term open label rollover trial assessing the safety and tolerability of combination tipranavir and ritonavir use in HIV-1 infected subjects. Boehringer Ingelheim Pharmaceuticals, Inc. Investigator August 2002.
Boehringer Ingelheim Pharmaceuticals, Inc. Investigator August 2002.

MV16812. Multicenter, open-label, early access program of fuzeon (enfuvirtide) T-20/Ro29-9800, HIV-1 Fusion Inhibitor) in combination with free choice antiretroviral regimen to assess serious adverse events, serious AIDS defining events, and tolerability in patients with advanced HIV-infection. F. Hoffmann-LaRoche LTD, Trimeris Inc., Investigator.

BI1182.12. Randomized, open-label, comparative safety and efficacy study of tipranavir boosted with low-dose ritonavir (TPV/RTV) versus genotypically-defined protease inhibitor/ritonavir (PI/RTV) in multiple antiretroviral drug-experienced patients (RESIST-1: Randomized Evaluation of Strategic Intervention in Multi-Drug ReSistant Patients with Tipranavir). Boehringer Ingelheim Pharmaceuticals, Inc. Investigator. Jan 2003.

BI1182.51. An open label, randomized, parallel group pharmacokinetics trial of tipranavir/ritonavir (TPV/RTV), alone or in combination with RTV-boosted saquinavir (SQV), amprenavir (APV) or lopinavir (LPV), plus an optimized background regimen, in multiple antiretroviral (ARV) experienced patients. Boehringer Ingelheim Pharmaceuticals, Inc. Investigator. Jan 2003.

BI1182.58. An open label safety study to evaluate the safety of tipranavir plus ritonavir when used in combination with other agents for the treatment of patients with HIV infection who have failed and/or are intolerant to combination antiretroviral therapy and have limited treatment options. Boehringer Ingelheim Pharmaceuticals, Inc. Investigator May 2003.

RESEARCH

NN210005. A phase I, multicenter, randomized, parallel, double-blinded dose ranging, placebo-controlled study to compare antiviral effect, safety, tolerability and pharmacokinetics of four oral dosage regimens of GW695634G monotherapy versus placebo over 7 days in NNRTI-experienced HIV-1 infected adults. GlaxoSmithKline. Investigator. July 2004

COL102060. An open-label, multicenter study to evaluate the efficacy and safety of a fixed-dose combination of abacavir 600mg/lamivudine 300mg once-daily in combination with atazanavir 300mg + ritonavir 100mg once-daily in antiretroviral-naïve HIV-1 infected subjects over 48 weeks. GlaxoSmithKline. Investigator. October 2004.

ML18018D. A 12-week, prospective, open-label, multicenter, cohort study to assess HIV-patient quality of life and tolerability after administration of enfuvirtide-containing HAART (Qualite). Roche. Investigator. December 2004.

BI1182.70. An open label, non-randomized treatment protocol of tipranavir co-administered with low-dose ritonavir (TPV/r) in protease inhibitor-experienced patients with HIV-1 infection (the tipranavir expanded access program). Boehringer Ingelheim. Investigator. December 2004.

CCR102881. A Phase IIb, 96 week, randomized, partially double-blinded, multicenter, parallel group, repeat dose study to evaluate the safety, tolerability, pharmacokinetics and antiviral effect of GW873140 in combination with COMBIVIR (lamivudine and zidovudine) upon selected immunological and virological markers of HIV-1 infection in antiretroviral therapy naïve adults. GlaxoSmithKline. Investigator. March 2005.

CCR104627. A screening protocol to determine eligibility for one of three Phase III treatment studies evaluating the efficacy and safety of GW873140 in R5-tropic and R5/X4-tropic HIV -1 infected, treatment-experienced subjects with drug-resistant virus or an observational study in X4-tropic or non-phenotypeable HIV-1 infected, treatment-experienced subjects with drug-resistant virus. GlaxoSmithKline. Investigator. July 2005.

HPR20001. A phase IIb, randomized, multicenter, parallel group study to evaluate the short-term safety, pharmacokinetics and antiviral activity of four blinded dosing regimens of GW640385/ritonavir therapy compared to open-label current protease inhibitor therapy in HIV-1 infected, protease inhibitor experienced adults for 2 weeks with long-term evaluation (>48 weeks) of safety, pharmacokinetic and antiviral activity of selected GW640385/ritonavir dosing regimen(s) vs. a ritonavir-boosted, protease inhibitor containing regimen. GlaxoSmithKline. Investigator. October 2005.

RESEARCH

TMC114-C211. A randomized, controlled, open-label trial to compare the efficacy, safety and tolerability of TMC114/ritonavir versus lopinavir/ritonavir in treatment naïve HIV-1 infected subjects. ARTEMIS TRIAL. Tibotec Pharmaceuticals Ltd. Investigator. November 2005.

TMC114-C226. Early access to TMC114 in combination with low-dose ritonavir (RTV) and other antiretrovirals (ARVs) in highly treatment experienced HIV-1 infected subjects with limited or no treatment options. Tibotec Pharmaceuticals Ltd. Principal Investigator. November 2005.

References available upon request