

# Jacob Paul Lalezari, MD

## Curriculum Vitae

**Birthdate** May 2, 1959; New York City

**Office Address** Quest Clinical Research,  
2300 Sutter Street, Suite #202 & 208  
San Francisco, CA 94115

**Employment** Director, Quest Clinical Research  
(1997-present)

Co-Director, HIV Clinical Research Center  
Mt. Zion Medical Center  
University of California, San Francisco  
(1989-1997)

**Medical Staff  
Appointments** Assistant Clinical Professor of Medicine  
Department of Medicine  
University of California, San Francisco  
(1991-present)

Saint Francis Memorial Hospital  
900 Hyde Street,  
SF, CA 94109

**Education**

1986 MD, University of Pennsylvania, Philadelphia, PA  
1982 MA, University of Virginia, Charlottesville, VA  
(English Literature)  
1981 BA, University of Rochester, Rochester, NY  
1977 Scarsdale High School, Scarsdale, NY

**Professional Licensure** California License: G 61660

**Professional Training**  
1986-1989 Internal Medicine Intern and Resident,  
Mount Zion Hospital, San Francisco, California

**Board Certification**  
1990 American Board of Internal Medicine

**Awards**

1981 Phi Beta Kappa

**Teaching**

Director, Monthly Teaching Conference on HIV  
(Housestaff and Attending Physicians, 1989-1997)

**Community Service**

AIDS Project Advisory Committee, Jewish Family and  
Children's Services (1991-1997)

Report from the International AIDS Conference. Radio  
interview on KQED. Wednesday, July 10, 1996

Update on AIDS. Radio interview on KQED radio. Friday,  
May 1, 1998

**Community Publications:** Double Jeopardy: The HIV/HCV Co-Infection Handbook  
(1998).

The Future of HIV Treatment (1999).

PK and You!(2001).

**MAJOR PUBLICATIONS:**

Zalcitabine Compared with Zidovudine in Patients with Advanced HIV-1 Infection  
Who Received Previous Zidovudine Therapy. Fischl MA, Olson RM, Follansbee ST,  
**Lalezari JP**, Henry DH, Frame PT, Remick SC, Salgo MP, Lin AH, Nauss-Karoi C,  
Lieberman J, Soo W. Annals of Internal Medicine. 1993; 118: 762-769.

A Randomized Controlled Study of the Efficacy and Safety of Maintenance Treatment  
with Oral Ganciclovir for Newly Diagnosed Cytomegalovirus Retinitis in People with  
AIDS. Drew WL, Ives D, **Lalezari JP**, et al. New England Journal of Medicine.  
1995;333:615-20.

Decreased HIV-1 Plasma Viremia During Antiretroviral Therapy Reflects Down  
regulation of Viral Replication of Lymphoid Tissue. Cohen OJ, Pantaleo G, Holodniy  
M, Schnittman S, Niu M, Graziosi G, Pavlakis GN, **Lalezari JP**, Bartlett J, Steigbigel R,  
Cohn J, Noval R, McMahon D, Fauci AS. Proceedings National Academy of Science,  
1995; 92: 6017-21.

HPMPC: Results of a Phase I/II Study of a Novel Antiviral Nucleotide Analogue.  
**Lalezari JP**, Drew WL, Glutzer E, et al. Journal of Infectious Diseases, 1995;171: 788-96.

A Randomized, Double-Blind Trial of Oral Ganciclovir for the Prevention of Cytomegalovirus Disease in Persons with AIDS. Spector SA, McKinley G, **Lalezari JP**, Samo T, Andruczk R, Follansbee S, Sparti PD, Havlir DV, Simpson G, Buhles W, Wong R, Stempien MJ. New England Journal of Medicine. 1996;334:1491-97.

Intravenous Cidofovir for Peripheral Cytomegalovirus Retinitis in Patients with AIDS. **Lalezari JP**, Stagg RJ, Kuppermann BD, et al. Annals of Internal Medicine. 1997;126:257-63

A Randomized, Double-Blind Study of Cidofovir Topical Gel for Acyclovir-Resistant Herpes Simplex Virus Infections in Patients with AIDS. **Lalezari JP**, et al. Journal of Infectious Diseases. 1997; 176:892-99.

The Efficacy and Safety of Inhaled Zanamivir in the Treatment of Influenza in Otherwise Healthy and "High Risk" Individuals in North America. **Lalezari JP**, Klein T, Stapleton et al. J Antimicrob Chemother 1999; 44(Suppl A), 42, P8.

Low-Dose Daily Subcutaneous Interleukin-2 in Combination with Highly Active Antiretroviral Therapy in HIV+ Patients: a Randomized Controlled Trial. **Lalezari JP**, Beal JA, Ruane PJ, et al. HIV Clinical Trials 2000;1(3) 1-15.

Zanamivir for the Treatment of Influenza A and B Infections in High Risk Patients: A Pooled analysis of Randomized Controlled Trials. **Lalezari JP**, Champion K, Keene O, and Silagy C. Arch of Intern Med. 2001;161:212-217.

A Phase I Dose Escalation Trial Evaluating the Pharmacokinetics, Anti-HCMV Activity, and Safety of 1263W94 in HIV-Infected Men with Asymptomatic HCMV Shedding. **Lalezari JP**, Aberg J, Wang LH, et al. Antimicrobial Agents and Chemotherapy 2002;46:2969-76.

A Safety Study of Oral Valganciclovir Maintenance Treatment of CMV Retinitis. **Lalezari JP**, Lindley J, Walmsley S, et al. J Acquir Immune Defic Syndr. 2002; 30:392-400.

Enfuvirtide, an HIV-1 Fusion Inhibitor, for Drug-Resistant HIV Infection in North and South America. **Lalezari JP**, et al. New England Journal of Medicine 2003; 348: 2175-85.

T-1249 Retains Potent antiretroviral Activity in patients Who had Experienced Virological Failure While on an Enfuvirtide-Containing Treatment Regimen. **Lalezari JP**, et al. Journal of Infectious Diseases. 2005; 191:1155-63.

Antiviral Activity and Safety of 873140, a Novel CCR5 Antagonist, During Short-Term Monotherapy in HIV-Infected Adults. **Lalezari JP**, et al AIDS. 2005; 19 (14).

The FUTURE II Study Group. Quadrivalent HPV vaccine against human papillomavirus to prevent high-grade cervical lesions. N Engl J Med 2007;356(19):1-13.

Efficacy and Safety of TMC-125 (Etravirine) in Treatment-Experienced HIV-1-Infected Patients in DUET-1: 24-Week Results From a Randomized, Double-Blind, Placebo-Controlled Trial. Madruga JV, Cahn P, Grinsztejn B, haubrich R, **Lalezari JP**, Mills A, Pailous G, Wilkin T, Peeters M, Vingerhoets J, de Smedt G, Leopold L, Trefiglio R, Woodfall B. The Lancet 2007; 370:29-38.

Efficacy of a Prophylactic Adjuvanted Bivalent L1 Virus-Like Particle Vaccine Against Infection with Human Papillomavirus Types 16 and 18 in Young women: an Interim Analysis of a Phase III Double-blind, Randomized, Controlled Trial. Paavonen J, et al. The Lancet 2007; 369:2161-70.

Motivate 1. Lalezari et el (manuscript in preparation).

Safety, Pharmacokinetics, and antiviral Activity of HGS 004, a Novel Fully Human IgG4 Monoclonal Antibody Against CCR5, Following a Single Intravenous Injection in HIV-Infected Adults. Lalezari, JP et al. JID 2008; 197: 721-7.

Safety and Immunogenicity of the MRK Adenovirus Type-5 HIV-1 Clade B Consensus gag/pol/nef Vaccine in healthy Adults. (manuscript in preparation).

#### **OTHER PUBLICATIONS:**

Treatment with Intravenous HPMPC of Acyclovir-Resistant Mucocutaneous Infection with Herpes Simplex Virus in a Patient with AIDS. **Lalezari JP**, Drew WL, Glutzer E, et al. Journal of Infectious Diseases, 1994; 170: 570-2.

Pharmacokinetic, Safety, and Antiviral Profiles of Oral Ganciclovir in Persons Infected with Human Immunodeficiency Virus: A Phase I/II Study. Spector S, Busch D, Follansbee S, Squires K, **Lalezari JP**, et al. Journal of Infectious Diseases, 1995; 171: 1431-1437.

Clinical Pharmacokinetics of Cidofovir in HIV-Infected Patients. Cundy CC, Petty BG, Flaherty F, Fisher PE, Polis MA, Wachsmann M, Lietman PS, **Lalezari JP**, Hithcock JM, Jaffe HS. Antimicrobial Agents and Chemotherapy, 1995; 39: 1247-52.

Failure of High Dose Oral Acyclovir to Suppress CMV Excretions in HIV Antibody Positive Patients. Drew WL, Anderson R, Lang W, Miner RC, Davis G, **Lalezari JP**. Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology. 1995; 8: 289-291.

Antiretroviral monotherapy in early stage immunodeficiency virus disease has no detectable effect on viral load in lymphoid tissue. Cohen OJ, Pantaleo G, Holodniy M, Fox CF, Orenstein JM, Schnittman S, Niu M, Graziosi G, Pavlakis GN, **Lalezari JP**, Bartlett J, Steigbigel R, Cohn J, Noval R, McMahon D, J Bilello, Fauci AS. Journal of Infectious Diseases, 1996; 173: 849-56.

Susceptibility of Human Cytomegalovirus (HCMV) to Cidofovir is Unchanged After Limited In Vivo Exposure to Various Clinical Regimens of Drug. JM Cherrington, R Miner, MJM Hitchcock, **JP Lalezari**, WL Drew. Journal of Infectious Diseases, 1996;173:987-92.

Quantification of Zidovudine (ZDV) and Individual ZDV Phosphates in Peripheral Blood Mononuclear Cells by a Combined Isocratic High Performance Liquid Chromatography-Radioimmunoassay Method. Peter K, **Lalezari JP**, Gambertoglio JG. Journal of Pharmaceutical and Biomedical Analysis. 14 (1996) 491-499.

Prevention and Treatment of CMV Retinitis in Patients with AIDS. **Lalezari JP**. Current Opinion in Infectious Diseases. 1996, 9:415-9.

Cidofovir: A New Therapy for Cytomegalovirus Retinitis. **Lalezari JP**. J Acquir Immune Defic Syndr Hum Retroviral. 14(Suppl. 1); S22-26, 1997.

Clinical Experience with Cidofovir in the Treatment of Cytomegalovirus Retinitis. **Lalezari JP** and Kuppermann BD. J Acquir Immune Defic Syndr Hum Retroviral. 14(Suppl. 1);S27-31, 1997.

Evolution of Mutations Confering Multidrug Resistance During Therapy for Cytomegalovirus Infection. Chou S, Marousek G, Guentzel S, Follansbee S, Poscher M, **Lalezari J**, Miner R, and Drew W. Journal of Infectious Diseases. 1997; 176:786-89.

The Safety and Efficacy of Adefovir Dipivoxil, a Novel Anti-HIV therapy, in HIV-infected Adults. Deeks SG, Collier A, **Lalezari JP**, Pavia A, Rodrigue D, Drew WL, Toole J, Jaffe HS, Mulato AS, Lamy PD, Li W, Cherrington JM, Hellmann N, and Kahn J. Journal of Infectious Diseases. 1997; 176:1517-23.

Quantification of CMV DNA in Peripheral Blood Leukocytes Using a Branched DNA Signal Amplification Assay. Chernoff D, Miner R, Hoo B, Shen L, Kelso R, Jeric-McMullen D, **Lalezari J**, Chou S, Drew W, Kolberg J. J Clin Micro, 1997; 35:2740-44.

Phenotypic Variability of Lymphocyte Populations in Peripheral Blood and Lymph Nodes from HIV-Infected Individuals and the Impact of Antiretroviral Therapy. Landay A, Bethel J, Schnittman S, Bartlett J, **Lalezari JP**, Steigbigel R, Cohn J, Novak R, McMahon K, and Holodniy M. AIDS Res Hum Retroviruses 1998; 14:445-51.

An Open-label Study of the Safety and Efficacy of Cidofovir for the Treatment of Relapsing Cytomegalovirus Retinitis in Patients with AIDS. **Lalezari JP**, et al. J Acquir Immune Defic Syndr Hum Retroviral. 1998; 17:339-44.

Sorivudine Versus Acyclovir for Dermatomal Herpes Zoster in HIV-infected Patients: Results from a Randomized, Controlled Clinical Trial. Gnann JW, Crumacker CS, **Lalezari JP**, Smith JA, Tyring SK, Baum KF, Pollard RB, Joseph WP, Mertz GJ, Steigbigel

RT, Cloud GA, Soong SJ, Sherrill LC, DeGertough DA, Laughlin CA, Whitley RJ, and the Niaid Collaborative Antiviral Study Group (CASG)/Aids Clinical Trials Group (ACTG) Herpes Zoster Study Group. Antimicrobial Agents and Chemotherapy, 1998; 42: 1139-45.

Improved Survival and Reduced Clinical Progression of HIV-Infected Patients with Advanced Disease Patients with Saquinavir Plus Zalcitabine. Haubrich R, **Lalezari JP**, Follansbee SE, Gill MJ, Hirsch M, Richman D, Mildvan D, Burger HU, Beattie D, Donatucci L, Salgo MP, and the NV14256 Study Team. Antiviral Therapy, 1998; 3:33-42.

Comparison of zidovudine phosphorylation in lymph nodes and peripheral blood mononuclear cells in patients infected with the human immunodeficiency virus. Peters K, **Lalezari JP**, Thevanayagam L, Gambertoglio JG. AIDS, 1998; 12:1729-31.

Selecting the Optimum Dose for a New Soft Gelatin Capsule Formulation of Saquinavir—results of a phase I/II study. **Lalezari JP**, et al. J Acquir Immune Defic Syndr Hum Retroviral. 1998; 19:195-6.

In Vitro Antiviral Susceptibilities of Isolates from CMV Retinitis Patients Receiving First or Second Line Cidofovir Therapy: Relationship to Clinical Outcome. Cherrington JM, Fuller MD, Lamy PD, Miner R, **Lalezari JP**, Nuessle S, and Drew WL. Journal of Infectious Diseases. 1998; 178:1821-25.

Oral Ganciclovir in Patients with Cytomegalovirus Retinitis Treated with a Ganciclovir Implant: A Randomized Controlled Trial. Martin DF, Kuppermann BD, Wolitz RA, et al. New England Journal of Medicine. 1999;340:1063-70.

Loss of Cytomegalovirus-specific CD4+ T Cell Responses in HIV-1 Infected Subjects with High CD4+ T Cell Counts and Recurrent Retinitis. Komanduri KV, Feinberg J, Hutchins RK, Frame RD, Schmidt DK, Viswanathan MN, **Lalezari JP**, and McCune JM. Journal of Infectious Diseases. 2001; 183:1285-9.

Valganciclovir For Induction Treatment of Newly Diagnosed Cytomegalovirus Retinitis: A Randomized, Controlled Trial. Martin DF, Stempien MJ, Sierra-Madero JS, et al. New England Journal of Medicine. 2002;346:1119-26.

Efficacy and safety of twice-daily versus three-times daily saquinavir soft gelatin capsules as part of triple combination therapy for HIV-1 infection. Wheat LJ, Farthing C, Cohen C, Pierone G, **Lalezari J**, Pilson RS, Siemon-Hryczyk P, for the TIDBID (NR15520) study team. Antiviral Therapy 2002; 7(3):199-209.

The Safety, Plasma Pharmacokinetics, and Antiviral Activity of Subcutaneous T-20, a Peptide Inhibitor of gp41-Mediated Virus Fusion, in HIV-infected Adults. Kilby JM, **Lalezari JL**, Eron JJ, et al. AIDS Res Hum Retroviruses 2002; 18:685-694.

A Comparison of Three Doses of Oral Ganciclovir Versus Intravenous Ganciclovir for Cytomegalovirus Retinitis. **Lalezari JP**, Friedberg D, Gioradano M, Hardy D, Drew WL, Stempien M, Robinson C, and the Syntex Cooperative Oral Ganciclovir Study Group Journal of Clinical Virology 24 (2002) 67-77.

A Phase II clinical study of the long-term safety and antiviral activity of enfuvirtide-based antiretroviral therapy Lalezari JP., Eron JJ., Carlson M, et al. AIDS, 17(5), 691-698, 2003.

A Controlled Phase II Trial Assessing Three doses of Enfuvirtide (T-20) in Combination with Abacavir, Amprenavir, Ritonavir, and Effavirenz in Non-Nucleoside Reverse Transcriptase Inhibitor naive HIV-Infected Adults. **Lalezari JP**, DeJesus E, Northfelt DW, et al. Antiviral Therapy 2003; 8:279-287.

Influence of Subcutaneous Injection Site on the Steady State Pharmacokinetics of Enfuvirtide (T-20) in HIV-1-Infected Patients. **Lalezari J**, Patel IH, Zhang X, et al. Clin Virol. 2003 Oct; 28(2):217-22.

Assessment of drug-drug interaction potential of enfuvirtide in human immunodeficiency virus type 1-infected patients. Zhang X, Lalezari JP, Badley AD Clin Pharmacol Ther. 2004 Jun;75(6):558-68

Safety, Tolerability, and Plasma Pharmacokinetics of High-Strength Formulations of Enfuvirtide (T-20) in Treatment-Experienced HIV-1-Infected Patients. Wheeler DA, Lalezari JP, Kilby JM, Wheat J, Delehanty J, DeMasi R, Patel, I, Salgo M. J Clin Virol. 2004 Jun;30(2):183-90.

Torriani FJ, Rodriguez-Torres M, Rockstroh JK, et al. Peginterferon Alfa-2A plus Ribavirin for Chronic Hepatitis C Virus Infection in HIV-Infected Patients. . New England Journal of Medicine 2004; 351: 438-450.

Trottier B, Walmsley S, Reynes J, et al. Safety of Enfuvirtide in Combination with an Optimized Background of Antiretrovirals in Treatment-Experienced HIV-1-Infected Adults Over 48 Weeks. J Acquir Immune Defic Syndr. 2005 Dec 1:40(4): 413-421.

Nelson M, Arasteh K, Clotet B, et al. Durable Efficacy of Enfuvirtide Over 48 Weeks in Heavily Treatment-Experienced HIV-1-Infected Patients in the T-20 Versus Optimized Background Regimen Only 1 and 2 Clinical Trials. J Acquir Immune Defic Syndr. 2005 Dec 1:40(4): 404-412.

De Bruyn G, Vargas-Cortez M, Warren T, et al. A Randomized Controlled Trial of a Replication Defective (gH deletion) Herpes Simplex Vaccine for the Treatment of Recurrent Genital Herpes Among Immunocompetent Subjects. Vaccine. 2006. 24: 914-920.

Preliminary safety and efficacy data of brecanavir, a novel HIV-1 protease inhibitor: 24 week data from study HPR10006. **Jacob P. Lalezari**; Douglas J. Ward; Susan A. Tomkins; Harmony P. Garges. Journal of Antimicrobial Chemotherapy 2007; doi: 10.1093/jac/dkm122

Restoration of Blood Glutathione Status and Lymphocyte Functions Following Alpha-Lipoic Acid Supplementation in Patients with HIV Infection. Jariwalla RJ, Lalezari JP, Cenko D, et al. Journal of Alternative and Complementary Med. 2008. 14;(2): 139-146.

Safety, Tolerability, Pharmacokinetics, and Efficacy of an Interleukin-2 Agonist Among HIV-Infected patients Receiving Highly Active antiretroviral Therapy. Davey TR, Pertel, Benson A, Cassell D, Gazzard B, Holodniy M, Lalezari JP, Levy Y, Mitsuyasu RT, Palella FJ, Pollard RB, Rajagopalan P, Saag MS, Salata RA, Sha BE, and Choudhri S. Journal of Interferon & Cytokine Research. 28:89-100. 2008.

An Open-Label Safety Study of Enfuvirtide Injection with a Needle-Free Injection Device or Needle/Syringe: The Biojector 2000 Open-Label Safety Study (BOSS). Lalezari et al. (submitted for publication).

Etravirine (ETR; TMC125) in Treatment-Experienced HIV-1 Infected Patients: Pooled 24-Week Analysis of Phase III Data from DUET-1 and -2. William Towner, Isabel Cassetti, Beatriz Grinsztejn, José Valdez Madruga, Jacob Lalezari, Adriano Lazzarin, Marie-Pierre de Bethune, Diego Miralles, Monika Peeters, Rekha Sinha, Johan Vingerhoets, Brian Woodfall, and Goedele De Smedt. (submitted for publication).

Efficacy and Safety of Etravirine (ETR; TMC 125) Over 48 Weeks in Treatment-Experienced HIV-1 Infected Patients: Pooled Analysis of Duet-1 and 2. C Katlama, R Haubrich, J Lalezari, et al. (submitted to JAMA).

## **Journals**

Journal of Viral Entry. Co-Editor in Chief (2005-present)

## **Books**

Viral Co-infections in HIV: Impact and Management. Edited by Jacob Lalezari and Graeme Moyle. ReMEDICA Publishing. January, 2002.

## **Book Chapters**

**Lalezari JP**, et al A Preclinical and Clinical Overview of the Nucleotide-Based Antiviral Agent Cidofovir (HPMPC). Antiviral Chemotherapy: New Directions in Antiviral Chemotherapy. Edited by Mills J and Corey L. 1996 Vol 4, pp 105-15.

**Lalezari, J.P.** Cidofovir for Cytomegalovirus Retinitis. Cytomegaly Virus Infection in AIDS. Edited by Hans Jager, M.D. 1998.

Drew WL and **Lalezari JP**. Cytomegalovirus. The AIDS Knowledge Base. Edited by Cohen PT, Sande MA, and Volberding PA. 1999 Third Edition.

Drew WL and **Lalezari JP**. Cytomegalovirus: Disease Syndromes and Treatment. Current Clinical Topics in Infectious Diseases. Edited by Remington JS and Swartz MN. 1999.

## **Invited Presentations:**

### **International:**

Oral Ganciclovir. Satellite Symposium-Clinical Update on New Antiviral Agents. Eighth International Conference on Antiviral Research, Santa Fe, New Mexico, April 23, 1995.

A Phase II/III randomized study of immediate versus deferred intravenous Cidofovir for AIDS patients with peripheral CMV retinitis. International Conference on Ocular Infections. Jerusalem, Israel, June 22, 1995.

Update on Cidofovir. Presented at the 1st International Consensus Symposium on Advances in the Diagnosis, Treatment, and Prophylaxis of CMV Infection. Fort Meyers, Florida, April 22, 1996.

Antiviral Activity of Lobucavir. Presented at the 1st International Consensus Symposium on Advances in the Diagnosis, Treatment, and Prophylaxis of CMV Infection. Fort Meyers, Florida, April 23, 1996

Management of CMV retinitis. Satellite Symposium at the Eleventh International Conference on AIDS. Vancouver B.C., July, 1996.

Saquinavir in Pretreated Patients. European launch of Invirase by Hoffmann-La Roche. Montreux, Switzerland, September 28, 1996.

CMV Disease: Optimising Prevention and Treatment. Satellite Symposium at the Third International Congress on Drug Therapy in HIV Infection. Birmingham, England, October, 1996.

CMV Retinitis in Patients with AIDS. First Swiss Conference on Cytomegalovirus. Bern, Switzerland, November, 1996.

Antiretroviral Therapy with Protease Inhibitors and Treatment and Prophylaxis of CMV Disease. Third National Spanish Symposium on HIV Infection, Barcelona, Spain, February, 1997.

New Approaches in the Management of CMV Disease. Toronto, Montreal, and Vancouver, Canada, April 7-9, 1997.

Treatment and Prevention of CMV Retinitis. Symposium on HIV Disease Management in Thailand. Pattaya, Thailand, July, 1997.

Use of Protease Inhibitors in Protease-Naive Patients. Satellite Symposium at the 4th International Congress on AIDS in Asia and the Pacific. Manila, Philippines, October, 1997.

Influenza Management in the 21st Century. European Launch of Relenza by GlaxoWellcome. Prague, Czech Republic. November 12, 1999.

The Management of Therapeutic Failures-Future Prospects with New Therapeutic Classes. Satellite Symposium at the European Conference on Lipodystrophy and HIV Infection. Marrakech, Morocco. March 25, 2000

New HIV Drugs: Update on Fusion Inhibitors. From Laboratory to Patient: Course in HIV Resistance and Pharmacology. San Francisco, CA, November 9-10, 2001.

Future Role of T-20 and Other Fusion Inhibitors. Eighth National Spanish Symposium on HIV Infection, Sitges, Spain, March, 2002.

EvoluT-20nary ART: Symbiotic Evolution-Optimizing the Patient Experience with T-20. Satellite Symposium at the XIV International AIDS Conference, Barcelona, Spain, July, 2002.

Anti-HIV Activity of T-20 and T-1249. IrsiCaixa Foundation: Satellite Symposium at the XIV International AIDS Conference, Barcelona, Spain, July, 2002.

## **National**

Clinical management of HIV disease. Burroughs-Wellcome Symposium. Update from the Ninth International Conference on AIDS. San Francisco Hilton Hotel, San Francisco, CA, July 14, 1993.

Nucleoside analogues in the treatment of advanced HIV disease. Twenty-second Annual Physician Assistant Conference. San Antonio, TX, May 23, 1994.  
Practical Management of CMV Retinitis. National Conference on Clinical Care of the AIDS Patient. San Francisco, CA, December 8-10, 1994.

CMV disease In HIV. University of Washington Harborview Medical Center AIDS Clinical Conference. Seattle, WA, April 12, 1995.

Treatment of CMV retinitis: Cidofovir. AmFAR Symposium on Critical Issues in AIDS Research. Washington, D.C., January, 1996.

Treatment of acyclovir-resistant HSV with topical cidofovir. Annual meeting of the National Institute of Allergy and Infectious Diseases Collaborative Antiviral Study Group. Washington, D.C., March, 1996.

Symposium on new perspectives in the management of ocular manifestations of AIDS. Los Angeles, CA., April, 1996.

Herpes virus infections in the AIDS patient. Presented at the Annual Meeting of the American College of Physicians. San Francisco, CA, April 24, 1996.

Hepatitis C transmission and HIV interactions. Santa Barbara Department of Public Health-Symposium on Hepatitis C. Santa Barbara, Ca, April 22 1999.

Symposium on Influenza prevention and treatment. Presented at the Annual Meeting of the American Academy of Physician Assistants. Atlanta, GA, May 29, 1999.

Antiviral therapy for Influenza. Medical Grand Rounds, Rose Medical Center, Denver, Colorado. September 14, 1999.

Influenza 2000: The role of neuraminidase inhibitors. Satellite Symposium presented at the Thirty-ninth ICAAC. San Francisco, CA. September 29, 1999.

Influenza in the 21st century: prevention, diagnosis, and treatment. Satellite Symposium at the American College of Chest Physicians (ACCP) World Congress. Chicago, Illinois. November 2, 1999.

The spectrum of Influenza. Symposium at the American College of Allergy, Asthma, and Immunology. Seattle, Washington. November 2, 2000.

HIV/Hepatitis C Coinfection. Poz Life Forum. San Diego, California. October 18, 2001.

Pharmacokinetics of HIV therapy. Poz Life Forum. San Diego, California, October 18, 2001.

Fusion Therapy Clinical Update. African American HIV Summit Meeting, San Francisco, CA, July, 2002.

Clinical Safety and Efficacy of a New Fusion Inhibitor. Symposium entitled New Hope: Advancing Care in HIV Infection at the 15th annual meeting of the Association of Nurses in AIDS Care. San Francisco, CA November, 2002

Clinical Experience with HIV Entry Inhibitors. Symposium of the Infectious Disease Association of California. Dana Point, CA. May, 2004

**Local:**

Antiviral Research at Mount Zion Medical Center. Francis Proctor Foundation Seminar, University of California, San Francisco, April 1992.

Controversies in CMV management. Symposium at California Pacific Medical Center, San Francisco, CA, June 1992.

Results of a phase I/II study of HPMPC. Presented at University of California, Intercampus Ophthalmology Symposium. Yosemite National Park, CA, February 1993.

HPMPC: A new antiviral compound. Infectious Disease Grand Rounds, San Francisco General Hospital, San Francisco, CA, September 22, 1993.

Management of CMV disease. AIDS Grand Rounds, Sutter Community Hospitals of Sacramento. April 20, 1995.

New antivirals: HPMPC. San Francisco AIDS Community Consortium-Symposium on CMV. June 3, 1995

Management of CMV disease. San Francisco General Hospital AIDS teaching conference. June 6, 1996.

New Directions in Antiviral Therapy. Grand Rounds presentation, UCSF/Mount Zion Hospital. May 22, 1998.

New approaches to the treatment of Influenza and HIV. St. Anthony's clinic, San Francisco, CA, March, 1999.

Double Jeopardy: The HIV/HCV Co-Infection forum. St. Mary's Church, San Francisco, April 27, 1999.

New currents in HIV research. St. Mary's Medical Center, San Francisco, May 18, 1999.

Research Studies in HIV: T-20, IL2, and HE2000. California Pacific Medical Center, San Francisco, July 13, 1999.

Antiviral Therapy for Influenza. Pulmonary Grand Rounds, University of California, SF. October 12, 1999.

Antiviral therapy for Influenza. Medical Grand Rounds, Mount Zion Medical Center, UCSF, December 17, 1999.

Antiviral therapy for Influenza. Medical Grand Rounds, Marin General Hospital, January 11, 2000.

Antiviral therapy for Influenza. Emergency Room Grand Rounds, Stanford Medical Center, January 12, 2000.

New Treatments for Influenza. Medical Grand Rounds, Santa Rosa Memorial Hospital, March 3, 2000

New treatment options for HIV:T20. Presentation at Mission Neighborhood Health Center May, 2001

Pharmacokinetics of HIV therapy. Poz Life Forum. San Diego, California, October 18, 2001.

Integrating Fusion Inhibitors in Clinical Practice. From Laboratory to Patient Course in HIV Resistance and Pharmacology. Stanford University. Oct 1, 2002.

HIV Resistance and Fitness: New drugs in the Pipeline, Symposium of the San Francisco Community Consortium. March, 2003

Integrating Fusion Inhibitors in Clinical Practice. From Laboratory to Patient Course in HIV Resistance and Pharmacology. Stanford University. Oct 7, 2003.

**Oral Abstract Presentations** (National/International meetings):

Evidence against CMV as an in-vivo cofactor for HIV replication. The Thirty-second ICAAC, Anaheim, CA, October 1992.

The safety, pharmacokinetics, and anti-CMV activity of weekly HPMPC in HIV-positive patients excreting CMV. The First National Conference on Human Retroviruses and Related Infections. Washington, DC, December 12, 1993.

Oral vs. intravenous ganciclovir (GCV) as maintenance treatment of newly diagnosed cytomegalovirus retinitis (CMVR) in AIDS. The Seventh International Conference of Antiviral Research. Charleston, SC, February 27, 1994.

A randomized, controlled study of cidofovir for relapsing cytomegalovirus retinitis in patients with AIDS. Presented at a late breaker session at the Thirty-fifth ICAAC, San Francisco CA, September, 1995.

A comparison of the safety and efficacy of 3g, 4.5g, and 6g doses of oral ganciclovir versus IV ganciclovir for maintenance treatment of CMV retinitis. The Eleventh International Conference on AIDS. Vancouver, B.C., July, 1996.

Improved survival and decreased progression of HIV in patients treated with Saquinavir plus HIVID. The Eleventh International Conference on AIDS. Vancouver, B.C., July, 1996.

Sixteen week analysis of heavily pre-treated patients receiving T-20 as a component of multi-drug salvage therapy. The Thirty-ninth Interscience Conference on Antimicrobial Agents and Chemotherapy. San Francisco, CA, September, 1999.

A controlled phase II trial assessing three doses of T-20 in combination with abacavir, amprenavir, low dose ritonavir, and efavirenz in non-nucleoside naive protease inhibitor experienced HIV-1 infected adults. The Eighth Conference on Retroviruses and Opportunistic Infections. Chicago, IL, February, 2001

Enfuvirtide (T-20) in combination with an optimized background (OB) regimen vs. OB alone: Week 24 response among categories of treatment experienced and baseline HIV antiretroviral resistance Lalezari JP, Henry K, O'Hearn M, et al. Presented at the Forty-Second ICAAC, San Diego CA, September, 2002.

Final analysis of T1249-102: T-1249 retains potent short term antiviral activity in patients who have failed a regimen containing enfuvirtide. **Lalezari J**, Bellos N, Richmond G, et al. Presented at the Forty-Third ICAAC, Chicago, IL, September, 2003.

873140, a novel CCR5 antagonist: antiviral activity and safety during short-term monotherapy in HIV-infected adults. Lalezari J, Thompson M, Kumar P, et al. Presented at the Forty-fourth ICAAC, Washington, D.C. October, 2004.

Safety and Antiviral Activity of PA-457, the First-In-Class Maturation Inhibitor, in a 10-Day Monotherapy Study in HIV-1 Infected Patients G. Beatty, J. Lalezari, J. Eron, et al. Presented at the Forty-fifth ICAAC, Washington, D.C. December, 2005.

A Phase 1, Randomized, Dose-Escalation, Placebo Controlled Study of a Fully Human Monoclonal Antibody Against CCR5 (HGS 004) in Patients with CCR5 Tropic HIV-1 Infection. J Lalezari, et al. Presented at the Forty-sixth ICAAC, San Francisco, CA, 2006

Efficacy and Safety of Maraviroc Plus Optimized Background Therapy in Viremic ART-Experienced Patients Infected with CCR5-tropic HIV-1: 24 Week Results of a Phase 2b/3 study in the US and Canada. The Conference on Retroviruses and Opportunistic Infections. Los angeles, CA, February, 2007.

Efficacy and Safety of Maraviroc (MVC) in Antiretroviral Treatment-Experienced Patients Infected with CCR5-Tropic HIV-1: 48 Week Results of MOTIVATE 1. J Lalezari, et al. Presented at the Forty-Seventh Interscience Conference on Antimicrobial Agents and Chemotherapy. Chicago, IL, September, 2007.

#### **Poster Presentations:**

In vivo antiviral efficacy of oral ganciclovir. Drew WL, **Lalezari JP**, et al. Presented at the Seventh International Conference on AIDS. Florence, Italy, June 1991.

Failure of highdose oral acyclovir to suppress CMV excretions in HIV antibody positive patients. Drew WL, **Lalezari JP**, et al. Presented at the Eighth International Conference on AIDS. Amsterdam, Netherlands, July 1992.

The safety, pharmacokinetics, and anti-CMV activity of weekly HPMPC in HIV-positive patients excreting CMV. **Lalezari JP**, Drew WL, et al. Presented at the Infectious Diseases Society of America Annual Meeting. New Orleans, LA, October 1993.

Pharmacokinetics of HPMPC in HIV-infected men with asymptomatic cytomegalovirus infection. Flaherty JF, **Lalezari JP**, et al. Presented at the Thirty-third ICAAC. New Orleans, LA, October 1993.

The safety, pharmacokinetics, and anti-CMV activity of weekly HPMPC in HIV-positive patients excreting CMV. **Lalezari JP**, Drew WL, Glutzer E, et al. Presented at the Ninth International Conference on AIDS. Berlin, Germany, June 1993.

The efficacy of zalcitabine (ddc, Hivid) versus zidovudine (zdv) as monotherapy in zdv naive patients with advanced HIV disease: a randomized, double-blind, comparative trial (ACTG 114; N3300). Presented at the Ninth International Conference on AIDS. Berlin, Germany, June 1993.

HIV-1 resistance mutations and plasma RNA during ZDV+ ddC combination therapy. S. Sylvester, A. Caliendo, D. An, A. Savara, R. Byington, D. Strick, R. Lillaney, L Sutton, K. Sepkowitz, M. Fischl, G. Simon, **JP Lalezari**, R. Mitsuyasu, R. D'Aquila. The Fourth International HIV Drug Resistance Workshop, Sardinia, Italy, July, 1995.

A randomized, double-blind study of the efficacy and safety of oral ganciclovir for the prevention of cytomegalovirus disease in HIV-Infected Persons. **JP Lalezari** for the Syntex Ganciclovir Study Group. Eighth International Conference on Antiviral Research, Sante Fe, New Mexico, April 27, 1995.

Discordance between blood plasma and seminal fluid HIV RNA codon 215 genotypes during acute HIV transmission. Holodniy M, **Lalezari JP**, Hong E, Mole L, Kolberg J, Eastman S. The Second National Conference on Human Retroviruses and Related Infections. Washington, DC, January 1995.

Human cytomegalovirus (HCMV) does not develop resistance following short-term treatment with cidofovir. R Miner, WL Drew, **JP Lalezari**, et al., The Second National Conference on Human Retroviruses and Related Infections. Washington, DC, January 1995.

A randomized, double-blind, placebo-controlled study of cidofovir topical gel for acyclovir-resistant herpes simplex virus infections in patients with AIDS. **JP Lalezari** et.

al. The Third Conference on Retroviruses and Opportunistic Infections. Washington D.C., January 1996

Sorivudine (BV-araU) versus acyclovir for herpes zoster in HIV-infected patients. J Gnnann, C Crumpacker, **JP Lalezari**, et. al. The Third Conference on Retroviruses and Opportunistic Infections. Washington D.C., January 1996

The relationship between blood and lymph node viral load. L. Mole, M Holodniy, **JP Lalezari**, et.al. The Third Conference on Retroviruses and Opportunistic Infections. Washington D.C., January 1996

A randomized, double-blind, placebo-controlled study of cidofovir topical gel for acyclovir-resistant herpes simplex virus infections in patients with AIDS. **JP Lalezari** et. al. The Eleventh International Conference on AIDS. Vancouver, B.C., July, 1996

In vivo anti-CMV activity and safety of oral lobucavir in HIV-infected patients. **JP Lalezari**, et al. The Fourth Conference on Retroviruses and Opportunistic Infections. Washington D.C., January 1997.

Pharmacokinetics and safety of oral lobucavir in cytomegalovirus-infected HIV patients. Flaherty J, **Lalezari JP**, et al. The Fourth Conference on Retroviruses and Opportunistic Infections. Washington D.C., January 1997.

In vitro antiviral susceptibilities of isolates from CMV retinitis patients receiving first or second line cidofovir therapy. JM Cherrington, MF Fuller, **JP Lalezari**, et al. The Fourth Conference on Retroviruses and Opportunistic Infections. Washington D.C., January 1997.

In vivo anti-CMV activity, safety, and pharmacokinetics of oral 1263W94 in HIV-infected subjects with asymptomatic CMV shedding. **Lalezari JP**, et al. The Fifth Conference on Retroviruses and Opportunistic Infections. Chicago, Ill., February 1998.

Immune reconstitution of advanced HIV patients (following HAART) R Schirer, F Torriani, D Durand, D Jeffrey, L Drew, **J Lalezari**. The Sixth Conference on Retroviruses and Opportunistic Infections. Chicago, Ill., February 1999.

Characterization of genotypic changes in gp41 ectodomain from patients receiving the fusion inhibitor T-20. Sista PR, Zhou J, Medinas DM, Mink M, Dusek A, Hopkins S, Mathews T, **Lalezari JP**, Eron J, and Bolognesi D. The Third Drug Resistance Workshop in HIV. San Diego, CA., June 1999.

The efficacy and safety of inhaled zanamivir in the treatment of influenza in otherwise healthy and "high risk" individuals in North America. **Lalezari JP**, et al. The Twenty-first International Congress of Chemotherapy. Birmingham, U.K., July 1999.

The efficacy and safety of inhaled zanamivir in the treatment of influenza A and B in high risk individuals-results of phase II and III clinical studies. **Lalezari JP**, Elliott M, Keene O. The Thirty-ninth Interscience Conference on Antimicrobial Agents and Chemotherapy. San Francisco, CA, September, 1999.

Low-dose subcutaneous IL-2 in combination with HAART therapy induces significant increases in NK cells and naive T-cells in patients with < 300 CD4+ T-cells: results of a randomized controlled trial MA9801. **Lalezari JP** et al. The Seventh Conference on Retroviruses and Opportunistic Infections. San Francisco, CA, February 2000.

Persistent deficits in Cytomegalovirus-specific CD4+ T-cell responses in HIV-1-infected subjects with relapsing CMV retinitis following successful highly active antiretroviral therapy. Komanduri K, Feinberg J, Hutchins R, Frame R, Schmidt D, Viswanathan M, **Lalezari J**, and McCune M. The Seventh Conference on Retroviruses and Opportunistic Infections. San Francisco, CA, February 2000.

TIDBID study 48 week analysis: Fortovase (FTV) TID regimen compared to FTV BID or FTV + Nelfinavir BID regimens in HIV-1 infected patients. **Lalezari J**, Feinberg J, Sension M, Macko J, Seput-Dingle f, Siemon-Hryczyk P, and Duff F. The Thirteenth International AIDS Conference. Durban, South Africa, July 2000.

Forty-eight week analysis of patients receiving T-20 as a component of multi-drug salvage therapy. **Lalezari J**, Cohen C, DeJesus E, et al. The Thirteenth International Conference on AIDS. Durbin, South Africa, July 2000.

Cytomegalovirus retinitis (CMVR) can progress in AIDS patients on HAART. **Lalezari J**, Kupperman B, Walmsley S, et al. The Fortieth Interscience Conference on Antimicrobial Agents and Chemotherapy. Toronto, Canada, September, 2000.

Comparative PK of Carbonate (CO<sub>3</sub>) and Tris buffer formulations of the peptide HIV fusion inhibitor T-20. **Lalezari JP**, Wheeler D, Kilby M, et. al. The First International AIDS Society Conference on HIV. Buenos Aires, Argentina, July, 2001.

A week 48 assessment of a randomized, controlled open-label phase II trial (T20-206) evaluating three doses of T-20 in PI-experienced NNRTI-naive patients infected with HIV-1. **Lalezari JP**, DeJesus E, Northfelt D, et al. The Ninth Conference on Retroviruses and Opportunistic Infections. Seattle, WA, February 2002.

Forty-eight week assessment of high strength T-20 in multi-class experienced patients. Wheat LJ, **Lalezari JP**, Kilby M, et al. The Ninth Conference on Retroviruses and Opportunistic Infections. Seattle, WA, February 2002.

Drug-drug interaction study with intravenous cidofovir and either trimethoprim-sulfamethoxazole, didanosine, or Fluconazole in HIV-infected individuals. Luber A, **Lalezari J**, Jaffe H et al. The Forty-second Interscience Conference on Antimicrobial Agents and Chemotherapy. San Diego, Ca, September, 2002.

Long term safety of T-1249, a potent inhibitor of HIV fusion. **Lalezari J**, Zhang Y, DeMasi r, Et l. The Forty-second Interscience Conference on Antimicrobial Agents and Chemotherapy. Washington, D. C. October, 2004.

Injection Site Reactions in the BOSS Study: An Open-Label Safety Study of Enfuvirtide (ENF) Injection With a Needle-Free Injection Device or Needle-Syringe. J Lalezari, et al. Presented at the Forty-Seventh Interscience Conference on Antimicrobial Agents and Chemotherapy. Chicago, IL, September, 2007.

Improved Virologic Response in Triple-class Experienced patients with Enfuvirtide (ENF) Combined with New antiretroviral Agents. Lalezari JP and Guittari CJ. Presented at the Forty-Fifth Infectious Disease Society of America Meeting. San Diego, CA, Oct, 2007.