

Jacob Paul Lalezari, MD

Curriculum Vitae

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1986	MD, University of Pennsylvania, Philadelphia, PA
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Awards

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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.

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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: Optimizing 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.

Major 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

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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.

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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.

A Phase 2 Safety and Efficacy Study of Bevirimat (BVM) in Heavily Treatment Experienced HIV1+ Patients Identifies the Target Phase 3 Study Profile. **J Lalezari**, et al. Presented at the Forty-Eight Interscience Conference on Antimicrobial Agents and Chemotherapy. Washington, DC, October 2008.

Potent Antiviral Activity of S/GSK 1349572, a Next Generation Integrase Inhibitor (INI), in INI-Naïve HIV-1 Infected patients. **Lalezari J**, et al. Presented at the International Aids Conference, Capetown South Africa, July 2009.

A Phase IIA Study of IDX 184 in Combination with Pegylated interferon and Ribavirin in Treatment-Naive Genotype 1 HCV-Infected Subjects. **Lalezari JP**, O’Riordan W, Poordad F, et al. Presented at American Association for the Study of Liver Disease meeting, Boston Mass, Oct 31, 2010.

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 high-dose 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.

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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.

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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 (CO₃) 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.

Hepatic Safety and Tolerability of Etravirine in HIV-1-Infected Treatment-Experienced patients: Pooled Analysis of the Duet-1 and Duet-2 Trials. **Lalezari J**, Leider J Wilkins T et al. Presented at the fifty-ninth meeting of the American Association for the Study of Liver Diseases. San Francisco, CA, Nov 2008.

Pharmacokinetics and Safety of a Novel 100 mg Tablet Formulation of MPC-4326 in subjects with HIV-1 Infection. **Lalezari**, et al. Presented at the Forty-Ninth Interscience Conference on Antimicrobial Agents and Chemotherapy. San Francisco, CA September 2009.

Antiviral Activity of Filibuvir in Combination with Pegylated Interferon Alfa-2a and Ribavirin for 28 Days in Treatment Naïve Patients Chronically Infected with HCV genotype 1 I. Jacobson, P.J. Pockros, **J. Lalezari**. Presented at Forty-Fourth European Association for the Study of the Liver meeting, Copenhagen, Denmark, March 2009

Pro 140 Achieves Similar HIV-1 Viral Load Reductions at Lower Systemic Exposures When Administered Subcutaneously Rather Than Intravenously. **Lalezari**, et al. Presented at the Forty-Ninth Interscience Conference on Antimicrobial Agents and Chemotherapy. San Francisco, CA September 2009.