

***Joseph Clayton Gathe, Jr., M.D., F.A.C.P., F.I.D.S.A.***

***Joseph C. Gathe, Jr., M.D., F.A.C.P.  
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Houston, Texas 77004  
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**BORN:**

***St. Louis, Missouri  
Houstonian since 1960***

**EDUCATION:**

***High School***

***Strake Jesuit College Preparatory  
August 1970 – May 1974***

***Credits***

***Class Rank – 2***

***First Rank Science Student***

***First Rank Foreign Language Student over four  
year period (Spanish)***

***Recipient Upjohn Company College Scholarship  
for Academic Achievement***

***Undergraduate***

***Trinity University, San Antonio, Texas  
August 1974 – May 1977***

***Degree***

***B.A. – Biology, Summa Cum Laude  
May 1978***

***First Year of medical school was accepted in lieu  
of the final college year.***

***Research***

***Organic Chemistry: Mode of Synthesis of Primary  
Amines bypassing the Hell-Volhard-Zelinsky  
Reaction and Utilizing Phase Transfer Catalysis.***

***Credits***

***Presidential Scholarship Recipient for three years  
at Trinity for maintenance of 4.0 GPA***

***Alpha Chi Honor Society  
February 1977***

***Junior Year Phi Beta Kappa  
May 1977***

***Joseph Clayton Gathe, Jr., M.D., F.A.C.P., F.I.D.S.A.***

*Selected for medical school after three years of Undergraduate training.*

***Graduate***

*Washington University School of Medicine St. Louis, Missouri  
August 1977 – May 1978*

*Baylor College of Medicine  
Houston, Texas  
July 1978 – June 1981*

***Degree***

*M.D. (Honors)  
June 8, 1981*

***Achievements***

*Alpha Omega Honor Society  
Henri J. Kaiser Merit Scholar Award*

**LICENSURE:**

*Texas – F9471  
August 1981*

**POSTGRADUATE:**

***PGY1 Internship***

*Baylor College of Medicine; St. Luke's Affiliated Hospital; July 1981 – June 1982*

***PGY2-3 Residency***

*Baylor College of Medicine; Affiliated Hospitals; July 1982 – June 1984*

***Credits***

*Recipient Henry O. McIntosh Award for Outstanding Resident in Internal Medicine.*

***PGY4***

*Chief Medical Resident – Baylor College of Medicine; St. Luke's Affiliated Hospitals  
July 1984 – December 1984*

***Credits***

*Diplomate American Board of Internal Medicine  
September 1984*

***PGY4-5***

*Fellowship Infectious Diseases  
Baylor College of Medicine  
The Methodist Hospital  
Infectious Disease Laboratory  
Temple Williams, Jr., M.D.  
January 1985 – December 1986*

***Credits***

*Diplomate American Board of Internal Medicine*

*Joseph Clayton Gathe, Jr., M.D., F.A.C.P., F.I.D.S.A.*

*Subspecialty Infectious Diseases  
November 1988*

**AFFILIATIONS:**

*Harris County Medical Society  
American College of Physicians  
Houston Society of Internal Medicine  
Texas Society of Internal Medicine  
American Society of Internal Medicine  
Texas Medical Association  
Houston Medical Forum  
American Society of Infectious Diseases  
International AIDS Society  
American Society of Microbiology  
Infectious Diseases Society of America*

**RESEARCH AFFILIATIONS:**

*Therapeutic Concepts, P.A.  
4900 Fannin St.  
Houston, TX 77004*

*Donald R. Watkins Memorial Foundation  
4900 Fannin  
Houston, TX 77004*

**APPOINTMENTS:**

<i>1997</i>	<i>Fellow Infectious Diseases Society Of America</i>
<i>1998</i>	<i>Fellow American College of Physicians</i>
<i>1987 -Present</i>	<i>Baylor College of Medicine Department of Internal Medicine Clinical Instructor</i>
<i>1987-Present</i>	<i>Co-Director, Special Disease Unit Park Plaza Hospital, Houston, Texas</i>
<i>1989-1991</i>	<i>Board of Trustees – AIDS Foundation of Houston</i>
<i>1997-Present</i>	<i>Medical Director - Donald R. Watkins Memorial Foundation Non-profit organization, provides primary healthcare services to indigent population</i>
<i>1997-2000</i>	<i>Advisory Board – Diocesan AIDS Ministry</i>

***Joseph Clayton Gathe, Jr., M.D., F.A.C.P., F.I.D.S.A.***

***2001-2007***                      ***Board of Directors- Integrated Minority AIDS Network  
Incorporated***

***2002-2008***                      ***Chief of Infectious Diseases-Park Plaza Hospital***

***2004***                                ***Scientific Director-Black Clinical Research  
Consortium***

***2006-2008***                      ***IDSА-HIVMA Board of Directors***

**WORK HISTORY**

***Private Practice, Houston, Texas  
Specialist in Infectious Diseases  
1987 – Present***

**HONORS**

***African-American Health Care Trailblazers Hall  
Of Fame, 1998, 1999***

***J P Morgan Chase – Center for Houston’s Future  
Leadership Award February 27,2003***

***Texas Women’s Empowerment Foundation,  
Empowerment Award Recipient, October 23, 2004***

**JOURNAL ARTICLES**

**PUBLICATIONS:**            ***Papers (28)***                      ***Abstracts (92)***

***“First in the World”:***

***Pope-Pegram L., Gathe J.C. Jr., et al. Treatment of Presumed Central  
Nervous System Toxoplasmosis with Doxycycline. [Abstract]. VII  
International Conference on AIDS. Florence; 1991.***

***Gathe J.C. Jr., et al. The Effectiveness of Paramomycin in the Treatment  
of Gastrointestinal Cryptosporidiosis. [Abstract].VII International  
Conference on AIDS. Florence; 1991.***

***Gathe J.C. Jr., et al. IMANI –1 TC3WP Single Drug-Proof of Concept  
Study: Pilot Study of the Safety and Efficacy of Kaletra (LPV/r) as Single  
Drug HAART in HIV+ ARV Naïve Patients Interim Analysis of Subjects  
Completing a 48 Week Study. XV IAS, 2004; Oral 1057.***

**Joseph Clayton Gathe, Jr., M.D., F.A.C.P., F.I.D.S.A.**

**PAPERS**

**Robin Wood, Joseph Gathe, Naomi Givens, Sangeeta Sedant, Katharine Cheng, and Jorg Sievers et al. A long-term safety study of fosamprenavir-containing regimens in HIV-1 infected patients HIV Clinical Trials; Ref.: Ms. No. HCT-D-13-00025R1.**

**E. Lefebvre, J. Enejosa, M. Béliveau, C. Jomphe, J.F. Marier, C.R. Rayner, P.F. Smith, J. Gathe et. al. Exposure-Response Relationship of Cenicriviroc with Week 24 Virologic Outcomes in Treatment-Naïve HIV-1-Infected Adults with CCR5-Tropic Virus.**

**J. Feinberg, M. Thompson, J. Cade, E. DeJesus, J. Gathe, J. Lalezari, A. Scarsella, M. Saag, J. Enejosa, E. Lefebvre et. al. Final Week 48 Analysis of Cenicriviroc (CVC) Compared to Efavirenz (EFV), in Combination with Emtricitabine/Tenofovir (FTC/TDF), In Treatment-Naïve HIV-1-Infected Adults with CCR5-Tropic Virus (Study 652-2-202;NCT0133883).**

**DeJesus E, Rockstroh JK, Henry K, Molina JM, Gathe J, Ramanathan S, et al. Co-formulated elvitegravir, cobicistat, emtricitabine, and tenofovir disoproxil fumarate versus ritonavir-boosted atazanavir plus co-formulated emtricitabine and tenofovir disoproxil fumarate for initial treatment of HIV-1 infection: a randomised, double-blind, phase 3, non-inferiority trial. *Lancet* 2012;379:2429-2438.**

**Gathe, J, Martin, D, Rawlins, M, Daquiaoag, B, Fuchs, J, Williams, V, Oie, K, Pakes, G, et al. for the COL40193 Study Team. Trizivir (Abacavir/Lamivudine/Zidovudine) Plus Lopinavir/Ritonavir Induction Therapy Followed by Trizivir-Alone Maintenance for HIV-1 Infected Patients: A 96-Week Pilot Treatment Simplification Study. *JAIDS*, doi:10.423/wja2012**

**Lalezari, J, Gathe, J et al. Safety, Efficacy, and Pharmacokinetics of TBR-652, a CCR5/CCR2 Antagonist, in HIV-1 –Infected, Treatment-Experienced, CCR5 Antagonist-Naïve Subjects, *J Acquir Immune Defic Syndr*; Vol 57, Number 2, June 1, 2011 pps. 118-124.**

**Zajdenverg, R, Podsadecki, T, Badal-Faesens, S, Andrade-Villanueva, J, Gathe, J, et al. Similar safety and efficacy of once- and twice-daily lopinavir/ritonavir tablets in treatment-experienced HIV-1-infected subjects at 48 weeks. *JAIDS*, Vol. 54, Number 2, June 1, 2010; 143-151.**

**Gathe, J et al. A Once-Daily Lopinavir/Ritonavir-Based Regimen Is Noninferior to Twice-Daily Dosing and Results in Similar Safety and Tolerability in Antiretroviral-Naïve Subjects Through 48 Weeks. *J Acquir Immune Defic Syndr*, Vol 50, Number 5, April 15, 2009.**

**Joseph Clayton Gathe, Jr., M.D., F.A.C.P., F.I.D.S.A.**

*Lisa Ross, Richard Elion, Randall Lanier, Edwin deJesus, Calvin Cohen, Robert R. Redfield, Joseph C. Gathe, et al. Modulation of K65R Selection by Zidovudine Inclusion-Analysis of HIV Resistance Selection in Subjects with Virologic Failure Receiving Once-Daily Abacavir/ Lamivudine/ Zidovudine and Tenofovir DF (Study COL40263). AIDS Research and Human Retroviruses.*

*Gathe, J Jr. et al. Resolution of severe cryptosporidial diarrhea with Rifaximin in patients with acquired immune deficiency syndrome. J Acquir Immune Defic Syndr. Vol. 48, Number 3, July 1, 2008; pps. 365-366.*

*Gathe, J. Experience with darunavir in HIV-infected adults enrolled in a US expanded access program: results from a single center. Current Medical Research and Opinion, Vol. 24, No. 3, 2008, p. 769-773.*

*DeJesus, E., Gottlieb, M., Gathe, J. et al. Safety and Efficacy of Enfuvirtide in Combination with Darunavir/Ritonavir and an Optimized Background Regimen in Triple-Class Experienced HIV-Infected Patients: the BLQ Study.*

*Johnson M, Gathe JC Jr., et al. A Once-Daily Lopinavir/Ritonavir-Based Regimen Provides Noninferior Antiviral Activity Compared With a Twice-Daily Regimen. JAIDS, Vol 43, Number 2, October 1, 2006.*

*Enron J Jr, Yeni P, Gathe J Jr, et al. Fosamprenavir/ritonavir versus lopinavir/ritonavir, each given BID in combination with the abacavir/lamivudine tablet for the initial treatment of HIV infection over 48 weeks. Lancet. 2006; 368:476-482.*

*Gathe JC Jr, et al. Long-term (120-week) antiviral efficacy and tolerability of fosamprenavir/ritonavir once daily in therapy-naïve patients with HIV-1 infection: an uncontrolled, open-label, single-arm follow-up study. Clin Ther. 2006:745-754.*

*Sax PE, Gathe JC, Jr. Beyond Efficacy: The Impact of Combination Antiretroviral Therapy on Quality of Life. AIDS Patient Care STDS. 2005; 19:563-576.*

*Simpson, David A; Estanislao, Lydia, A; Evans, Scott B; McArthur, Justin C; Marcus, Kendall D; Truffa, Melissa D; Lucey, et al. HIV-associated neuromuscular weakness syndrome. AIDS 2004, 18:1403-1412.*

*Gathe J.C., Jr. et al. Solo: 48 week efficacy and safety comparison of once-daily fosamprenavir/ritonavir versus twice-daily nelfinavir in naive HIV-1-infected patients; AIDS 2004, 18:1529-1537*

*Gathe, Joseph Jr. Adherence and Potency with Antiretroviral Therapy: A Combination For Success. JAIDS, 2003;34 (Suppl 2):S118-S122.*

**Joseph Clayton Gathe, Jr., M.D., F.A.C.P., F.I.D.S.A.**

*Nadler JP, Gathe JC Jr., et al. Twice-daily Amprenavir 1200mg versus Amprenavir 600mg/Ritonavir 100mg, in combination with at least 2 other antiretroviral drugs in HIV-1 infected patients. BMS Infectious Diseases 2003, 3:10 (10 Jun 2003).*

*Scally MC, Kovacs JA, Gathe JC, and Hodge AL. Uncontrolled case study of medical treatment for elimination of hypogonadism after androgen cessation in a man with Human Immunodeficiency Virus positively and secondary polycythemia related to continuous testosterone treatment for 2 years. Endocrine Practice. 2003 March/April; 9 (Supp 1): 13.*

*Shelburne SA III, Hamill RJ, Rodriguez-Barrada MC, et al. Immune reconstitution inflammatory syndrome: emergence of a unique syndrome during highly active antiretroviral therapy. Medicine (Baltimore). 2002, 81:213-227.*

*Gathe JC Jr., Chu A, Yen A, Petersen A. Durability of Nelfinavir combinationtherapy after four years: three year extension data from Agouron study 511 8<sup>th</sup> European Conference on Clinical Aspects and Treatment of HIV-infection, October 28-31, 2001*

*Gathe JC Jr. et al Minimal Pharmacokinetic Interaction between amprenavir and lopinavir. 11<sup>th</sup> Symposium on HIV Infection Toulou, France June 14 – 16, 2001 ABS E-18*

*Schlomo S, Philip K, Montaner J, Raffi F, Gathe JC Jr., et al. Abacavir-Lamivudine-Zidovudine vs Indinavir-Lamivudine Zidovudine in Antiretroviral Naïve HIV – Infected Adults A Randomized Equivalence Trial JAMA. 2001; 285: 1155- 1163*

*Staszewski S, Philip K, Montaner J, Raffi F, Gathe JC Jr., et al. Abacavir-Lamivudine-Zidovudine vs Indinavir-Lamivudine Zidovudine in Antiretroviral Naïve HIV – Infected Adults A Randomized Equivalence Trial JAMA. 2001; 285: 1155- 1163*

*Gildenberg PL, Gathe JC Jr., and Kim Hae Hyoo Stereotactic Biopsy of Cerebral Lesions in AIDS. Clinical Infectious Diseases. 2000;30:491-499*

*Pollard RB, Peterson D, Hardy D, Pottage J, Murphy R, Gathe JC Jr., et al. Safety and Antiretroviral Effects of Combined Didanosine and Stavudine Therapy in HIV Infected Individuals With CD4 Counts of 200 to 500 cell/mm<sup>3</sup>. Journal of Acquired Immune Deficiency Syndromes. 22:39-48.*

*Gathe J.C. Jr., Improving Patient Adherence with Antiretroviral Therapy Evaluation of Once-Daily Administration of Didanosine. AIDS Vol. 12, Supp 8. 1998*

*Lalezari, J. Schacker, T. Feinberg, J, Gathe JC Jr, Lee, S, Cheung, T, Kramer,*

***Joseph Clayton Gathe, Jr., M.D., F.A.C.P., F.I.D.S.A.***

*Kessler, H, Corey, L, Drew, L, Boggs, J, McGuire, B, Jaffe, H, Safrin, S. A Randomized, Double-Blind, Placebo-Controlled Trial of Cidofovir Gel for the Treatment of Acyclovir-Unresponsive Mucocutaneous Herpes Simplex Virus Infection in Patients with AIDS. The Journal of Infectious Diseases. 1997;176:892-8*

*Leiva, J, Etter, E.L, Gathe JC Jr, Bonefas, E, Melartin, R. Surgical Therapy for 101 Patients with Acquired Immunodeficiency Syndrome and Symptomatic. The American Journal of Surgery. 1997; Vol. 174.*

*Spruance S.L., Pavia A.T., Mellors J.W., Murphy R., Gathe J.C. Jr., Stool E.W., Jemsek J.G., Dellamonica P., Cross A., Dunkle L., for Bristol-Myers Squibb Stavudine/019 Study Group. Clinical Efficacy of Monotherapy with Stavudine Compared with Zidovudine in HIV – Infected, Zidovudine-Experience Patients. A Randomized, Double-Blind, Controlled Study. Annals of Internal Medicine. 1997; 126:355-63.*

*Gathe J.C. Jr. AIDS Patient with Bilateral CMV Retinitis. Case and Commentary, A Forum for The Management of CMV Retinitis.1997;Vol.1, Number 2.*

*Rodriguez-Barradas M., Stool E.W., Musher D., Gathe J.C. Jr., Goldstein J., Genta R., Yoffe B. Diagnosing and treating Cytomegalovirus Pneumonia in Patients with AIDS. Clinical Infectious Diseases. 1996;23:76-81*

*Dohn M., Weinberg W., Torres R., Follansbee S., Caldwell P., Scott J., Gathe J.C. Jr., et al. Oral Atovaquone Compared to Intravenous Pentamidine for Pneumocystis carinii Pneumonia in AIDS, Annals of Internal Medicine. 1994;121:174-88.*

*Gathe J.C. Jr., Harris R.L., Garland B., Bradshaw M., Williams T. Jr. Candida Osteomyelitis. Report of five Cases and Review of the Literature. American Journal of Medicine. 1987;82:927-37.*

*Harris R.L., Musher D.M., Bloom K., Gathe J.C. Jr., Rice L., Sugarman B., Williams T. Jr., Young E.J. Manifestations of Sepsis. Archives of Internal Medicine. 1987;147:1985-1906.*

**ABSTRACTS**

*Exposure-response Relationship of Cenicriviroc with Week 24 Virologic Outcomes in Treatment-naïve HIV-1-infected Adults with CCR5-tropic Virus*

*Moti Ramgopal, 1 Fritz Bredeek, 2 Joseph Gathe, 3 Robert Ryan, 4 Bruce Coate, 5 David Anderson. Metabolic, Bone, Renal, Inflammatory, and Lipodystrophic Marker Analysis in INROADS, a Multicenter, Single-Arm,*

**Joseph Clayton Gathe, Jr., M.D., F.A.C.P., F.I.D.S.A.**

***Open-Label Study of Once-Daily Etravirine (ETR) and Darunavir/Ritonavir (DRV/r) as Dual Therapy in Early Treatment-Experienced Subject***

***J Gathe, J Cade, E DeJesus, J Feinberg, J Lalezari, J Morales-Ramirez, A Scarsella, M Saag, M Thompson, E Lefebvre. Week 24 Primary Analysis of Cenicriviroc Vs Efavirenz in Combination With FTC/TDF, in Treatment- Naïve HIV-A Infected Adults With CCR5-TROPIC Virus. CROI 2013 Atlanta March 4-7,2013***

***C Brinson, J Bogner, M Nelson, J Gathe, A Quinson, M Drula. Verxve 144 Week Results: Nevirapine Extended-Release (NVP XR) QD Versus NVP Immediate-Release (IR) BID With FTC/TDF in Treatment- Naïve HIV-1 Patients***

***J Rockstroh, E DeJesus, K Henry, J Molina, J Gathe, X Wei, M Fordyce, M Rhee, J Szwarcberg. Elvitegravir/Cobicistat/Emtricitabine/Tenofovir DF (QUAD) has Durable Efficacy and Differentiated Safety Compared to Atazanavir Boosted by Ritonavir Plus Emtricitabine/Tenofovir DF at Week 96 in Treatment-Naive HIV-1-Infected Patients.***

***Gathe, J, Mayberry, C, Pakes, G, et al. Effect on CD4+ Cell Count of Switching from Tenofovir to Abacavir/Lamivudine in Tenofovir-treated HIV-infected Patients with Persistently Low CD4+ Counts. HIV Dart 2012 San Diego, CA Poster presentation December 4-7, 2012.***

***Gathe, J et al. Antiviral Effect of Vicriviroc (VCV) plus Ritonavir-Boosted Atazanavir (ATV/r) Similar to Tenofovir/emtricitabine (TEM) + ATV/r but Efficacy (%<50c/mL) Inferior as Initial Therapy. ICAAC September 12-15, 2010, Boston, MA; Poster H-938a.***

***Gathe, J. et al. 48 Week Efficacy, Pharmacokinetics, and Safety of Once a Day 400 mg Nevirapine (Viramune) Extended Release Formulation for Treatment of Antiretroviral Naïve HIV-1 Infected Patients, ICAAC September 12-15, 2010; Boston, MA.***

***Palleja S, Cohen C, Gathe J, et al. Safety and efficacy of TBR 652, a CCR5 antagonist, in HIV 1 infected, ART-experienced, CCR5 antagonist- naïve patients. CROI 2010, Oral #53.***

***Gathe, J et al. Phase 3 Trials of Vicriviroc in Treatment-experienced Subjects Demonstrate Safety but Not Significantly Superior Efficacy over Potent Background Regimens Alone. CROI 2010; Oral K-1008.***

***Zajdenverg, R, Badal-Faesen, S, Andrade-Villanueva, J, Gathe, J et al. Lopinavir/ritonavir (LPV/r) tablets administered once (QD) or twice-daily (BID) with NRTIs in antiretroviral-experienced HIV-1 infected subjects: Results of a 48-week randomized trial (Study M06-802). 5<sup>th</sup> IAS Conference on HIV***

***Joseph Clayton Gathe, Jr., M.D., F.A.C.P., F.I.D.S.A.***

***Pathogenesis, Treatment and Prevention, Cape Town, South Africa, 19-22 July 2009; Oral #TUAB104.***

***Gathe JC et al. Switching HIV-infected, suppressed patients from ABC/3TC to FTC/TDF improves lipids – the SETTLE study. 10th International Workshop on Adverse Drug Reactions and Lipodystrophy in HIV London, UK, November 6-8, 2008; #37.***

***Gathe JC, et al. Single Agent Therapy with Lopinavir/Ritonavir Suppresses HIV-1 Viral Replication in ARV Naïve Patients: IMANI II - 96 Week Final Results. 48th Annual ICAAC/IDSA 46th Annual, Washington, DC, October 25-28, 2008; # H-1241.***

***William Towner, MD, FACP, Jacob Lalezari, MD, Michael G Sension, MD, Michael Wohlfeiler, MD, Joseph Gathe, MD et al. Efficacy, Safety and Tolerability of Etravirine With and Without Darunavir/ritonavir and/or Raltegravir in Treatment-experienced Patients: Analysis of the Etravirine Early Access Program in the United States. 17th International AIDS Conference (AIDS 2008) in Mexico City, Mexico, August 3–8, 2008.***

***Gathe JC, et al. Study M05-730 Primary Efficacy Results at Week 48: Phase 3, Randomized, Open-Label Study of Lopinavir/ritonavir (LPV/r) Tablets Once Daily (QD) versus Twice Daily (BID), Co-Administered with Tenofovir DF (TDF) + Emtricitabine (FTC) in Antiretroviral-Naïve (ARV) HIV-1 Infected Subjects. 15<sup>th</sup> Conference on Retroviruses and Opportunistic Infections (CROI), February 3-6, 2008, Boston, MA; Poster 775.***

***Yeh RF et al. Single Agent Therapy (SAT) with Lopinavir/ritonavir (LPV/r) Controls HIV-1 Viral Replication in the Female Genital Tract. 11th European AIDS Conference (EACS) - Madrid, Spain - October 24-27, 2007; #7.70/2.***

***DeJesus, E., Gottlieb, M., Gathe, J. et al. Safety and Efficacy of Enfuvirtide in Combination with Darunavir/Ritonavir and an Optimized Background Regimen in Triple-Class Experienced HIV-Infected Patients: the BLQ Study. 47<sup>th</sup> Annual Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), September 17-20, 2007, Chicago, IL.***

***DeJesus, E. et al. Response to Darunavir/Ritonavir (DRV/r) combined with Enfuvirtide Containing ARV in Triple-Class Experienced Patients Was Not Predicted by Baseline DRV sensitivity: the BLQ Study Final Results. 47<sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, 17-20 September 2007, Chicago, IL; ABS H-367.***

***Gathe JC Jr, Yeh RF, Mayberry C, et al. Single-agent therapy with lopinavir/ritonavir suppresses plasma HIV-1 viral replication in HIV-1 naive subjects: IMANI-2 48-week results. Program and abstracts of the 4th IAS Conference; July 22-25, 2007; Sydney, Australia. Abstract WEPEB034.***

***Joseph Clayton Gathe, Jr., M.D., F.A.C.P., F.I.D.S.A.***

***Yeh RF, Letendre S, Novak I et al. Single-agent therapy with lopinavir/ritonavir controls HIV-1 viral replication in the central nervous system. 14th Conference on Retroviruses and Opportunistic Infections. February 25-28, 2007; Los Angeles, California.***

***Gathe, JC et al. Neurocognitive Dysfunction: Immunologic Mechanisms, Biomarkers, and CNS Drug Penetration. 14<sup>th</sup> Conference on Retroviruses and Opportunistic Infections, Feb. 2007; ABS 381.***

***Campo R, et al. Predictors of Loss of Virologic Response in Subjects Who Detintensified in Subjects Who Deintensified to Lopinavir/Ritonavir Monotherapy after Achieving Plasma HIV-1 RNA <50 copies/ml on LPV/r plus Zidovudine/Lamivudine. 14<sup>th</sup> Conference on Retroviruses and Opportunistic Infections, Feb. 2007; ABS 514.***

***Gathe Jr., J. et al. IMANI-1 A 48 week pilot study of the safety and efficacy of lopinavir/riotonavir (LPV/r) as single agent therapy in ARV naïve patients post study follow-up. The 8<sup>th</sup> International Congress on Drug Therapy, Glasgow, UK, Nov. 12-16, 2006; ABS 950521.***

***Gathe JC, et al. Tolerability and Therapy Preference of Lopinavir/ritonavir (Kaletra) Soft-gel Capsules and Tablets as Single Agent in a Cohort of HIV Positive Adult Patients (IMANI-2). 8<sup>th</sup> International Congress on Drug Therapy in HIV Infection, Glasgow, UK, November 12-16, 2006; Poster P62.***

***Richard Elion, MD, Calvin Cohen, MD, Edwin deJesus, MD, Robert Redfield, MD, Joseph Gathe, MD et al. Once-Daily Abacavir/Lamivudine/Zidovudine plus Tenofovir for the Treatment of HIV-1 Infection in Antiretroviral-Naïve Subjects: A 48-Week Pilot Study, HIV Clinical Trials, Vol. 7, Number 6; Nov-Dec 2006.***

***Norris D, Morales, Gathe J Jr., et al. Phase 2 Efficacy and Safety of the Novel Entry Inhibitor, TNX355 in Combination with Optimized Background Regimen XVI IAS, Aug 2006, ABS TuPE0058.***

***Gathe Jr. J, Martin, D et al. Simplification from Trizivir/Kaletra to Trizivir provides a durable treatment regimen for AZT naïve patients COL 40193. XVI IAS, Aug 2006; ABS CPB0480.***

***Eron J, Yeni P, Gathe Jr. J, et al. The Klean Study: Fosamprenavir + Ritonavir vs. Lopinavir/Ritonavir in ART naïve adults over 48 weeks. XVI IAS, Aug 2006; THLB0205.***

***Gathe J.C. Jr., et al. Sustained Virologic and Immunologic Response over 120 Weeks in Antiretroviral Therapy (ART)-Naïve Subjects Receiving Fosamprenavir/Ritonavir (FPV/r) Q. HIV DART 2004, Poster 61.***

***Joseph Clayton Gathe, Jr., M.D., F.A.C.P., F.I.D.S.A.***

***DeJesus, Gathe J.C. et al. Week 24 Analysis of Once-Daily (QD) Trizivir (TZV) and Tenofovir DF (TDF) in antiretroviral naïve subjects (COL40263), ICAAC 2004; Pos 2950.***

***Gathe J.C., Jr. et al. Long term follow-up on GW43390/ ritonavir (908/r) QD: sustained virologic and immunologic response in antiretroviral treatment naïve subjects over 96 weeks. 15<sup>th</sup> IAC, 2004; Poster 4507.***

***Gathe J.C., Jr. et al. IMANI-1 TC3WP single drug HAART- proof on concept study. Pilot study of the safety and efficacy of Kaletra (LPV/r) as single drug HAART in HIV+ ARV-naïve patients interim analysis of subjects completing final 48 week data, 15<sup>th</sup> IAC 2004; Oral 1057.***

***Gathe J.C., Jr. et al. IMANI-1 TC3WP Single drug HAART proof of concept study pilot study of the safety and efficacy of Kaletra (LPV/r) as single drug HAART in HIV+ ARV naïve patients interim analysis of subjects completing at least 24 weeks of a 48 week study, The 43<sup>rd</sup> Annual ICAAC Conference, 2003; ABS 2608.***

***Gathe J.C., Jr. et al. LPV/r Qd vs Bid Study 48 Week Regimen, 11<sup>th</sup> CROI, 2004; ABS 418.***

***Kohlbrener, V, Gathe, J et al. Tipranavir/Ritonavir demonstrates potent efficacy in multiple protease inhibitor experienced patients at 24 week, BI 1182.52, 9<sup>th</sup> European AIDS Conference, Oct 2003; ABS 7.2/2.***

***Podzamcer, D, Gathe J et al. Efficacy and safety of once daily Lopinavir/Ritonavir vs. twice daily Lopinavir/Ritonavir in antiretroviral – naïve patients: 24 week results. 9<sup>th</sup> European AIDS Conference, Oct 2003; ABS F1/3.***

***Chiu, Y-L, Gathe, J et al. Multiple-Dose Pharmacokinetics (PK) and Initial Antiviral Effect of Once Daily (QD) Lopinavir/Ritonovir (LPV/r) In Combination With Tenofovir (TDF) and Emtricitabine (FTC) In HIV-Infected Antiretroviral (ARV)-Naïve Subjects, IAS Conference, July 2003; ABS .***

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**RESEARCH**

*(Total Protocols 166)*

**BI 1100-1486**

*A randomized, double blind, double dummy, parallel group, active controlled trial to evaluate the antiviral efficacy of 400mg QD nevirapine extended release formulation in comparison to 200 mg BID nevirapine immediate release in combination with Truvada in antiretroviral therapy naïve HIV-1 infected patients.*

**NP303-101 (ADVENT)** *Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Two-Stage Study to Assess the Efficacy and Safety of Crofelemer 125mg, 250mg, and 500mg Orally Twice Daily for the Treatment of HIV-Associated Diarrhea (ADVENT Trial)*

**TMC125-C238**

*A randomized, exploratory, open-label 48-week trial with a 2 week pre-treatment phase to investigate the pharmacokinetics, safety, tolerability and antiviral activity of etravirine (ETR) in combination with ritonavir-boosted*

**Joseph Clayton Gathe, Jr., M.D., F.A.C.P., F.I.D.S.A.**

*atazanavir (ATV/rtv) and 1 NRTI in treatment-experienced HIV-1 infected subjects.*

- KD 1002** *A Study of the Safety, Tolerability, Pharmacokinetics of KD-247, A Humanized Monoclonal Antibody that Recognizes the Principal Neutralizing Determinant of HIV-1, in Asymptomatic HIV-1 Seropositive Individuals Who Are Not Receiving Concurrent Antiretroviral Therapy.*
- Tobira 652-2-201** *A Proof of Concept, Multiple Dose-Escalating Study to Evaluate the Antiviral Activity, Safety, and Pharmacokinetics of the CCR5 Antagonist TAK-652 in HIV-1-Infected, Antiretroviral Treatment-Experienced, CCR5 Antagonist-Naïve Patients*
- M10-336** *A Randomized, Open-label, Study of Lopinavir/Ritonavir 400/100mg Tablet Twice Daily + Co-formulated Emtricitabine/Tenofovir Disoproxil Fumarate 200/300 mg Once-Daily Versus Lopinavir/Ritonavir 400/100 mg Tablet Twice-Daily + Raltegravir 400 mg Twice-Daily in Antiretroviral-Naïve, HIV-1 Infected Subjects*
- BMS AI424-376** *A Multicenter, Randomized, Open-Label, Active-Controlled Pilot Study to Evaluate the Safety and Antiretroviral Activity of Unboosted Atazanavir BID Plus Raltegravir BID and Boosted Atazanavir QD in Combination with Tenofovir/Emtricitabine QD in Treatment Naïve HIV-Infected Subjects*
- IMPACT AI424-128** *A Phase IV, Multicenter, Cross-Sectional Study to Evaluate 150L Substitution among Subjects Experiencing Virologic Failure on a HAART Regimen Containing Atazanavir (ATV)*
- MK518-07** *A Phase III Multicenter, Double-Blind, Randomized, Active Comparator-Controlled Clinical Trial to Study the Safety and Efficacy of Once Daily Raltegravir (MK-0518) Versus Twice Daily Raltegravir, Each in Combination With TRUVADA™, in Treatment-Naïve HIV Infected Patients*
- MK518-055** *A Phase III Open-Label Single Arm Study to Evaluate the Safety, Tolerability, and Efficacy of MK-0518/Raltegravir in a Diverse Cohort of HIV-Infected Patients*

**Joseph Clayton Gathe, Jr., M.D., F.A.C.P., F.I.D.S.A.**

- GS US 216-0105**      ***A Phase 2, Randomized, Double-Blinded Study of the Safety and Efficacy of GS-9350-boosted Atazanavir (ATV/GS-9350) compared to Ritonavir-boosted Atazanavir (ATV/r) in Combination with Emtricitabine/Tenofovir Disoproxil Fumarate (FTC/TDF) in HIV-1 Infected, Antiretroviral Treatment-Naïve Adults***
- GS US 236-0104**      ***A Phase 2, Randomized, Double-Blinded Study of the Safety and Efficacy of Elvitegravir/Emtricitabine/Tenofovir Disoproxil Fumarate/GS-9350 Versus Atripla®(Efavirenz 600 mg/Emtricitabine 200 mg/ Tenofovir Disoproxil Fumarate 300 mg) in HIV-1 Infected, Antiretroviral Treatment-Naïve Adults***
- GS US 183-0144**      ***A Multicenter, Randomized, Double-Blind, Double-Dummy, Phase 3 Study of the Safety and Efficacy of Ritonavir-Boosted Elvitegravir (EVG/r) Versus Raltegravir (RAL) Each Administered With a Background Regimen in HIV-1 Infected, Antiretroviral Treatment-Experienced Adults***
- GS US 183-0145**      ***A Multicenter, Randomized, Double-Blind, Double-Dummy, Phase 3 Study of the Safety and Efficacy of Ritonavir-Boosted Elvitegravir (EVG/r) Versus Raltegravir (RAL) Each Administered With a Background Regimen in HIV-1 Infected, Antiretroviral Treatment-Experienced Adults***
- GS US 164-0216**      ***(SWIFT) A Prospective, Randomized, Open-Label Phase IV Study to Evaluate the Rationale of Switching from Fixed-Dose Abacavir (ABC)/Lamivudine (3TC) to Fixed-Dose Tenofovir DF (TDF)/Emtricitabine (FTC) in Virologically-Suppressed, HIV-1 Infected Patients Maintained on a Ritonavir-Boosted Protease Inhibitor-Containing Antiretroviral Regimen***
- GS US 01-934**      ***A Phase 3, Randomized, Open-Label, Multicenter Study of the Treatment of Antiretroviral-Naïve, HIV-1 Infected Subjects Comparing Tenofovir Disoproxil Fumarate and Emtricitabine in Combination with Efavirenz Versus Combivir® (lamivudine/zidovudine) and Efavirenz***
- TMB 202**      ***A Phase 2b, Randomized, Double-Blinded, 48-Week, Multicenter, Dose-Response Study of Ibalizumab Plus an***

**Joseph Clayton Gathe, Jr., M.D., F.A.C.P., F.I.D.S.A.**

***Optimized Background Regimen In Treatment-Experienced Patients Infected With HIV-1***

***TMC278-TiDP6-C215: (Thrive) A Phase III, randomized, double-blind trial of TMC278 25 mg q.d. versus efavirenz 600 mg q.d. in combination with a background regimen consisting of 2 nucleoside/nucleotide reverse transcriptase inhibitors in antiretroviral-naïve HIV-1 infected subjects.***

***APV30005 An Open Label Phase III Study to Assess the Longterm Safety Profile of GW433908 Containing Regimens With HIV Infected Subjects.***

***A1455-110 A Long Term Safety and Tolerability. Stavudine (D4T) Extended Release (ER) Versus Conventional (Immediate Release, IR) Formulation , Each in as Part of Potent Antiretroviral Combination Therapy.***

***1182-52 Double-Blind Randomized, Dose Optimization Trial of Three Dose of Tipranavir Boosted with Low Dose Ritonavir in Multiple Antiretroviral Drug-Experienced Subject.***

***1182-17 A Long-Term Open-Label Rollover Trial Assessing the Safety and Tolerability of Combination Tipranavir and Ritonavir use in HIV-1 Infected Subjects.***

***AI424-900 Atazanavir Early Access Program for HIV Infected Amendment #3 Individuals.***

***P00738 Phase 3 Study of PEG-Intron in Heavily Treatment-Experienced Infected Patients.***

***ESS-30008 Open-Label Randomized Study of the Safety & Efficacy of Abacavir/Lamivudine Fixed Dose Combination Tablet Versus Abacavir + Lamivudine Administered Bid As Part of a Potent Antiretroviral Regimen.***

***ESS-30005 Phase IV Open-Label Treatment with Trizivir Twice Daily and Tenofovir Once Daily in Subject Experiencing Early Virologic Failure.***

***M02-418 Randomized Open-Label Study Lopinavir QD Versus Lopinavir Bid In Combination with a Potent Antiretroviral Background.***

***MV-16812B Fuzeon early access program.***

**Joseph Clayton Gathe, Jr., M.D., F.A.C.P., F.I.D.S.A.**

- CAN-30032** *Retrospective Case Control Study to Investigate Polymorphesims in Subject Who Developed Hypersensitivity Following Treatment with Abacavir.*
- PR01-29-024** *Open-Label to Evaluate the Effect of Every Other Week Procrit Dosing on Maintaining Quality of Life and Target Hemoglobin Levels in Anemic HIV Infected Subjects.*
- COL40263** *Open-Label to Evaluate to Efficacy and Safety of a Once Daily Regimen of Trizuvir in Combination with Terofovir in Antiretroviral Therapy in Naïve Subject with Viral Loads Greater Than or Equal 30,000 copies.*
- CAN-30021** *Phase III Randomized Double-Blind Study to Evaluate the Safety and Efficacy of Abacavir 600mg Once Daily Versus Abacavir 300mg in Combination with Lamivudine 300mg Once Daily and Efavirenz 600mg Once Daily in Naïve HIV Infected Subjects.*
- ACH-443-006** *Phase II Trial of 4 Week of ACH-126, 443 in Comparison with Continued Lamivudine in Stable Triple Antiretroviral Combination Therapy in HIV-Infected Subject with Detectable Viral Loads.*
- ACH-443-902** *Open-Label Rollover Study form ACH-443-006 Open-Label to Provide Continued ACH-126, 443 to Subject.*
- ESS40013** *Phase IV 48 Week Induction Treatment with Trizivir +\_ Efavirenz followed by 48 week Randomized Open-Label Maintenance Treatment With Trezivir + Efavirenz in HIV Antiretroviral Therapy in Naïve Subjects.*
- COL20069** *Investigation to Determine Agenerase and Kaletra Plasma Trough Levels.*
- CBIG** *Retrospective Study Reviewing Viral Load and Genotypes in Subject Receiving Lopinavir/Retonavir.*
- 100-99004** *Vigilance II Study. Use of Genotyping in HIV-1 Therapy.*
- AI424067** *Phase IIIB Open-Label Randomized Multi-Center Study Evaluating the Effect on Serum Lipids Following a switch to Protease Inhibitor (PI) Atozaravir in HIV-1 Infected Subject Experiencing Virologic Suppression on Their first PI Based Regimen.*

**Joseph Clayton Gathe, Jr., M.D., F.A.C.P., F.I.D.S.A.**

- ITG-20001**                      *Phase II Randomized, Placebo-Controlled Study to Compare Antiviral Effect, Safety, Tolerability and Pharmacokinetics of Four Oral Doses of S-1360 Versus Placebo for 10 days in Antiretroviral Naïve HIV-1 Infected Subjects.*
- 0104T0523**                      *Phase I/II to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of S-1360 Given Open-Label Monotherapy Administered to Treatment Experienced HIV-1 Infected Subjects.*
- COL40193**                      *“A phase IV Multi-Center Study of the Efficacy and Safety of 48-week Induction Treatment with TRIZIVIR †(Abacavir 300 mg/Lamivudine 150 mg/Zidovudine 300 mg Combination Tablet BID) + KALETRA (Lopinavir 400 mg/Ritonavir 100 mg Combination Capsules BID) Followed by 48- Maintenance Treatment with TRIZIVIR in HIV-1 Infected Antiretroviral Therapy Naïve Subjects”*
- FTC-301**                        *“A Randomized, Double –Blind, Equivalence Trial Comparing Emtricitabine to Stavudine within a Triple Drug Combination Containing Didanosine Plus Efavirenz, in Antiretroviral-Drug Naïve HIV-1 Infected Patients”*
- A1424-037**                      *“A Phase III Study Comparing the Antiviral Efficacy and Safety of Atazanavir with Nelfinavir; Each in combination with dual Nucleoside Therapy in HIV-1 Infected subjects who have failed a regimen not containing a protease inhibitor”*
- COL 20069**                      *“An investigation to determine Agenerase™ and Kaletra™ Plasma Trough Levels”*
- Tenofovir**                        *“Expanded access program for Tenofovir Disoproxil Fumarate (Tenofovir DF) in the treatment of HIV-1 infected patients who have limited treatment options- Protocol GS-00-955”*
- APV30003**  
**Amendment #1**                      *“A phase III, Randomized, Multicenter, Parallel group, open-label, three arm study to compare the efficacy and safety of two dosing regimens of GW433908/ritonavir (700mg/100mg twice daily or 1400 mg/200mg once daily) versus lopinavir/ritonavir (400mg/100mg twice daily) for*

**Joseph Clayton Gathe, Jr., M.D., F.A.C.P., F.I.D.S.A.**

*48 weeks in Protease Inhibitor experienced HIV-infected adults experiencing Virological failure”*

**APV30002**

**Amendment #2**

*“A randomized, open label two arm trail to compare the safety and antiviral efficacy of GW433908/Ritonavir QD to Nelfinavir BID when used in combination with Abacavir and Lamivudine BID for 48 weeks in antiretroviral therapy naïve HIV-1 infected subjects”*

**ORTHO-BIOTECH “Prevalence of Anemia in HIV-Infected Patients”**

**PR99-29-032**

**APV30002**

*“A Randomized, Open-Label, Two Arm Trial to compare the safety and Antiviral Efficacy of GW433908/Ritonavir QD to Velfinavir BID when used in combination with Abacavir and Lamivudine BID for 48 weeks in Antiretroviral Therapy Naïve HIV-1 Infected Subjects”.*

**NR15720**

*“An Open-Label, Randomized, Multicenter study to evaluate Fortarase*

**ROCHE**

*(Saquinavir) SGC QD, Vonir (Ritonavir) QD plus two NRTI’s vs Sustival (Efavirenz) QD plus two NRTI’s in HIV Infected Patient’s”*

**AG1549-529**

*“A long-term extension of studies AG1549-503 and AG1549-504: A long-term study of the safety and efficacy of Capravirine when used in combination with Viracept <sup>TM</sup> and Combivir <sup>TM</sup> in Antiretroviral-treatment-naïve patients”*

**AG1343-1127**

*“A Randomized, Open-Label, study of Velfinavir or Efavirenz in HIV-1 Infected Patient’s”*

**AG1549-505**

*“A Phase II, Open-label study of Efavirenz in combination with protease inhibitors and 2 nucleoside reverse transcriptase inhibitors in HIV-Infected patients who have experienced virologic failure in study AG1549-303 or AG1549-504”*

**HE2000-005**

*“A Phase I/II, Open-label study of the Safety, Tolerance, Pharmacokinetics, Drug-interaction and Anti-HIV activity of Intramuscularly administered  $\alpha$ -Epi-BR (HE2000) in HIV-Infected Patients on Salvage Therapy.*

**CS-MM-9901**

*A Bridging Dose Escalation Study of The Safety And*

**Joseph Clayton Gathe, Jr., M.D., F.A.C.P., F.I.D.S.A.**

- IL2** *Pharmacokinetic Properties Of Subcutaneous L-7001 (Recombinant Human Interleukin-2) in patients infected with HIV and CD4 + Tcell counts 300-500 and viral burden under 10,000 on HAART.*
- P00737  
PEG-Intron** *Antiviral Activity and Tolerability of PEG-Intron in HIV infected subjects failing HAART.*
- TARHEEL  
ESS40010** *Trial To Assess The Regression Of Hyperlactatmeia And To Evaluate The Regression Of Established Lipodystrophy In HIV Positive Subjects. A multi-center, Phase IV, open label switch study designed to assess the regression of Lipodystrophy Syndrome and Hyperlactatmeia in HIV-1 positive subjects currently treated with (d4T) when Abacavir (Ziagen), Abacavir/Lamivudine, or Combivir is substituted.*
- ZORRO  
ESS40009** *A Phase IV open-label study to assess the safety and tolerability of Abacavir in HIV-1 infected individuals and to investigate the effect of Baseline Genotype with virtual phenotype on the response to Abacavir in therapy experienced subjects in the clinical setting*
- 430  
VERTEX** *Open Label Phase IV Pilot Study of the use of RTV/Amprenavir following Nelfinavir failures.*
- AG1549-504** *A Randomized, Double Blind, Placebo-Controlled Study of AG1549 in combination with Viracept and Combivir in treatment Naïve HIV infected patients.*
- BMS  
AI455-099** *The Safety and Antiviral Efficiency of Stavudine Extended Release Formulation as composed to Stavudine immediate release formulation each as part of potent Antiretroviral Combination Therapy.*
- ESS40005** *A Phase IIIB Randomized, Multi-Center Study of the Efficiency and Safety of Combivir tablet BID + Ziagen vs combination tablet (Trizivr) administered for 24 weeks in subjects with HIV-1 infection.*
- ESS40011  
STARR** *A 24 week Randomized, Open-label, Multi-center Trial to compare the Safety and Efficiency of Licensed Agenerase dose (1200mg BID) to a lower Agenerase dose (600mg BID) in the presence of Norvir (100mg BID) when combined with other background Antiretroviral drugs in HIV-1 infected subjects.*

***Joseph Clayton Gathe, Jr., M.D., F.A.C.P., F.I.D.S.A.***

- PR98-29-002***                      ***The effects of a weekly dosing regimen of procrit (Epoetin Alfa) on the quality of life in the treatment of anemia in HIV- Infected patients on antiviral therapy.***
- Protocol  
Salvage  
Zolopa***                              ***HIV-1 Virologic Response to Saquinavir/Ritonavir  
Therapy after Nelfinavir Failure: A Multicenter Clinic-  
Based Study.***
- PR100-98002***                      ***Study Effectiveness of Antiretroviral Regimens Chosen  
by HIV Genotype: the SEARCH Study***
- HE2000-0022***                      ***A phase I/II, open label study of the safety, tolerance,  
pharmacokinetics, drug interaction and anti HIV activity  
of subcutaneously administered ~ Epi-Br (HE2000) in  
HIV infected patients on salvage therapy.***
- RCV00105***                              ***Method of treating HIV positive (AIDS) Patient with  
Indium (Targeted Biological Therapy) 111 Chelated gp  
120/41 Antibiotics***
- Protocol  
M98-888***                              ***A Randomized, Open-Label, Phase III Study of ABT-378  
Ritonavir in Combination with Nevirapine and Two  
Nucleoside Revers Transcriptase Inhibitors (NRTI's) vs  
Investigator Selected Best Protease Inhibitor(s) In  
Combination with Nevirapine and Two NRTIs in  
Antiretroviral-Experienced HIV-Infected Subjects.***
- Protocol  
FTC-303***                              ***A Randomized, Open-Label Equivalence Study of FTC  
Versus Lamivudine in Patients on a Stable Triple Anti-  
Retroviral Therapy Regimen Containing Lamivudine,  
Stavudine or Zidovudine, and a Protease Inhibitor or Non-  
Nucleoside Reverse Transcriptase Inhibitor.***
- Protocol  
M98-863***                              ***“A Randomized, Double-Blind, Phase III Study of ABT-  
378/Riton Plus Stavudine and Lamivudine vs Nelfinavir  
Plus Stavudine and Lamivudine in Antiretroviral – Naive  
HIV Infected Subjects”.***
- Protocol***                                      ***Evaluation of HIV RNA Suppression Produced by a  
Triple***
- AI454-152-004***                      ***Combination Regimen Containing An Enteric Coated  
Formulation of Didanosine (ddi EC) Administered Once-  
Daily To A Reference Combination Regimen.***

**Joseph Clayton Gathe, Jr., M.D., F.A.C.P., F.I.D.S.A.**

- NZTA-4006**      *A Phase IIIb, Open-Label, Randomized Study of the Effect of an Education Intervention on Virologic Outcomes, Adherence, Immunologic Outcome, and health Outcomes in HIV-Infected Subjects from Under-Represented Populations Treated with Triple Nucleoside Therapy (Combivir, Lamivudine 150 mg/ Zidovudine 300 mg, PO BID Plus Abacavir 300 mg PO BID) for Twenty Four weeks.*
- BMS-005**      *An Open-Label, Randomized study, Randomized study, Randomized of the additive effect of Hydroxyurea (DROXIA,HU) in combination with Stavudine (ZERIT, d4T) + Didanosine (VIDEX, ddI) + Efavirenz (SUSTIVA, EFV) in Protease Inhibitor- Experienced subjects.*
- W-003**      *Open Label Study of the effects of Thaldomide on Body Composition in Adults with HIV – Associated Wasting.*
- 37,554-210**      *A Double-Blind Randomized, Placebo-Controlled multi – center study to assess the Efficacy and Safety of Orally Administered SP-303 for the treatment of Diarrhea in Acquired Immunodeficiency Syndrome (AIDS)Patients.*
- AI454-148**      *A Randomized Study of the long-term Suppression of Plasma HIV-RNA Levels by Triple Combination Regimens in Treatment Naïve Subjects.*
- GS97-423**      *PREVEON (Adefovir Dipivoxil) Expanded Access Program*
- DMP-266-903**      *Sustiva (Efavirenz) Expanded Access Program*
- CNAA/B3005**      *A Phase III Randomized, Double-Blind, Multi-Center Study to Evaluate The Safety and Efficacy of 3TC/ZDV/1592U89 and 3TC/ZDV/IDV in HIV –1 infected Antiretroviral Therapy Naive Subjects*
- NRI5520**      *A Phase III B, Open-Label Protocol to Evaluate Saquinavir Soft Gel Capsules, in Treatment in Combination with other Antiretrovirals in HIV-1 Infected Antiretroviral Experienced Patients.*
- NR1553**      *A Phase III B, Open-Label Protocol to Evaluate Saquinavir Soft Gel Capsules (SGC), in Treatment in Combination with other Antiretrovirals In HIV-1 Infected Antiretroviral Naive Patients.*

***Joseph Clayton Gathe, Jr., M.D., F.A.C.P., F.I.D.S.A.***

- AI455-056***                      ***A Randomized Blinded Study of the Antiretroviral Effect and Safety of Didanosine (ddi) + / -Stavudine (d4T) + / - Indinavar (IDV) in Treatment Naive HIV-Infected Subjects.***
- GS-96-307***                      ***Open-Label Study of Cidofovir Gel for Acyclovir-Unresponsive Mucocutaneous Herpes Simplex Disease in Patients with AIDS.***
- ALRT1057***                      ***A Phase III Trial to Evaluate the Safety and Efficacy of PARENTINTM Topical Gel in the treatment of HIV-Infected Patients with Kaposi's Sarcoma.***
- AG1343-511***                      ***A Phase III Randomized, Double-Blind, Placebo-Controlled, Study of VIRACEPT in Combination with Zidovudine (AZT) plus lamivudine (3TC) Versus AZT plus 3TC Alone in HIV Positive Patients with <1 Month or No Prior Antiretroviral Treatment.***
- AG1343-515***                      ***VIRACEPT Expanded Access Program***
- A1455-048***                      ***A Randomized Double-Blind Study of Safety, Virologic and Immunological Effects of Stavudine plus 3TC versus Zidovudine plus 3TC in HIV-Infected Subjects Following At Least Six (6) Months of Zidovudine Therapy.***
- Protocol 001.002***                      ***Multi-Center Phase III Trial to Evaluate the Efficacy of Recombinant Human Granulocyte-Macrophage Colony Stimulating Factor (rhu Gm-CSF) in Patients with Acquired Immune Deficiency Syndrome (AIDS).***
- GS-95-120***                      ***Vistide (Cidofovir Intravenous) Treatment IND Protocol For Relapsing Cytomegalovirus Retinitis in Patients with AIDS.***
- Ampligen 101***                      ***A Multi-Center Controlled Study of the Efficacy and Safety of Ampligen in Patients with AIDS-Related Immune Dysfunction.***
- 89-FOS-09***                      ***Foscarnet Treatment of Serious Herpes Infections in Patients with AIDS.***
- Ganciclovir 1967***                      ***A Randomized, Controlled Study of Intravenous Ganciclovir Therapy for Peripheral Cytomegalovirus Retinitis Patients with AIDS.***
- Ganciclovir TX303***                      ***Open-Label Protocol for Patients with Sight Threatening Cytomegalovirus Retinitis.***

***Joseph Clayton Gathe, Jr., M.D., F.A.C.P., F.I.D.S.A.***

- Ganciclovir  
1691***                      ***Open-Label Protocol for Immunocompromised Patients  
with Life Threatening Cytomegalovirus Disease.***
- BW566-02***                      ***A Pilot Study of 566c80 for the Salvage Treatment of  
Toxoplasmosis Encephalitis in Patients Infected with the  
Immunodeficiency Virus (HIV) Who Have Failed or are  
Intolerant of Pyrimethamine Sulfadiazine.***
- A1455-019***                      ***A Double-Blind Comparison Zidovudine (ZDV) versus  
Stavudine (d4t) (BMY27857) for the Treatment of  
Patients with HIV Infection who have Received at Least  
Six (6) Months of Zidovudine Therapy and who have  
Absolute CD4 counts Between 50 and 500 Cell/mm<sup>3</sup>.***
- A1455-900***                      ***A Randomized, blinded Evaluation of Two Doses of  
Stavudine (2'3' - Didehydro-3' - Deoxythymidine, d4t)  
to Make Treatment Available to Severely  
Immunocompromised Patients with HIV Infection who  
have failed or are Intolerant of Alternative Antiretroviral  
therapy.***
- NV14147***                      ***An Open-Label Program of Dideixyxytidine (DD C) to be  
Used in Combination with Zidovudine (ZDV) for  
Treatment of Advanced HIV Disease.***
- COO41T20***                      ***Centacor: HA-1A Efficacy in Septic Shock Trial.***
- TLC G-65***                      ***Multi-Center Open-Label of TKC G-65 (Liposomal  
Gentamicin) Single Agent Loading Dose with  
Subsequent Combination Therapy in the Treatment of  
Disseminated MAI in AIDS Patients.***
- IX 100-058***                      ***Phase I/II Study of IVX-E-59 (AZT-O-ddI) Dimer in  
Patients with Asymptomatic HIV Disease.***
- M/330/0018***                      ***Randomized, Double-Blind, Placebo-Controlled  
Comparative Dose response Study of Two Doses of  
Ateviridine Mesylate in Combination with Fixed Doses of  
Zidovudine (ZDV) In HIV+ Patients.***
- M/3331-0017***                      ***A Double-Blind, Randomized, Comparative Study of  
Delavirdine Mesylate (U90-152S) in Combination with  
Didanosine (ddI) Versus ddI Alone in HIV-1 Infected  
Individuals with CD4 Counts of <300/mm<sup>3</sup>.***

**Joseph Clayton Gathe, Jr., M.D., F.A.C.P., F.I.D.S.A.**

- 33384-10** *Open-Label Oral 566c80 for the Treatment of Patients with Severe PCP who are Intolerant and/or Unresponsive to Therapy with Trimethoprim/Sulfamethoxazole and Parenteral Pentamidine.*
- 566-501** *A Treatment IND for 566c80 Therapy of Pneumocystis carinii pneumonia.*
- M/3331-0023** *Optional, Open-Label, Extended Use Delavirdine Mesylate (DLV) Treatment in Triple Combination for HIV-1+ Patients who Participated in Other Delavirdine Mesylate (DLV) Protocols.*
- CDC** *Fungal infections and CD4+Lmphocyte Depletion.*
- HPMPC** *A Phase I/II Study of the Safety and Efficacy of Topical (s)-l[3-Hydroxy-2-(Phosphonylemethoxy) Propyl] Cytosine (HPMPC) in the Treatment of Refractory Mucocutaneous Herpes Simplex Disease in Patients with AIDS.*
- 1038** *A Multi-Center, Placebo-Controlled, Double-Blind, Randomized Trial Comparing the Activity, Safety and Tolerance of: 1) 400 mg Nevirapine in Combination with 500-600mg/day of Zidovudine vs. Zidovudine Alone in Asymptomatic HIV-1 Infected Patients with 4-12 Months Prior Zidovudine Therapy and 200-5—CD4+ Cells/mm<sup>3</sup> And,2)400mg Nevirapine vs Nevirapine Placebo in Asymptomatic HIV-1 Nucleoside Naïve Patients with 200-5—CD4+ Cells+Cells/mm<sup>3</sup>.*
- SS-GB-L-01** *The Effectiveness of Minocycline for Prophylaxis of Toxoplasmosis in Individuals with Advanced HIV Infection.*
- DATRI-002** *Zidovudine Treatment in Patients with Primary (Acute) Human Immunodeficiency Virus Type 1 Infection: A Randomized, Double-Blind, Placebo-Controlled Trial.*
- Ranitidine** *A Pilot, Randomized, Double-blind, Placebo-Controlled, Parallel Designed Multi-Center Trial to Evaluate the Effect of Ranitidine on Immunologic Indicators in Asymptomatic HIV-1 Infected Subjects with a CD4 Count Of Between 400-700/mm<sup>3</sup>.*
- 006-189/189B** *A Randomized, Double-Blind Comparative Study of Azithromycin vs. Clarithromycin in Combination with Ethambutol for the Treatment of Disseminated*

**Joseph Clayton Gathe, Jr., M.D., F.A.C.P., F.I.D.S.A.**

***Mycobacterium Avium Complex (MAC) Infection in AIDS Patients.***

**A1460-001**

***A Pilot, Randomized, Double-Blind, Study to Compare The Safety and Biological Effects of Combinations of Didanosine and Stavudine in HIV-Infected Subjects with CD4 Cell Counts of 200-500/mm<sup>3</sup> and With No Prior Antiretroviral Therapy.***

**028574-PR003**

***A Randomized, Double-Blind, Active-Controlled, Dose-Ranging Study of the Safety and Efficacy of Chronically Administered MDL 28,574A in the Treatment of HIV-Infected Patients.***

**AG1343-510**

***A Phase I/II Study of VIRACEPT (AG1343) in Combination with Stavudine (d4t) Versus Stavudine (d4t) Alone in HIV Positive Patients.***

**95-0-10.1**

***Compassionate Use of Ambisome for Treatment of Invasive Fungal Infections in Patients Intolerant to or With Disease Unresponsive to Standard Antifungal Therapy Retinitis.***

**GCVI-601-CMV**

***A Multi-Center, Randomized Controlled Study to Evaluate the Safety and Efficacy of an Intravitreal Ganciclovir Implant in Patients with Newly-Diagnosed Cytomegalovirus Retinitis.***

**GCVI-603-CMV**

***A Multi-Center, Randomized Study to Evaluate the Safety Of an Intravitreal Ganciclovir Implant in Patients with Newly-diagnosed Cytomegalovirus Retinitis.***

**GCVI-605-COM**

***A Multi-Center, Open-Label Protocol to Evaluate the Use Of an Intravitreal Ganciclovir Implant in Patients with Sight-Threatening Cytomegalovirus Retinitis and No Central Venous Access.***

***Protocol  
1100.1090***

***An International, Double-Blind, Randomized, Phase III Study to Evaluate the Tolerance, Safety and Effectiveness of Viramune (Nevirapine) in Preventing Clinical AIDS Progression Events of Death when Used in Combination With lamivudine (3TC) and stable(>four weeks) Background Nucleoside Therapy.***

**M93-069**

***A Randomized, Open-Label Study of Tolerability and Efficacy of Clarithromycin and Ethambutol in***

***Joseph Clayton Gathe, Jr., M.D., F.A.C.P., F.I.D.S.A.***

***Combination with or without Clofazimine for the Treatment of DMAC in Patients with AIDS.***

***Foscarnet  
88-FOS-01***

***An Open-Label Study of Foscarnet Treatment of First Episode CMV Retinitis in AIDS Patients.***

***Foscarnet  
88-FOS-02***

***An Open-Label Study of Foscarnet Treatment of CMV Retinitis in AIDS Patients Not Eligible for Ganciclovir Treatment Failures.***

***E90-527-00***

***Open-Label Safety Study with Sch39304 in Patients with Systemic Fungal Infections.***

***CIFN-9002***

***Recombinant-Methionyl Human Interferon-Concensus (r-metHulCon). Phase I/II Randomized, Open-Label Study in Patients with AIDS-Associated Kaposi's Sarcoma to Determine the maximum Tolerated Dose (MTD) of f-meetHulFN-CON and Interon-A when Each is Administered in Combination with Zidovudine.***

***102-109.01.1***

***A Multi-Center Randomized Blind Comparative Study of Zidovudine Alone Versus Zidovudine with Acyclovir as Treatment for Patients with AIDS.***

***BW29, 102-04***

***A Multi-Center Randomized Blind, Comparative Study of Zidovudine Alone Versus Zidovudine with Acyclovir as Treatment for Patients with AIDS.***

***Clarithromycin***

***An Open-label Trial to Evaluate the Safety and Efficacy of Clarithromycin in the Treatment of Disseminated MAC Infection in AIDS Patients (Compassionate Plea Basis).***

***M90-978***

***A Phase II Study and Efficacy Study of Clarithromycin In the Treatment of Disseminated Mycobacterium Avium Complex (MAC) in Patients with AIDS.***

***Intraconazole***

***Randomized, comparative Study of Intraconazole Versus Fluconazole for the Treatment of AIDS-Related Cryptococcal Meningitis.***

***GCSF-9116***

***A Phase III Trial of Neupogen (Recombinant-methionyl Human Granulocyte Colony Stimulating Factor) as an Adjunct to Ganciclovir Therapy for Cytomegalovirus***

***103-09***

***A Randomized Phase III Clinical Trial of DaunoXome Versus Combination Chemotherapy with Adriamycin, Bleomycin, and Vincristine (ABV) in the Treatment of***

**Joseph Clayton Gathe, Jr., M.D., F.A.C.P., F.I.D.S.A.**

*HIV-Associated Kaposi's Sarcoma).*

- 103-14** *DaunoXome 60mg/m<sup>2</sup>, in Patients with Advanced Kaposi's Sarcoma.*
- N3663** *A Treatment Protocol for the Use of Dideoxycytidine (ddc) in Patients with AIDS or Advanced ARC who Cannot Be Maintained on Zidovudine (ZDVZ) Therapy.*
- Ns8-91-02-009** *Phase II Study of Safety and Surrogate Marker Efficacy Of SC-48834 and AZT in Symptomatic HIV-1 Infected Patients with >200 - <500 CD4+ cells/mm<sup>3</sup>.*
- 087085-999** *Rifabutin Therapy for the Prevention of Mycobacterium Avium Complex (MAC) Bacteremia in HIV Positive Patients with CD4 Counts <200 Treatment IND.*
- GS-01-934** *A Phase 3, Randomizes, Open-Label, Multicenter Study Of the Treatment of Antiretroviral-Naïve, HIV-1-Infected Subjects Comparing Tenofovir Disoproxil Fumarate and Emtricitabine in Combination with Efavirenz Versus Combivir and Efavirenz*
- TMC 125-C223** *A Randomized, Controlled, Partially Blinded Phase IIB Dose-finding trial of TMC 125, in HIV-1 infected subjects With Documented Genotypic Evidence of Resistance to Currently Available NNRTIs and with at least three Primary PI Mutations*
- TMC 125-C229** *An open-label trial with TMC 125 in HIV-1 infected Subjects, who were randomized to a TMC 125 treatment Arm in a sponsor-selected TMC 125 trial and were treated For at least 48 weeks.*
- TMC 125-C211** *An open-label trial of TMC 125 in HIV-1 infected Subjects who were randomized in any sponsor-selected TMC125 trial to an active control arm and either Virologically failed or complete the entire treatment Period, or to placebo arm and were treated for at least 48 weeks.*
- IMANI 2** *A Phase II, Open Label, Single Arm Study of the 48-week Virologic and Immunologic Response to Lopinavir / Ritonavir (Kaletra) as a Single Agent in a Cohort of HIV Positive Adult Patients*
- BI 1182.12** *Randomized, open-label, comparative safety and efficacy*

***Joseph Clayton Gathe, Jr., M.D., F.A.C.P., F.I.D.S.A.***

***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)***

***BI 1182.58***

***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.***

***BI 1182.70***

***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)***

***ML 18021***

***A 48-Week, Open-Label, Multicenter, Prospective Study Comparing Treatment with Double-Boosted Saquinavir Mesylate + Lopinavir/Ritonavir in Combination with Enfuvirtide HAART versus Double-Boosted Saquinavir Mesylate + Multiple Nucleoside Combination to evaluate Efficacy in HIV-1 Positive Patients.***

***ML 18413***

***A 48- Week, Randomized,Open-Label, 2-Arm Study to Compare the Efficacy of Saquinavir/Ritonavir BID plus Emtricitabine/Tenofovir QD in Treatment- Naïve HIV-1 Infected Patients (Gemini Study)***

***M03-613***

***A Randomized, Open Label Study Assessing Safety, Tolerability, Efficacy, and Metabolic Effects of a Simplified Lopinavir/ritonavir-based Induction/Maintenance Therapy in Antiretroviral- Naïve HIV- Infected Subjects***

***NV 17751***

***Observational Cohort Study of Pneumonia in Fuzeon-Exposed and Non-exposed Patients***

***COL 101310***

***Virologic and Immunologic Outcomes in Patients Form A Clinical Practice Switched from AMPENAVIR ( AGENERASE ) to FOSAMPRENAVIR ( LEXIVA )***

**Joseph Clayton Gathe, Jr., M.D., F.A.C.P., F.I.D.S.A.**

- INCB 8721 RVT-203**      *A Placebo-Controlled, Double-Blinded, Parallel Dose Group Study Exploring the Safety, Tolerability and Virological Effect of 50, 100 and 200 mg of Raltegravir (RVT) in HIV Infected Antiretroviral Therapy Experienced Subjects When Used in Combination with Other Antiretroviral Agents.*
- INCB 8721 RVT-901**      *A Long-Term Open-Label Non-Randomized Study to Evaluate the Safety of 100 and 200 mg Raltegravir (RVT) in HIV-Infected Antiretroviral Therapy- Experienced Subjects When Used in Combination with Other Antiretroviral Agents.*
- TNX- 355.03**      *A Phase 2, Multicenter, Randomized, Double- Blinded, Placebo- Controlled, Three-Arm Study of the Anti-CD 4 Monoclonal Antibody TNX- 355 with Optimized Background Therapy in Treatment- Experienced Subjects Infected with HIV-1*
- ESS 100732**      *A Phase IIIB, Randomized, Open-Label, Multicenter Study of the Safety and Efficacy of GW433908 (700 mg BID) plus Ritonavir (100mg BID) Versus Lopinavir/ Ritonavir (400mg/ 100mg BID) When Administered in Combination with the Abacavir/Lamivudine (600mg/ 300mg) Fixed-Dose Combination Tablet QD in Antiretroviral-Naïve HIV-1 Infected Adults Over 48 Weeks*
- M05-730**      *A Phase 3, randomized, Open-Label Study of Lopinavir/ Ritonavir tablets versus Soft Gel capsules and Once Daily Versus Twice Daily Administration, when Coadministered With NRTIs in Antiretroviral Naïve HIV-1 Infected Subjects*
- ML 18596(ENF-404)**      *A Randomized, Open Label, Two-Way Crossover Study to Assess the Tolerability of the B2000 needle-free Injection Device (NFID) for Administration of Enfuvirtide (ENF).*
- TMC114-C229**      *Early Access of TMC114 in Combination with Low-Dose Ritonavir (RVT) and other Antoretrovirals (ARVs) in highly Treatment Experienced HIV-1 Infected Subjects with limited To No Treatment Options.*
- GS-US-164-0115**      *Boosted Atazanavir and Truvada Given Once-Daily- the BATON Study: A Phase 4, Prospective, Open Label, Multi Center Study of the Safety, Efficacy, and Adherence in HIV Infected, Antiretroviral Naïve Subjects Treated with a Simple Once- daily Regimen.*

***Joseph Clayton Gathe, Jr., M.D., F.A.C.P., F.I.D.S.A.***

- P03672*** ***Vicriviroc (SCH 417690) in Combination Treatment With Optimized ART Regimen in Experienced Subjects (Victor E-1)***
- AI424-131*** ***A Phase IV, Open-Label, Randomized, Multicenter Trial Assessing A Reyataz-Based Substitution Approach in the Management of Lipodystrophy Syndrome (The REAL Study)***
- ML 19712*** ***A Multicenter, Open-Label Study Evaluating the Safety and Efficacy of a New Investigational Protease Inhibitor (PI) with FUZEON (Enfuvirtide) Plus Optimized Background in HIV-1 Infected Triple-Class Treatment-Experienced, Enfuvirtide-Naïve Patients (BLQ Study).***
- TMC114-C226*** ***Early Access of TMC114 in Combination with Low-Dose Ritonavir (RVT) and Other Antiretrovirals (ARVs) in Highly Treatment Experienced HIV-1 Infected Subjects with Limited To No Treatment Options.***
- GS-US-183-0105*** ***A Phase 2, Randomized Study of the Treatment of Antiretroviral Treatment-Experienced HIV-1 Infected Subjects Comparing Ritonavir-Boosted (GS9137/r) Versus A Comparator Ritonavir-Boosted Protease Inhibitor(CPI/r) In Combination with Background Antiretroviral Therapy.***