

Valganciclovir use to prevent CMV in Individuals at Risk: a nation-wide clinical trial

by Francesca J. Torriani, M.D.

Infection with cytomegalovirus is very common: up to 2/3 of the general population and over 90% of gay men are exposed to CMV in their lifetime. CMV can reactivate when the body's immune defenses are low, such as in advanced HIV infection. In fact, prior to the availability of HAART, when CD4 counts dropped below 50 cells/mm³, up to 40% of persons developed CMV retinitis, an infection of the inner layer of the eye. For unclear reasons, retinitis is by far the most common manifestation of CMV in the HIV-infected population, followed by infection of the gut, the lung and the brain. If untreated, CMV retinitis invariably results in blindness because it destroys the retina, the organ responsible for vision. Specific treatment with ganciclovir, foscarnet, or cidofovir (all given intravenously) only slows progression of the disease without curing the infection. With the exception of the oral formulation of ganciclovir, all currently FDA-approved drugs for the treatment of CMV require intravenous administration. Because of an unfavorable bioavailability profile, oral ganciclovir requires thrice daily administration and is expensive. Therefore, even though oral ganciclovir was approved in 1995 for prophylaxis and maintenance treatment of CMV retinitis, in practice it is seldom used.

Valganciclovir is an oral prodrug of ganciclovir, that is converted almost entirely to ganci-

clovir in the gut wall. The oral bioavailability of ganciclovir is increased to more than 60% and a single dose of 900 mg of valganciclovir reaches levels similar to those achieved with an intravenous dose of 5 mg/kg. The side effects of valganciclovir are similar to those of intravenous ganciclovir and include leukopenia and anemia, diarrhea, nausea and flatulence.

Potent antiretroviral therapy has changed the course of CMV retinitis, even in patients who have not experienced tight control of HIV replication or a CD4 count increase. Since 1996, new cases of CMV retinitis have decreased dramatically and the immune restoration induced by HAART has resulted in complete healing of the retina as well as suppression of CMV viremia even in the absence of specific anti-CMV therapy. In the face of these encouraging results it is estimated that up to 25% of patients failing HAART (that is with CD4 counts dropping below 50 cells) and who eventually have CMV viremia, will experience either new or reactivation of CMV disease. Patients who have been exposed to CMV, are failing or are not on antiretroviral therapy and have CD4 counts below 100 cells/mm³ and detectable HIV RNA, are most likely at greatest risk of developing CMV viremia, followed by CMV retinitis. To date, it remains unclear whether treating CMV viremia will benefit these patients in the long term. Therefore, the use of CMV-specific therapy to prevent CMV viremia, seeding of the eye and ultimately CMV retinitis, would seem a reasonable approach.

ACTG 5030 has just opened nationwide with the objective to answer this question. This is a placebo-controlled, double-blind study of the efficacy and safety of valganciclovir for the prevention of CMV retinitis in patients with detectable CMV viremia. Up to 750 patients will be enrolled nationwide. Eligible participants are CMV seropositive individuals, currently receiving no CMV treatment, without CMV retinitis, with CD4 counts < 100 cells/mm³, and a plasma HIV RNA > 400 copies/mL. Subjects must either have been on HAART continuously for 3 months or not on HAART and not planning to

see **CMV** on page 5.

Ron is Retiring

Ron Snyder, RN has retired from the UCSD Treatment Center 01/01/2001. Ron has worked at the Treatment Center for 12 years as a clinical research nurse. He has coordinated multiple HIV research studies within the ACTG, CCTG and, also, private industry studies. Ron's many years of experience with clinical trials and patient management will be greatly missed.

Ron plans to enjoy his retirement by traveling and working in his garden. All of us at the Treatment Center wish Ron a very Happy Retirement!

Mission Statement

To develop and perform high quality research protocols which enhance the overall management of HIV infection while respecting and supporting the best interests of our clients. We will maintain a safe, caring, and confidential

The Treatment of Hyperlipidemia in HIV-infected Individuals

by Scott Letendre, M.D.

Hyperlipidemia is a common problem in the United States and is a major risk factor for atherosclerotic coronary heart disease (CHD). Several types of lipid disorders have now been described in persons living with HIV. Isolated hypertriglyceridemia is the most commonly reported lipid abnormality. Combined elevations in low-density lipoproteins (LDL) and triglycerides (TGs) also occur while isolated elevations in LDL are uncommon. The overall prevalence of combined hyperlipidemia varies from 25-40% in selected studies depending upon the population and type of antiretroviral therapy.

This high prevalence of hyperlipidemia in our patient population raises concern for an epidemic of accelerated atherosclerosis. While the long-term consequences of persistently elevated cholesterol and TG levels in HIV-infected persons are not known, cases of premature myocardial infarction have now been reported. As the survival of our patients improves, interventions to decrease the risk of mortality from common diseases, such as atherosclerotic CHD, become increasingly important. Therefore, more information on the appropriate management of lipid disorders in persons with HIV infection is needed.

Recommendations for the management of hyperlipidemia have been made by the National Cholesterol Education Program (NCEP). Currently, lipid-lowering therapy is recommended if the concentration of low-density lipoproteins (LDL) exceeds 160 mg/dL without other cardiovascular risk factors (CVRFs) or 130 mg/dL if there are at least two additional risk factors present (e.g., cigarette smoking or hypertension). These recommendations are likely to be updated within the next year. The most likely change will be that primary intervention is recommended for those whose LDL exceed 130 mg/dL, even if they do not have other cardiovascular risk factors.

Of course, diet and exercise are mainstays in the management of lipid disorders. However, if these fail, two classes of drugs are commonly prescribed to treat hyperlipidemia, the HMG-CoA reductase inhibitors (HRIs) and the fibrates. Several pilot studies have investigated the use of these drugs to treat hyperlipidemia in persons with HIV infection. For example, Penzak and colleagues found that treatment with HRIs produced mean declines in total cholesterol (TC) by 17-25% and TGs by 11-53%. Similarly, Slayter and colleagues found that treatment with a fibrate alone resulted in a mean decline in TG by 72% after 3 months. By combining agents from both classes, Henry and colleagues demonstrated reductions in TC by 30% and TG by 60% in 20 subjects. Notably, no significant adverse events were observed in this study of combined therapy. Despite these favorable results, no large, randomized trial of lipid-lowering therapy has yet been conducted in persons with HIV infection who are taking antiretroviral therapy.

The AIDS Clinical Trials Group recognized the need for systematic investigation of this important problem. ACTG 5087 was designed to address this need and will be a randomized, open-label, 48-week clinical trial comparing the safety and efficacy of fenofibrate (200 mg daily) and pravastatin (40 mg daily) in the management of HIV-related hyperlipidemia. The primary endpoints are a composite analysis of LDL, TG, and high-density lipoproteins (HDL) at week 12 and changes in safety measures between baseline at week 12. The composite efficacy analysis incorporates the following elements;

- 1 LDL levels below 100 mg/dL for subjects with two or more CVRFs or 130 mg/dL for subjects with fewer than two CVRFs;
- 2 TG levels below 200 mg/dL for subjects with entry TG 200-800 mg/dL or 400 mg/dL for subjects with entry TG > 800 mg/dL; and
- 3 HDL levels above 35 mg/dL.

Enrolled subjects who do not satisfy all criteria by week 12 will be asked to start combined therapy with both drugs at week 16. All subjects will be asked to follow-up for 48 weeks.

Eligible participants will be adults living with HIV infection and hyperlipidemia who have already failed a 30-day trial of diet and exercise; who have been off lipid-lowering therapy (including niacin) for at least 2 weeks; and who have been treated with antiretrovirals for at least 6 months total (including a stable regimen for at least 4 weeks). Individuals with pregnancy, uncontrolled hypertension, known CHD, diabetes mellitus, hypothyroidism, or a history of rhabdomyolysis will not be eligible to enroll. If you have a patient who meets these eligibility criteria and is interested in participating, please call the Screening Coordinator at 619-543-8080.

A new research study (ACTG 5087)

Opening soon...

Fenofibrate vs. Pravastatin

in HIV-infected individuals
with lipid abnormalities

Inclusion Criteria:

- Stable on treatment for at least 4 weeks
- Fasting triglycerides > 200
- Fasting LDL > 130

**Call the screening coordinator about
ACTG 5087 at 619-543-8080**

HIV Treatment and Children

By Heidi Aiem, Health Educator

The UCSD Mother, Child, & Adolescent HIV Program is located at the UCSD Treatment Center and offers a myriad of services for families living with HIV and AIDS. Through this program, specialists in HIV care for pregnant women, mothers, children, and adolescents. The program also provides HIV testing for infants and children and health education for patients and the community. Our social services program helps patients and families to access resources and support groups in English and Spanish, obtain individual or family counseling, obtain crisis intervention, assist with disclosure to family members or schools, and obtain peer and family advocacy.

A major component of our program is clinical trials. Our program director, Dr. Stephen Spector is the chairman of the Executive Committee of the Pediatric AIDS Clinical Trial Group (PACTG). The PACTG trials are designed to examine the best options for treating HIV, boosting the immune system, preventing HIV transmission from a mother to her infant, and treating and understanding complications of HIV. Every eligible patient receiving care in our program is offered the opportunity to participate in these studies. A list of the studies open to pediatric, adolescent, and pregnant patients is included in the quarterly UCSD Treatment Center Newsletter.

It is well understood that HIV infection progresses differently in children than in adults. In children, CD4 counts are dependent on the child's age. A young child would be considered severely immunocompromised with a CD4 count under 750 cells/mm³, whereas an older child isn't considered severely immunocompromised until CD4 cells fall under 200 cells/mm³. There are also distinct differences in the initial plasma HIV RNA levels of adults and children, such that children have significantly higher initial HIV RNA levels than adults and these levels remain high for up to 3 years before declining. Antiretroviral therapy alternatives for HIV in children, historically, have been limited. Recently, however, we have seen an increase in the number of effective antiretroviral medications available to children. Despite the availability of these medications, there continues to be a need to evaluate appropriate dosing of these medications in children. Although some information regarding the efficacy of antiretroviral drugs for children can be taken from clinical trials involving adults, trials for children are important in order to determine the impact of antiretroviral drugs on specific areas of HIV infection in children, including growth, development, and neurologic disease.

One such treatment trial, which has had very large participation in San Diego and nationwide is PACTG 382. PACTG 382 is an open-label, treatment study using two nucleoside reverse transcriptase inhibitors in combination with efavirenz and nelfinavir in children. The primary objectives of the study are to determine the dosing regimen and to study the safety profile of efavirenz in combination

with nelfinavir in children. The protocol is also designed to determine the pharmacokinetics and safety of nelfinavir and the liquid preparation of efavirenz in infants and children.

This study has shown some promising preliminary data including a very positive immune response in the vast majority of children participating in the study. The adult dosing of both efavirenz and nelfinavir in adults is well established, however, the appropriate dosing of both of these medications in children is still under investigation. The study, which includes two or more extended pharmacokinetic evaluations, provides us the opportunity to assure appropriate dosing of efavirenz and nelfinavir and to adjust these doses as needed.

The development of new antiretroviral, immune and vaccine-based therapies have helped prevent mother to child transmission of HIV, prevent disease progression, and prolong the life of HIV-infected individuals including children. As a result, we are seeing a growing number of pregnant women and children begin antiretroviral therapy. Short-term safety, efficacy and toxicity of these treatments have been evaluated in clinical trials. When providing treatment and care to HIV-infected pregnant women and children, one of the first questions we are confronted with is: "How are the medications going to affect my infant or my child in the long-

see *Children* on page 5



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High Dose Lopinavir/Ritonavir Study for multi-drug experienced patients

By Ashok Kurup, M.D.

Protease inhibitor (PI) containing regimens lead to profound and sustained suppression of viral replication. Despite their potency, however, the pharmacokinetics, short-term tolerability, long-term toxicity and convergence of late-resistance pathways of current PIs affect their use. With its approval by the US Food and Drug Administration (FDA) in September 2000, lopinavir/ritonavir (LPV/RTV or Kaletra™, Abbott Lab) represents a new paradigm in PI development with its unique co-formulation regimen providing convenience of therapy and enhanced potency without compromising tolerability.

Ritonavir inhibits the hepatic cytochrome P450 mediated metabolism of lopinavir thereby providing increased plasma levels of lopinavir well in excess of the EC50 for wild type HIV. Only a small pharmacokinetic enhancing amount of ritonavir is present in the drug whose potency is derived almost exclusively from lopinavir. LPV/RTV was also designed to reduce interactions with valine 82 of the HIV protease which has been known to mutate in response to other PIs. The recommended dosage for adults is 400/100 mg (3 capsules or 5.0 mL) twice daily with food. A dose increase to 533/133 mg (4 capsules or 6.5 mL) twice daily taken with food should be considered when used in combination with efavirenz or nevirapine.

Accumulating data from ongoing clinical trials demonstrate impressive evidence of efficacy of LPV/RTV. In antiretroviral-naïve patients with mean baseline HIV RNA of 4.8 log₁₀ copies/mL, triple therapy with LPV/RTV plus stavudine and lamivudine produced a decline in viral load to < 400 copies/ml in 99% of patients on treatment after 108 weeks. In an ongoing antiretroviral-naïve comparative Phase III study, the LPV/RTV containing regimen continues to be more virologically efficacious than the nelfinavir containing arm (93% vs. 82% < 400 copies/mL at 48 weeks).

Treatment of single PI-experienced, NNRTI-naïve patients with LPV/RTV, nevirapine and two NRTIs produced a virologic response to < 400 copies/ml in 88% of subjects on treatment after 24 weeks. In multiple PI-experienced NNRTI naïve patients, treatment with LPV/RTV plus efavirenz and NRTIs produced a decline in viral load to < 400 copies/ml in 86% of subjects on treatment after 24 weeks. This study also analyzed the clinical relevance of reduced *in vitro* susceptibility to lopinavir by assessing the virologic response with

respect to baseline viral genotype and phenotype. After 24 weeks of therapy plasma HIV RNA was suppressed to < 400 copies/mL in 93% and 65% of patients with <10-fold and >10-fold reduced susceptibility to lopinavir at baseline, respectively. In addition, virologic response was observed in up to 67% of patients whose baseline viral isolates contained 6 or more mutations. While the use of efavirenz undoubtedly affected the overall response rate, the correlation of response with baseline susceptibility to LPV/RTV demonstrates the antiviral activity of LPV/RTV in this population.

LPV/RTV is well tolerated and diarrhea of mild to moderate severity was the most common adverse event associated with combination therapy with LPV/RTV in 612 patients in Phase I/II and Phase III clinical trials. Lipid abnormalities are likely to be the most common dose-limiting adverse event. About 40% of treatment-experienced patients experienced significant increases in cholesterol (>300 mg/dL) or triglycerides (> 750 mg/dL) within 24 weeks.

Selection of resistance to LPV/RTV in antiretroviral naïve patients has not been characterized to date. In Phase II studies of 227 treatment naïve and PI experienced patients, isolates

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Research Study: Switch Regimens in individuals with Metabolic Disorders (CCTG 577)

Study Design:

Stay on same regimen or switch to efavirenz (same NRTIs).

Inclusion Criteria:

- ◆ Currently having metabolic complications
- ◆ Currently on Protease Inhibitor with 2 NRTIs;
- ◆ HIV RNA < 50

Call the Screening Coordinator
at 619-543-8080

A special "Thank you" to Ken Campos
and Bill Bailey, Ph.D. for their
contributions to UCSD Treatment
Center patient care areas.

start HAART for at least 3 months after entering the study.

After enrollment (Step 1), CMV DNA in the blood will be measured every 8 weeks and an ophthalmologic exam will be performed every 6 months. If CMV DNA is positive, participants will be randomized to Step 2 to either oral valganciclovir, 900 mg twice daily for 3 weeks, followed by 900 mg once daily for 9 weeks, and then 450 mg daily or matching placebo thereafter. Following randomization (Step 2), subjects will be monitored for the development of CMV retinitis with an eye examination every 8 weeks and for extra-ocular CMV disease with symptoms questionnaire every 8 weeks. It is estimated that about 150 of the initial 570 patients will be randomized to step 2.

Participants who develop CMV end organ disease (Step 3) will be treated with anti-CMV therapy and followed every 12 weeks with an ophthalmologic examination, other clinical and laboratory evaluations, and a quality-of-life assessment. Because valganciclovir appears to be as effective as intravenous ganciclovir for the treatment of CMV retinitis, this therapy will be offered to persons diagnosed with CMV retinitis and entering Step 3.

I believe this study will answer the very important question of how best to prevent CMV retinitis when patients are failing potent antiretroviral therapy. Even though not all patients will receive treatment, careful ophthalmologic examinations at two months' intervals will enable us to detect CMV disease earlier than in standard practice and before it can cause any serious damage to the vision. Please do not hesitate calling me for more information or, to refer, the Screening Coordinator at the UCSD Treatment Center, at 619-543-8080.

Cognitive Intervention Studies

- HIV is associated with cognitive impairment.
- 35% of asymptomatic and 50% of people with AIDS may experience symptoms.
- Some people who experience cognitive symptoms are failing on their current antiretroviral regimen.

UCSD researchers are investigating the cognitive effects of physician prescribed changes in antiretrovirals.

**Call Scott Holder to find out more:
(619) 543-5020**

**HIV Neurobehavioral Research Center
150 W. Washington Suite 200 San Diego, CA 92103**

Children

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term?" Because infants and children are still growing and developing, the potential long-term outcomes, including benefits, toxicities or other adverse outcomes are particularly important.

PACTG 219c, also known as the "Pediatric Late Outcomes Protocol", was designed to investigate these concerns. The major aim of the study is to follow HIV-infected infants, children, and adolescents who have participated in perinatal and pediatric clinical trials into young adulthood in order to monitor late consequences of treatment. The late outcomes include long-term survival and quality of life. Other general areas of study will be the effects on growth and development (including neuropsychological development), organ toxicity, and risk of developing secondary cancers. Secondly, the study will provide data describing the demographic, medical and treatment characteristics of children at PACTG clinical trial sites and track improvements in survival and quality of life over time. Infants and children who are not infected but were born to an HIV-infected mother will also be eligible to participate. This group of perinatally-treatment-exposed, but uninfected, children offers the opportunity to cleanly distinguish between perinatal/neonatal antiretroviral therapy exposure and disease progression effects.

Great advances have been made in the care and treatment of HIV-infected children however; there remain some unanswered questions. As children live longer, healthier lives, there is a continued need for clinical trials in order to address the pediatric-specific issues associated with antiretroviral treatment, HIV disease in children, and issues surrounding long-term treatment effects.

Research study for individuals who are at risk for CMV (ACTG 5030)

Inclusion Criteria:

- ◇ **CMV antibody positive**
- ◇ **CD4 <100**
- ◇ **HIV RNA >400**
- ◇ **Receiving HAART or not planning to start HAART for at least 3 months**

Patients receive:

- ◇ **CMV viremia screening every 8 weeks**
- ◇ **Eye exams every 6 months (every 8 weeks if CMV viremic)**
- ◇ **Valganciclovir vs. placebo when CMV viremia is detected**

**Call 619-543-8080,
ask for the Screening Coordinator**

High Dose Lopinavir/Ritonavir Study for multi-drug experienced patients

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from 4 of 23 patients with quantifiable (>400 copies/mL) viral RNA following treatment with LPV/RTV for 12 to 100 weeks displayed significantly reduced susceptibility to lopinavir compared to the corresponding baseline viral isolates. All 4 patients had at least 4 mutations associated with PI resistance immediately prior to therapy and following viral rebound, isolates from these patients all contained additional mutations associated with PI resistance. Thus, the genetic barrier to resistance is high when therapy with LPV/RTV is begun with wild-type virus (no new mutations detected following rebound) as opposed to beginning therapy with 4-5 mutations from prior PI (virus progresses toward resistance i. e. low genetic barrier). Therefore, in subjects failing multiple regimens, high level resistance is likely, necessitating a higher LPV/RTV concentration than in less experienced subjects to obtain adequate response.

The UCSD Treatment Center is currently recruiting PI and NNRTI experienced HIV-infected patients for a randomized, open label, phase II study to characterize the safety, tolerability, pharmacokinetics and antiviral activity of high dose LPV/RTV and LPV/RTV at standard dose administered with additional ritonavir. Subjects who have a plasma HIV RNA of more than 1000 copies/ml and a CD4 cell count of less than 200 cells/mm³ will be randomized to receive either 667 mg LPV/167 mg ritonavir (5 co-formulated capsules) BID or 400 mg LPV/300 mg ritonavir (3 co-formulated capsules + two 100 mg ritonavir capsules) BID. NRTIs may be

changed at the discretion of the investigator. Samples for pharmacokinetic evaluation will be collected at Day 21 of therapy. Participants will be followed for 48 weeks with regular physical examinations and blood tests.

In summary, LPV/RTV is a new, well-tolerated, twice daily protease inhibitor with good activity in PI-experienced subjects. A higher dose formulation is now available at the UCSD Treatment Center in a new study for highly experienced patients. Questions about the protocol or referrals may be directed to the screening coordinator at 619-543-8080.

HIV and Atherosclerosis Are patients at risk?

A new research study (ACTG 5078) will compare HIV positive individuals on different regimens with HIV negative controls.

Subclinical atherosclerosis will be determined by carotid artery intima-media thickness, measured at baseline and follow-up.

We are seeking individuals who have never taken a protease inhibitor and who have HIV RNA < 10,000.

Call the screening coordinator at
(619) 543-8080
(ACTG 5078)

Merck Therapeutic Vaccine Study HIV-1 gag DNA vaccine

Purpose:

To establish the safety and tolerability of a HIV vaccine in individuals who have achieved viral suppression on HAART

Inclusion criteria:

- 2 years undetectable and on antiretroviral treatment (RNA < 400)
- CD4 cells greater than 500 and never less than 200

For more information call
The Screening Coordinator at 619-543-8080

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Treatment Center News

**RESEARCH STUDIES
AVAILABLE FOR
ANTIRETROVIRAL-EXPERIENCED
INDIVIDUALS**

1. **High Dose ABT 378 (lopinavir) Study** — Evaluate escalating dosing of lopinavir/ritonavir in patients to see if PI resistance can be overcome. Regimen includes lopinavir, ritonavir and up to three NRTIs. Must have experience with at least two protease inhibitors and one NRTI. CD4 count must be less than 200 and viral load more than 1000 copies/mL.
2. **Salvage Study for PI, NNRTI experienced patients with treatment to include tenofovir** — uses amprenavir + ritonavir + abacavir + another NRTI (based on phenotype results) + either tenofovir or efavirenz. CD4 count must be more than 50 and viral load >1000 copies/mL. (*PEARL*)
3. **Salvage Study for PI experienced patients** — compares two dosages of indinavir + ritonavir + 2 NRTIs. Must be naïve to indinavir and ritonavir. Viral load must be between 1000 and 50,000 copies/mL (*ACTG 5055*).
4. **DAPD Study** — adds DAPD (an experimental NRTI) to current regimen. Must currently be on antiretroviral therapy and have past experience with AZT/3TC or d4T/3TC. This is a phase 1, 15-day study. Viral load between 5000 and 250,000. CD4 count must be more than 50 copies/mL.

For information on any of the above studies,
call the screening coordinator at (619) 543-8080

**ADHERENCE RESEARCH
STUDY (AEH 003)
MAXIMALLY ASSISTED THERAPY
(direct observation) vs. SELF-
ADMINISTERED THERAPY**

Inclusion criteria:

- Treatment Naive
- CD4>100

All patients receive ddI, d4T, efavirenz, and nelfinavir

For more information call (619) 543-8080 and ask for the Screening Coordinator

**TENOFOVIR RESEARCH STUDY
FOR TREATMENT NAÏVE
INDIVIDUALS**

**Tenofovir + 3TC + efavirenz
vs.
d4T + 3TC + efavirenz**

Inclusion criteria:

- Treatment Naive
- HIV RNA > 5000

*Call (619) 543-8080.
Ask for the Screening Coordinator*

Treatment Center News

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