

The STEP Ezine

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The Seattle Treatment Education Project's (STEP) EZINE is an electronic treatment resource newsletter distributed monthly to case managers, front-line workers, people affected by HIV/AIDS, physicians, other public health and allied health professionals and people living with HIV/AIDS. STEP's contact information is: Seattle Treatment Education Project, PMB 998, 1122 East Pike Street, Seattle, WA 98122-3934, (206) 329-4857 or 1-877-597-STEP (WA, OR, AK, HA, ID, MT)

The FDA has approved a new Protease Inhibitor: Atazanavir

FDA Talk Paper

FDA Approves a Once Daily Protease Inhibitor for HIV Infection

June 20, 2003

The Food and Drug Administration (FDA) today announced the approval of Reyataz (atazanavir sulfate), a protease inhibitor to be used in combination with other anti-retroviral agents for the treatment of patients with HIV infection. As with other anti-retroviral agents, Reyataz does not cure and does not prevent transmission of HIV infection or AIDS.

Approval of this drug will now allow patients access to a protease inhibitor that only needs to be taken once daily with food and has a low "pill burden" (two pills each day).

FDA based its approval of Reyataz on data from two Phase 2 48-week trials and from 24-48 week data from Phase 3 studies. Results from these trials showed a decrease in viral load (the amount of HIV-1 virus circulating in plasma) and an increase in CD4 cell counts (a measure of immune cells created by the body) in patients taking Reyataz in combination with other anti-retroviral agents. These treatment benefits were observed both in patients who had not been previously treated and in patients who had previously received other anti-retroviral therapy.

A significant safety concern commonly observed with the use of protease inhibitors is hyperlipidemia (high cholesterol). Reyataz appears to have minimal impact on lipid parameters such as triglycerides and cholesterol.

The most common laboratory abnormality observed with the use of Reyataz is hyperbilirubinemia. This laboratory abnormality resulted in the clinical adverse event of jaundice (yellowing of the skin) or scleral

icterus (yellowing of the eyes) in 15-24% of subjects taking Reyataz. This abnormality was shown to be reversible upon discontinuation of the drug. Hyperbilirubinemia with Reyataz did not appear to be associated with an increased risk of liver injury.

The most frequently reported adverse events among patients in the clinical trials were nausea, infection, headache, vomiting, diarrhea, abdominal pain, somnolence (drowsiness), insomnia, and fever.

Currently there are six other protease inhibitors approved by FDA for the treatment of HIV infection. These medications work at the final stages of viral replication and attempt to prevent HIV from making new copies of itself by interfering with the HIV protease enzyme. As a result, the new copies of HIV are not able to infect new cells.

Atazanavir is manufactured by Bristol-Myers Squibb Company of Princeton, NJ.

Media Inquiries: 301-827-6242

Consumer Inquiries: 888-INFO-FDA

IATEC presents the *2NN Study* results

The 2NN Study

Lara Strick, MD

The non-nucleoside reverse transcriptase inhibitors (NNRTIs), Sustiva (Efavirenz) and Viramune (Nevaripine), are now very commonly used as part of first-line HAART regimens. Previously, there was no data directly comparing the two NNRTIs nor the combination of the two. The eagerly awaited **2NN study**, presented by the International Antiviral Therapy Evaluation Center (IATEC) at the 10th CROI, compared the efficacy and safety of Sustiva and Viramune in a open-label large-scale, randomized multicenter head-to-head trial. In this 48-week analysis, 1,216 people were randomized to either Viramune 400mg once daily, Viramune 200mg twice daily, Sustiva 600mg once daily, or Sustiva 800mg + Viramune 400mg once daily. All persons received a HAART backbone of Efavirenz + Zidovudine + Zalcitabine (d4T), but this was altered if necessary due to toxicity. Eighty four percent of participants completed the 48 weeks of the study.

This study compared the percentage of people who developed treatment failure, the number of people who attained viral suppression, the increase in the number of CD4 cells, and the incidence of adverse events. The participants in all the groups were similar at baseline (median CD4 cell count 190 cells/mm³, median viral load (VL) of 4.7 log copies/ml). There were no significant differences in treatment success (viral suppression or change in the CD4 count) among all four treatment arms. The proportion of individuals who were considered a treatment success at 48 weeks was 56 percent in the once-daily and twice-daily Viramune group, 62 percent in the Sustiva group, and 47 percent in the dual-NNRTI group. The only statistical difference in efficacy was seen between the Sustiva and the dual-NNRTI group. Surprisingly, Viramune and Sustiva alone were clinically better than the combination mainly because there was less toxicity and therefore fewer dropouts.

Since all the treatment arms had similar efficacy, the focus turned to the number of adverse events in each group. The two Viramune arms had more liver toxicity and rash, but a better lipid profile and less central nervous system effects (CNS effects include sleep disturbance, abnormal dreams, and anxiety) than Sustiva. It appears that once a

day Viramune is as effective as twice a day, but may have more side effects. Twenty-five participants died during the study, and two were attributable to Viramune (1 liver toxicity, 1 severe rash). In conclusion, **two NNRTIs are not better than one**. The decision to use Viramune or Sustiva as part of a first-line regimen, given their similar efficacy, should be based upon the acceptability of the adverse event profile to the physician and HIV-positive individual.

	Viramune once a day	Viramune twice a day	Sustiva	Viramune + Sustiva
	N = 220	N = 387	N = 400	N = 209
Patients who changed tx (%)	29	22	20	34.5
Treatment failure (%)	44	44	38	53
Suppressed VL (%)	70	65	70	63
CD4 increase (cells/mm ³)	170	160	160	150
Total clinical adverse events (%)	28	27	22	35
CNS side effects (%)	2	5	6.5	8
Grade 3-4 liver lab Abnormalities (%)	13	8	4.5	9
Other lab abnormalities (%)	8	13	9	10

All about ‘ACAP’

ACAP connects persons living with HIV/AIDS to:

- experienced doctors
 - dental care
- health insurance options

Which doctors are available?

What dental care is available?

[How do I access ACAP services?](#)

What else does ACAP do?

We can also refer you to care management, transportation, treatment information and other social services.

How do I access ACAP services?

- We’re open Mon.-Fri., 8:00am-5:00pm.
- We’ll give you options so you can make the choice that’s best for you.
 - We can set up the appointment for you.
- We can give you the names and numbers of several doctors and dentists who match your needs.

Which doctors are available?

Among the many excellent doctors in King County who treat HIV/AIDS, you can request:

- a male or female doctor

- a doctor with a practice near your home or office
 - a doctor who charges lower fees
 - a private doctor or community clinic

What dental care is available?

It is best to see the dentist before you have an emergency because most coverage emphasizes preventative care.

Basic dental care can be covered through:

- Medicaid (also known as DSHS or medical coupons)
- Ryan White (call us to find out if you are eligible)
 - Private dental insurance

Call us!

(206) 284-9277
(800) 577-4023 toll free

MultiFaith Works *News*

MULTIFAITH WORKS CELEBRATES ITS 15TH YEAR!

Originally founded in 1988 as Multifaith AIDS Projects (MAPS), Multifaith Works has grown and changed over the years, all while maintaining its focus on serving the local AIDS community. Included under the Multifaith Works organizational umbrella is the *Shanti* program, which is 20 years old this year. Other Multifaith Works programs are: *Multifaith AIDS Projects Housing (MAPS)*, *AIDS CareTeams*, *Ariel MS House*, and the *Multifaith Alliance of Reconciling Communities (MAPS)*.

Multifaith Works is sponsoring a number of upcoming events. For more information, be sure to call 206.324.1520 or email info@multifaith.org.

GIVE US HOPE: AIDS Benefit Concert

Featuring the Sinikithemba HIV+ Choir of South Africa

Thursday, July 17th, 7:30 p.m., St. Mark's Episcopal Cathedral, 1245 - 10th Ave. E, Capitol Hill, Seattle

AIDS CareTeam Volunteer Training

Saturday, October 4th, 8:30 a.m. to 4:45 p.m., Tabernacle Missionary Baptist Church, 2801 South Jackson, Seattle. This training is for people interested in becoming HIV/AIDS volunteers as members of AIDS CareTeams. Through their caring attitudes, AIDS CareTeam members encourage empowerment, acceptance and hope.

Multifaith Works AIDS CareTeam Breakfast

Wednesday, October 15th

7:00 a.m. Registration, 7:30 to 8:30 a.m. Breakfast & Program

Town Hall Seattle, 1119 Eighth Avenue

Special Guest: The Honorable Rom Sims, King County Executive. Everyone is invited to this First Annual fundraising breakfast, "AIDS CareTeams: Caring for Communities."

Shanti Volunteer Training

November 1st & 2nd, 8th & 9th

Shanti volunteers provide one-to-one, nonjudgmental emotional support to people living with HIV/AIDS or other life-threatening illnesses. The Shanti training and volunteer experience has been described as life-changing for many volunteers.

Clinical Trials Updates

AIDS Clinical Trials Unit
325-9th Avenue, Second Floor
Seattle WA 98104
(206) 731-3184
actu@u.washington.edu

Therapeutic Drug Monitoring Study (Study # 5146)

Purpose: to study the safety of increasing doses of protease inhibitor (PI) drugs based on Therapeutic Drug Monitoring.

- Needing to change 2nd, 3rd, or 4th anti-HIV drug regimen
- No serious illnesses
- Men and non-pregnant women

Study for HIV-treatment Naïve Subjects (Study # 5142)

Purpose: to examine the use of a lopinavir/ritonavir (a ritonavir-enhanced, second- generation protease inhibitor)-based regimen, a non-nucleoside reverse transcriptase inhibitor (NNRTI)-based regimen, and a nucleoside-sparing regimen as the first treatment of HIV-1 infection.

- No prior antiretroviral therapy
- HIV RNA (viral load) of 2,000 copies or greater
- Planning to start anti-HIV treatment

Antiretroviral Therapy Switching (Study # 5115)

Purpose: to see and compare if it is better to change anti-HIV medications as soon as a viral load is 200 or wait until viral load is slightly higher. Changing medications at different viral load levels might matter in terms of 1) the immune system's ability to repair itself even HIV viral load is not completely suppressed and 2) whether HIV is more or less likely to develop resistance if changes in medications are delayed.

- Taking antiretroviral medications for more than 4 months
- CD4 count of 200 or above.
- HIV RNA less than 500 copies at one time and between 200 and 10,000 copies currently

- No severe medical conditions or infections
- Men and non-pregnant females

Cognitive Function in Individuals Receiving Potent Antiretroviral Therapy (Study # 736)

Purpose: to see how levels of HIV in the blood compare to those in the cerebrospinal fluid (CSF) before and after treatment with potent antiretroviral therapy.

- Starting a new potent antiretroviral therapy (HAART) either starting as new therapy or changing current therapy
- No recent treatment for acute infection
- No active brain infection
- Men
- Women of childbearing potential must not be pregnant

Want to find out about more studies at the ACTU? Visit our new website!

<http://depts.washington.edu/actu>

Thank you for supporting the ACTU

Community Events and Updates

5th Annual POZSeattle Picnic in the Park

Put it on your calendar

**Labor Day Weekend/Sunday August 31st
Seward Park in Seattle
Free for POZSeattle Members & Guests**

Looking for Picnic Volunteers!!

To make the picnic a big success, we need your help. This is a great way to support our community!!

We'll need help with a variety of things. Some of them are: cooks; providing ice chests or coolers; set up for food, beverages, and all the fixins' on the day of the event; icing down the beverages; and setting up volleyball, horseshoes, and croquet; and all the other ideas and things that make the POZSeattle *Picnic in the Park* a big success for the approximately 100 men who attend each year.

For more information or to volunteer for *Picnic in the Park*, contact Mike, 206-568-0513 or [email Mike](#)

ACKNOWLEDGEMENTS

- Please note that this is not a complete list of all HIV-related treatment information. STEP strives to provide the very latest in HIV treatment information, research and drug development information. The most current research directions and antiretroviral drug data are provided throughout the Ezine publications. You will find highlight reports as well as extensive follow-up reports from many of the AIDS research and science conferences on the Ezine. In addition, all STEP quarterly treatment journals are available on our Web site at <http://www.thebody.com/step/steppage.html> or by calling our Talkline at 1-877-597-STEP. STEP works hard to give unbiased treatment information to all interested parties. If you have comments, questions, suggestions or grievances, please contact ezine@stepproject.org.

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STEP Publications Advisory Committee:

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