

[National AIDS Treatment Advocacy Project](#)

Wednesday in Vancouver, July 10

Last night I went to a Glaxo Wellcome meeting where the updated data for 1592U89 was previewed for us as the data won't be officially presented until Thursday (see [article about 1592U89](#)). Glaxo requested that I not reveal the data before their official presentation tomorrow. So, stay tuned.

Also, they discussed plans for development of 141W94 (their protease inhibitor), and although the plans discussed were tentative, they seem to have a good approach to designing a broad spectrum of studies for 141W94. As you know, we are in a new era where 3 protease inhibitors are approved and available; this complicates the design of trials for all drugs, but even moreso for a protease inhibitor. It is expected that Glaxo will soon be moving ahead with these trials.

AZT/3TC and [nelfinavir](#) (Agouron's protease inhibitor)

This morning I viewed a poster presentation of a trial studying this combination. I will outline the vital information and discuss it in more detail after returning from the Conference. This is an important small pilot trial of treatment-naive individuals, that is open-label, and examines safety, pharmacokinetics and efficacy.

Data was presented for 12 study subjects with median baseline RNA of 81,270 (4.91, with a range of 17,990-864-900) and median CD4 baseline of 253 (with a range of 37-557).

Subjects received AZT (200 mg 3X/day), 3TC (150 mg 2X/day), and nelfinavir (750 mg 3X/day).

SAFETY. No serious side effects reported.

- 1/12 withdrew at week 6 for grade 2 diarrhea
- diarrhea most common adverse event: mild to moderate
- nausea and fatigue common during first 2 weeks

The data is preliminary as the ongoing study follows individuals out to 16 weeks. By 8 weeks, the RNA reduction for the 12 subjects averaged 2.6 logs and then proceeded to be undetectable for the remaining 8 weeks as measured by the second generation bDNA viral load test which measures down to 500 RNA copies. After 16 weeks the CD4s were up about 100 cells from baseline. Actually, all 11 subjects had under 25 RNA copies by 16 weeks, as measured by a sensitive laboratory research RNA test. Some subjects will be undergoing lymph node biopsies to discover the activity of virus in this "compartment" and to discern whether we can drain the virus from the lymph nodes.

I have to run now to cover the afternoon sessions.