National AIDS Treatment Advocacy Project
Human Retrovirus Conference
January 28-February 1, 1996, Washington, DC

DAY 1: HIGHLIGHTS FROM CONFERENCE

This is Jules Levin reporting up-to-the minute from the 3rd Retrovirus Conference. It's 10:30 AM and I've just returned from the "State of the Art" Lecture on Protease Inhibitors presented by Emilio Emini of Merck. It was an exciting moment in the development of treatments for HIV. The room was packed like sardines. Emini presented data on the same 5 protease inhibitors that were the subject of the NY Protease Inhibitor Forum that I (NATAP) organized and presented on Jan. 6 at NYU. In fact, most of the slides Emini presented today were shown at our Forum on Jan. 6. Of course, additional data is being presented at this conference and I'll be making it available both in our written report and at the Feb. 3 video presentation.

PROTEASE INHIBITORS

- Emini presented the some of the Merck Crixivan data: In a study of 15 patients taking Crixivan monotherapy, a median peak 2 log viral load drop was reached by 24 weeks and sustained at 48 weeks for 40% of the study participants.

- Emini briefly mentioned data on the ongoing AZT/3TC/Crixivan study, #035. He couldn't elaborate because Trip Gulick is presenting on this subject here on Thursday. This study has, I believe, 20 persons per treatment arm; however, in the #035 (AZT experienced population-very significant) study almost 90 % of the participants being administered the 3-drug combination had their viral load drop to undetectable and were still undetectable at 24 weeks; the median baseline viral load for the study participants was 40,000; the 24 week data from this study is as much as Merck has been able to accumulate so far. They are continuing to accumulate data from this study and we'll get more at a later date.

Based on the data in these 2 immediately above paragraphs, Emini concluded that if 40% sustained their viral load drop with monotherapy to 48 weeks, that he would expect that maybe 70% or more of those taking the 3-drug combination should have their viral load drop sustained out to at least 1 year.

WHEN TO START TREATMENT

There has been much discussion here about when to initiate therapy for HIV, both for treatment naive and experienced individuals, now that, seemingly, we now have much more potent therapies. Yesterday, at a treatment workshop Doug Richman, a noted AIDS researcher from UCSD, was strongly supporting the notion of "early" intervention with a multi-drug combination which would include a potent protease inhibitor. I asked him, how early he means? His respone was more general, but he encouraged consideration of the possibility of initiating treatment soon after sero-conversion, as well as intervention at the higher CD4 ranges. There have been other researchers here who have been encouraging the same considerations.

For those who are treatment experienced, some researchers here are encouraging treatment immediately with a multi-drug combination (with a potent protease inhibitor)--soon after ritonavir and Crixivan are available. I suggest to individuals that they be circumspect and give due consideration to their treatment decisions; consultation with a knowledgeable physician is recommended. Your doctor needs to be as well educated as possible on the relevant issues which include, but are not limited to: resistance, cross-resistance, the efficacy and side-effect profile of each drug, the drug interactions of each drug.

However, others have discouraged this "early" intervention approach until we can accumulate data on it. They encourage conducting studies to determine when would be the best times to intervene with treatments. I will tell you, that these studies will take time to gather data. In the meantime, some doctors and people with HIV may decide to try these "early" intervention approaches. In NY at the Aaron Diamond Research Center, David Ho, the Executive Director, and Martin Markowitz, the Director of Clinical Trials, have just started a trial testing this concept with a 3-drug combination (including ritonavir) on individuals who very recently sero-converted. I have learned here that there will be a White House Presidential initiative to assure the conducting of studies on how to best use these protease inhibitors.

- At this meeting, data will presented tomorrow (Tuesday) on the combination of AZT/ddI/Crixivan, the Abbott study of ritonavir for individuals with 100 CD4, the Abbott Frech study of ritonavir/AZT/ddC. I will send you highlights from here and full reports subsequently.

- Yesterday, Australian ritonavir researchers--Andrew Carr and Anthony Kelleher--presented data on immunological improvements for those recieving ritonavir in their study. From a small study, their slides displayed a median peak improvement in CD8 cells of 900 which was still sustained at 200 above baseline at, I think, 32 weeks. There has been discussion about whether these cells are "naive" or "memory" cells, and the significance of that. Mario Roederer noted from his research--others have supported this notion as well-- that it is better to have more naive CD8 cells. I asked David Ho if this CD8 cell improvement from ritonavir treatment would include naive cells; he said, we were not yet sure, but he thinks it probably contained some measure of them.

IL-2

I spent time talking to NIH researcher, Cliff Lane, about IL-2. Of course, he is leading the IL-2 research effort, but he strongly believes in the treatment. There are many doubters of the efficacy of this treatment. For one reason, while there is a considerable CD4 rise, there is no viral load improvement. I have been told here that a clinical endpoint study will probably be started fairly soon to examine whether IL-2 actually has meaningful benefit; this trial will study progression to AIDS and survival.

OK, I have to sign off now to attend another meeting about Serono's human growth hormone, used for treatment of wasting. In late February, I will be appearing before a FDA hearing for consideration of approval.

Hopefully, I'll send you more updates sometime tomorrow after the Merck and Abbott presentations.

report from day 2 of conference