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

2nd DAY- Tuesday HIGHLIGHTS from 3rd Retrovirus Conference from Jules Levin

I'm filing this report at 5:30 am, Wednesday morning, from my room. I'm so stimulated from all the events down here, that I can't sleep. The days are long and filled with meetings and presentations from 7 am til 10 pm. This 3rd Conference seems to be a watershed event. Because of the advent of protease inhibitors, their use in multi-drug combinations and the import of the accumulating data about the use of viral load testing (HIV RNA), many researchers are saying at this conference that we are truely entering a new era for HIV treatment (which I have been saying); the accumulating viral load data is strongly supporting its validity of predicting disease progression and survival. The mood here is very optimistic about future treatment of HIV for those of us with HIV and AIDS. The discussions and presentations are suggesting a major shift in the approaches to treatment (see Monday's 1st day HIGHLIGHTS---"When to start treatment") of the virus and to the approaches to the research efforts of clinical trials.

Tuesday morning started with an exciting, progressive opening "State-of-the-Art Lecture" by David Cooper, a noted AIDS researcher from down under--Australia. Dr. Cooper conducted some of the Abbott protease inhibitor clinical trial research. He suggested major shifts in the approaches to treatment and clinical trials research. Cooper said, large clinical endpoint trials (C.E.T. study progression to AIDS and survival--they can take years to conduct and consume resources) should no longer be conducted, but for 3 exceptions:

- where the drug in question has marginal benefits, or
- a situation like IL-2, where the immunological benefits (rises in CD-4) are not accompanied by apparent and significant changes in viral load, or
- where you want to discover benefits of a therapy for heavily drug pre-treated individuals.

Up til this point in the history of the regulation of AIDS research, clinical endpoint studies have been absolutely required for each and every drug before it receives approval. Before receiving accelerated approval, an "adequate" clinical endpoint study must be established and ongoing (by FDA regulation).

Cooper also called for changes in the approach to treatment. He said, we need to study and collect data on early intervention for treatment of HIV. The classical approach, as I understand it, by infectious disease specialists to this type of disease (HIV), is to treat as early as possible before a virus has a chance to gain a strong foothold in your body. Now that we have potent drugs (protease inhibitors), we can take this approach. He called for studies to test a new concept, but one also suggested months ago by John Leonard of Abbott Labs: study individuals who have oppotunistic infections-- treat them with

antivirals (protease inhibitor therapy), and monitor them for improvements and remission. This also is a new approach to clinical trials.

d4t

For the first time, viral load data was presented for d4T, as studies in treatment naive individuals. An improvement of viral load ranging from .6 to 1.0 log was presented by Christine Katlama (a French AIDS researcher), for study particpants in a trial examing "early" intervention for individuals in the CD4 range of 350 to 700. Further details will be reported following my return from the conference.

D4T/ddI

Dr. Pollard, an AIDS researcher at the Univ. of Texas, presented data on the results of a study done of a combination of d4T and ddI in people with aCD4 count of 200-500. All subjects were treatment naive and, as a whole, showed significant CD4 and viral load benefits from this combo. The data is from a small group of 76 individuals but is impressive. After 52 weeks, there was a mean viral load decrease of 1.4 logs; the CD4 increase of 60 to 80 cells was sustained at 44 weeks. Further details will be reported.

HIV RNA (viral load)

The Roche assay was submitted to the FDA for review and approval in November of 1995 (see my article, "Perspectives on Viral Load Testing", in the December issue of BETA; the AIDS publication of the San Francisco AIDS Foundation--I will have the article posted to this home page). It has been reported to me, that an April hearing date has been set by the FDA. If all goes well, which I expect to occur, we should have FDA approval and access to this test by May. Much of the data on viral load, that has been accumulated and submitted to the FDA, was presented today. It is a convincing argument that HIV RNA is a predictor of disease progression and survival. Seemingly, changes in viral load from the use of therapy have predictive value for progression and survival.

Other important information was presented at the conference today. But, I have to sign off now to prepare for the 8:30 am, "State-of-the-Art Lecture" by Doug Richman about "Resistance to Antiretroviral Drugs". If you don't get down to the lobby early for breakfast it becomes too crowded to eat. Other important subjects from yesterday, that I will report on are: longer term AZT/3TC data, the Abbott protease inhibitor French study of ritonavir/AZT/ddC, impressive but early results of a new antiviral from Glaxo Wellcome--1592U89, a new Ciba-Geigy protease inhibitor about to enter a phase I trial, and the impressive 6-month data results of the Merck study of indinavir/AZT/ddI.

report from days 3 and 4 of conference