Lesbian /Gay Health

Expanded Availability of ddI

Secretary of the U.S. Department of Health and Human Services (HHS) Louis W. Sullivan, M.D., announced that the Food and Drug Administration (FDA) and the National Institutes of Health (NIH) have developed a comprehensive plan for clinical evaluation and expanded availability of ddI (dideoxyinosine). This promising antiviral agent that has shown activity against the AIDS virus in laboratory studies and in limited human studies although in some persons there have been potentially serious side effects.

"This plan offers some additional options for people with AIDS, and particularly for the thousands of AIDS patients who cannot tolerate therapy with AZT," Dr. Sullivan said.

Dideoxyinosine, which was initially developed by Samuel Broder, M.D. and Robert Yarchoan, M.D. at the National Cancer Institute (NCI), is one of a group of drugs including zidovudine, that inhibits replication of the AIDS virus. Phase I safety trials of ddI were recently completed by NCI and AIDS Clinical Trials Group, (ACTG) of the National Institute of Allergy and Infectious Diseases (NIAID), investigators at the University of Rochester and New York University.

These studies showed that, while ddI appears promising, it has toxicities related to the dose taken; thus, its use requires careful monitoring.

Despite the promising early results with ddI, it is important to emphasize that zidovudine is the only drug with proven efficacy for the treatment of patients with AIDS and advanced ARC.

Under the Treatment IND, AIDS patients who have experienced severe anemia or other dose-limiting adverse reactions to zidovudine will be eligible to receive ddI through a program administered and funded by Bristol-Myers Company of New York. The patients on this protocol will be monitored by their physicians for evidence of toxicity also.

In addition, an open safety protocal sponsored by the company will allow ddI to be studied in AIDS patients whose disease has progressed substantially despite zidovudine therapy.

Although Bristol-Myers is not charging for the cost of the drug in any of these programs, there are likely to be physician and laboratory charges associated with receiving ddI through either Treatment IND or open safety protocols.

Physicians, patients, and others interested in the clinical trials can call 1-800-TRIALS-A, a toll-free service offering information about AIDS clinical trials from 9 am to 7pm Eastern Time, Monday through Friday.

Physicians interested in details of the Treatment IND and open safety protocol can call the Bristol-Myers toll-free number at 1-800-662-7999 daily from 8 am to 8 pm., Eastern Time. The company will immediately begin processing applications from physicians for their patients for the Treatment IND and open safety protocol. Bristol-Myers estimates that physicians with patients eligible for participation in these protocols should begin to receive the drug in about 2 weeks.

For confidential

AIDS Information

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Call

1-800-882-AIDS

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Come to our Next Meeting

Monday, Nov 10 th
7:30 pm
30 Elmwood Ave,
Burlington
(Above VT CARES)