National Institute of Allergy and Infectious Diseases

Update

October 12, 1988

The National Institute of Allergy and Infectious Diseases (NIAID) and Biogen, Inc., a biotechnology company located in Cambridge, Mass., are sponsoring clinical tests of a genetically engineered drug that promises to block the AIDS virus in humans.

Researchers at Massachusetts General Hospital and Cedars-Sinai Medical Center, Los Angeles, will study Biogen's version of recombinant soluble CD4 in patients infected with the AIDS virus. The two medical centers are part of NIAID's AIDS Clinical Trials Group, a nationwide, multicenter network of experienced clinical investigators who collaborate in the evaluation of experimental drugs for AIDS and AIDS-related conditions.

The Phase I dose escalation study, which is designed to determine the safety of the drug in humans, will be conducted initially in approximately 25 patients with AIDS and AIDS-related-complex.

The human immunodeficiency virus (HIV), which causes AIDS, cripples the immune system by attacking and destroying specific immune cells, especially T4 cells and monocyte/macrophages. These and a few other cell types have on their surfaces a receptor, a protein known as CD4. Scientists have shown that to gain entry into human cells, the envelope (outer coat) protein of HIV attaches to the CD4 receptor. This discovery spawned the idea of cloning copies of the CD4 molecule or parts of it, and then trying to fool the AIDS virus into attaching itself to this free-floating or soluble CD4 rather than to healthy cells.

(more)

Through genetic engineering, scientists in a number of laboratories have made synthetic versions of CD4. Their products are called recombinant soluble CD4, or rCD4, or recombinant soluble T4 receptor analogue. In the test tube, these products have been shown to bind to HIV and neutralize the activity of the virus. These findings have generated great interest among researchers attempting to find new drugs to treat persons infected with HIV.

Scientists at Biogen, in collaboration with researchers at Massachusetts General Hospital, showed in laboratory experiments that their recombinant soluble CD4 product blocked direct infection of T4 cells by HIV as well as cell-to-cell transmission of the virus.

Biogen scientists head one of NIAID's 18 National Cooperative Drug Discovery Groups (NCDDGs), which are teams of experts from biotechnology companies, pharmaceutical houses, universities, medical centers, and federal agencies. The overall goal of the NCDDGs is to develop new AIDS drugs targeted to specific cellular or viral proteins. Smith, Kline and French and GeneLabs, both participants in the NCDDG program, also have CD4 products in preclinical research.

During the past year, the staff of the NIAID AIDS Program has been working with these groups and others to bring CD4 products to clinical trials. The Institute is collaborating with Genentech, which recently launched the first human trials of rCD4 at three medical centers. If the data from these studies are promising, NIAID will encourage the various companies to conduct further studies through the NIAID AIDS Clinical Trials Group.

The NIAID/Biogen study will be conducted by Robert Schooley, M.D., Massachusetts General Hospital, Boston, a Harvard Medical School affiliate, and David Ho, M.D., Cedars-Sinai Medical Center, University of California, Los Angeles.

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