

HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOR RELEASE
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The Food and Drug Administration announced today that Syntex Corporation and the National Institute of Allergy and Infectious Diseases are initiating a controlled clinical trial of Syntex's investigational drug, ganciclovir, in AIDS patients with cytomegalovirus (CMV) retinitis, an eye infection that can lead to blindness.

CMV retinitis occurs in patients whose immune systems are compromised, such as recipients of organ and bone marrow transplants and persons with AIDS. The new study will include all patients with newly diagnosed AIDS-related CMV retinitis that is not immediately sight-threatening, estimated to be about 20 patients a month.

Those patients with immediately sight-threatening CMV retinitis will be eligible for treatment with ganciclovir under a new Treatment IND sponsored by NIAID. The Treatment IND was approved by FDA under its recently revised regulations, which make available promising drugs that are still under study to patients with severe or life-threatening diseases.

For several years, Syntex Corporation has been supplying ganciclovir to AIDS patients and others on a compassionate use basis. The company will continue to furnish the drug, free of charge, to all patients who are currently receiving the drug under compassionate use.

FDA Commissioner Frank Young, M.D., said, "I am very pleased that, working together, Syntex, NIAID, and the FDA have designed a framework that will meet the needs of all patients who may benefit from treatment with ganciclovir." He explained that the controlled

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clinical trial will answer the question of whether ganciclovir effectively arrests or prevents the progression of sight-threatening retinitis.

"Regardless of geographic location, all eligible, newly diagnosed patients can participate in the controlled clinical trials or the Treatment IND," said NIAID Director Anthony S. Fauci, M.D. Any physician in the United States may enroll a patient in the controlled trial or the Treatment IND. Some patients may be treated through NIAID's nationwide network of AIDS Clinical Trials Units.

The patients with non-sight-threatening CMV retinitis will be randomized into one of two treatment groups in the controlled trial. One group will begin immediate treatment with intravenous ganciclovir and the other group will receive delayed treatment. All patients will be closely monitored for any changes in their clinical condition. At the first sign of worsening disease, patients in the delayed treatment group will be offered ganciclovir and monitored for response.

Study participants who have been taking zidovudine (AZT), the only approved anti-AIDS drug, must discontinue AZT when they begin treatment with ganciclovir. Because both drugs are toxic to white blood cells, AZT and ganciclovir cannot safely be taken simultaneously.

Physicians and patients interested in either the controlled trial or the Treatment IND may call the Ganciclovir Study Center at (301) 497-9888.

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