

Pharmacia & Upjohn and Gilead Sciences Receive European Recommendation for VISTIDE®

December 20, 1996 4:34 PM ET

London and Foster City, CA -- December 20, 1996

Pharmacia & Upjohn, Inc. and Gilead Sciences, Inc. announced today that the Committee for Proprietary Medicinal Products (CPMP) has recommended that VISTIDE (cidofovir injection), an intravenous treatment for cytomegalovirus (CMV) retinitis in patients with AIDS, be cleared for marketing in Europe.

A viral infection of the retina, CMV retinitis is an opportunistic infection that progressively affects a patient's vision over time and may ultimately lead to blindness. CMV retinitis affects 15 to 40 percent of AIDS patients, usually those with fewer than 50 CD4 T-cells. It is believed that the number of patients at risk for developing CMV retinitis may increase as people with AIDS live longer.

In August, Gilead licensed to Pharmacia & Upjohn the exclusive right to market VISTIDE in all countries outside the United States. Gilead Sciences has marketed VISTIDE in the United States since June, when the U.S. Food and Drug Administration cleared the product as a treatment for newly diagnosed or relapsing CMV retinitis in patients with AIDS.

Commenting on the regulatory development, Ley S. Smith, Pharmacia & Upjohn's executive vice president and president, pharma product center, U.S., said, "CMV retinitis can be a devastating disease, and we are gratified by the opportunity to make this vital medication available to AIDS patients in Europe. The introduction of VISTIDE provides further evidence of Pharmacia & Upjohn's determination to play a major role in the treatment of infectious diseases in general, and HIV/AIDS in particular."

The VISTIDE application was reviewed by the CPMP under the European Union's centralized procedure for product approvals. Under the label recommended by the CPMP, VISTIDE would be indicated for the treatment of CMV retinitis in patients with AIDS without compromised renal function. Until additional experience is obtained in Europe, the CPMP recommended that VISTIDE should be used after consideration of other agents.

The dose-limiting side effect of VISTIDE is renal impairment. The potential for renal impairment is managed with the co-administration of probenecid and hydration.

When the CPMP recommendation is accepted by the European Medicines Evaluation Agency (EMEA), Pharmacia & Upjohn will begin launching VISTIDE in the European Union.

A broad-spectrum, long-acting, systemic treatment, VISTIDE is delivered by intravenous infusion once a week for two weeks (induction) and once every other week thereafter (maintenance). In contrast, other approved intravenous treatments for CMV retinitis are given daily or multiple times each day and often require that a catheter be surgically implanted in the chest or arm for chronic administration.

In the treatment of AIDS patients, Pharmacia & Upjohn currently markets Mycobutin for the treatment of pulmonary tuberculosis and for the prophylaxis and treatment of mycobacterium avium complex (MAC). The company anticipates it will soon receive its first regulatory clearance (in the United States) to market the antiretroviral Rescriptor, a non-nucleoside reverse transcriptase inhibitor for the treatment of HIV-1 infection.

Gilead Sciences is a leader in the discovery and development of a new class of human therapeutics based on nucleotides, the building blocks of DNA and RNA. The Company's research and development efforts encompass three interrelated programs: small molecule antivirals, cardiovascular therapeutics and genetic code blockers for cancer and other diseases. Gilead's expertise in each of these areas has also resulted in the discovery of non-nucleotide product candidates that expand the Company's technology platforms.

Pharmacia & Upjohn, Inc., is a research-based pharmaceutically focused company dedicated to helping people around the world live longer and fuller lives. The company was formed through a merger of Pharmacia AB and The Upjohn Company and began operating in November 1995. Pharmacia & Upjohn is a provider of human health care and related products, and operates on a global basis. The company has a corporate management center in London and manufacturing centers in the United States,

Sweden and Italy.