Drugs recently approved or pending approval

EPIVIR-HBV

The United States Food and Drug Administration approved marketing of Epivir-HBV (lamivudine) by Glaxo Wellcome (Research Triangle Park, NC) as the first oral treatment for chronic hepatitis B associated with evidence of hepatitis B viral replication and active liver inflammation. Epivir was previously indicated in combination with Retrovir for the treatment of HIV infection. Drug efficacy of Epivir-HBV was measured in four controlled studies involving patients (n = 967) with chronic hepatitis B infection accompanied by evidence of hepatitis B vaccine replication and elevated alanine transaminase levels (ALT) and/or chronic inflammation of the liver. In three of the studies, Epivir-HBV (100 mg once daily) was compared with placebo for a period of 52 weeks. In all three studies, the Epivir-HBV arms were associated with greater histologic improvement, better seroconversion response, and greater normalization of serum ALT levels compared with the placebo arms. Potential adverse reactions associated with Epivir-HBV include ear, nose, and throat infections; malaise and fatigue; and headache. More serious adverse events may include lactic acidosis and severe hepatomegaly with steatosis, posttreatment exacerbations of hepatitis B, pancreatitis, and emergence of drug resistant viral mutants. The recommended dose of Epivir-HBV is 100 mg once daily; dosage may be adjusted according to each patient's renal function.

LYMERIX

The Food and Drug Administration approved LYMErix (recombinant OspA) by SmithKline Beecham Pharmaceuticals (Philadelphia, PA) as the first Lyme disease vaccine. LYMErix is indicated for active immunization against Lyme disease in individuals ages 15 to 70 years. Efficacy of LYMErix was measured in a randomized, double-blind, multicentered, placebo-controlled trial conducted in highly endemic areas of the United States. Patients (n = 10,936) were randomized to receive three doses of LYMErix or placebo at 0, 1, and 12 months and were observed for 20 months after the initial injection. Vaccine efficacy against definite Lyme disease was 78% after three doses and 50% after two doses. Efficacy against asymptomatic *Borrelia burgdorferi* infection was 100% after three doses and 83% after two doses. Adverse reactions associated with LYMErix may include pain and redness at the injection site, arthralgia, myalgia, and headache. Primary immunization against Lyme disease consists of a 30 µg/0.5 mL dose of LYMErix administered intramuscularly at 0, 1, and 12 months.

ZIAGEN

Glaxo Wellcome (Research Triangle Park, NC) received approval to market Ziagen (abacavir sulfate). Ziagen is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection. Drug efficacy in previously untreated adults was measured in an ongoing, multicenter, double-blind, placebo-controlled study. Patients (n = 173) with HIV infection were randomized to Ziagen (300 mg twice daily), lamivudine (150 mg twice daily), and zidovudine (300 mg twice daily) or lamivudine (150 mg twice daily) and zidovudine (300 mg twice daily). Drug efficacy in previously treated pediatric patients was measured in an ongoing, randomized, double-blind study. Patients (n = 205) were randomized to Ziagen (8 mg/kg twice daily), lamivudine (4 mg/kg twice daily), and zidovudine (180 mg/m^2 twice daily) or lamivudine (4 mg/kg twice daily) and zidovudine (180 mg/m^2 twice daily). In both studies, the number of patients achieving plasma HIV-1 RNA levels ≤ 400 copies/mL after 16 weeks of treatment was significantly higher in the Ziagen/lamivudine/zidovudine treatment arms when compared with the lamivudine/zidovudine arms. Adverse events associated with Ziagen include nausea and vomiting, fever, headache, and diarrhea. The most serious adverse event associated with Ziagen is a hypersensitivity reaction that may include life-threatening hypotension and death. The recommended adult dose of Ziagen is 300 mg twice daily in combination with other antiretroviral agents. The recommended pediatric dose is 8 mg/kg twice daily (up to a maximum of 300 mg twice daily) in combination with other antiretroviral treatment.

Compiled from press reports and pharmaceutical company press releases. For more information, contact Deidre Yoder, Hospital Physician, *125 Strafford Avenue, Suite 220, Wayne, PA 19087-3391.*