

Drugs recently approved or pending approval

TRIZIVIR

Approval was granted to Glaxo Wellcome (Research Triangle Park, NC) to market Trizivir (abacavir sulfate, lamivudine, and zidovudine) tablets. Trizivir is a fixed-dose combination of Ziagen (abacavir), Retrovir (zidovudine), and Epivir (lamivudine) and is indicated alone or in combination with other anti-retroviral agents for the treatment of HIV-1 infection in adults and adolescents. This indication is based on analyses of surrogate markers in controlled studies with abacavir of up to 24 weeks' duration. At present, there are no results from controlled trials evaluating long-term suppression of HIV RNA or disease progression with abacavir therapy. There are limited data on the use of this triple-combination regimen in patients with higher viral load levels ($> 100,000$ copies/mL) at baseline. Trizivir is contraindicated in patients with hypersensitivity to abacavir sulfate (Ziagen), one of Trizivir's components, which can cause a life-threatening or fatal reaction. Trizivir may also cause lactic acidosis and severe hepatomegaly with steatosis, bone marrow suppression, and myopathy. Common adverse events associated with Trizivir therapy include nausea and vomiting, diarrhea, loss of appetite, and insomnia. The recommended oral dose of Trizivir is 1 tablet twice daily. Trizivir is not recommended in patients who weigh less than 40 kg.



ZYPREXA

Eli Lilly and Company (Indianapolis, IN) received approval to market Zyprexa (olanzapine) for the long-term therapy and maintenance of treatment response of schizophrenia. Zyprexa's approval was based on results of a double-blind, placebo-controlled discontinuation study of 326 clinically stable outpatients with few or no symptoms for at least 6 weeks. Subjects received oral Zyprexa therapy for another 6 weeks, followed by an 8-week observation period to confirm stability. Following the observation period, 224 patients were randomized to Zyprexa 10 to 20 mg daily, and 102 patients were randomized to placebo. The Zyprexa group was made up of 177 patients with schizophrenia (79%) and 47 patients with schizoaffective disorder (21%). In the placebo group, 89 patients had schizophrenia (87.3%), and 13 patients had schizoaffective disorder (12.7%). The likelihood of patients discontinuing treatment because of an adverse event or lack of efficacy was significantly less for those receiving Zyprexa than for those receiving placebo. The 6-month cumulative relapse rate for Zyprexa (6%) was statistically superior to placebo (55%, $P < .0001$). Common

adverse events associated with Zyprexa are somnolence, dizziness, constipation, weight gain, and postural hypotension. Zyprexa should be administered once daily, beginning with 5 to 10 mg initially, with a target dose of 10 mg daily within several days. Although no evidence is available to determine how long a patient should be treated with Zyprexa, clinical trials have demonstrated the effectiveness of oral Zyprexa (10 to 20 mg daily) as maintenance therapy.

TAMIFLU

The United States Food and Drug Administration approved marketing of Tamiflu (oseltamivir phosphate) capsules by Roche Pharmaceuticals, Inc (Nutley, NJ) and Gilead Sciences, Inc (Foster City, CA) for a new indication. Tamiflu is now indicated for the prophylaxis of influenza in adults and adolescents 13 years and older. This indication is supported by data from

3 randomized, double-blind, placebo-controlled Phase III trials involving 3434 healthy patients. In a pooled analysis of 2 seasonal prophylaxis studies in healthy unvaccinated adults and adolescents, Tamiflu 75 mg taken once daily for 42 days during a community outbreak reduced the incidence of laboratory confirmed clinical influenza from 4.8% for the placebo group to 1.2% for the Tamiflu

group. In a seasonal prevention study in elderly residents of nursing homes, Tamiflu 75 mg taken once daily for 42 days reduced the incidence of influenza from 4.4% for the placebo group to 0.4% for the Tamiflu group. Approximately 80% of this population were vaccinated against influenza. In a study of post-exposure prophylaxis in households, Tamiflu 75 mg administered once daily within 2 days of symptom onset and continued for 7 days reduced the incidence of influenza from 12% in the placebo group to 1% in the Tamiflu group. Adverse events associated with Tamiflu include headache, nausea, cough, and fatigue. The recommended dose of Tamiflu for prevention of influenza following close contact with an infected individual is 75 mg once daily for at least 7 days. Therapy should begin within 2 days of exposure. During a community outbreak of influenza, the recommended dose for prophylaxis is 75 mg once daily. The duration of protection lasts for as long as dosing continues.

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