

Drugs recently approved or pending approval

KALETRA

Abbott Laboratories (North Chicago, IL) received approval to market Kaletra (lopinavir/ritonavir) for the treatment of HIV infection in combination with other antiretroviral (ARV) agents. In a double-blind, ongoing clinical trial comparing 2 protease inhibitors (PIs) in 653 patients new to ARV therapy, Kaletra in combination with stavudine (d4T) and lamivudine (3TC) reduced the viral load to below detectable levels (< 400 copies/mL) in 79% of patients, compared with 70% of patients receiving a combination of the PI nelfinavir, d4T, and 3TC through 24 weeks. The difference in viral load between the Kaletra and nelfinavir treatment groups was statistically significant. Additional open-label studies of Kaletra in combination with other ARV agents in both treatment-naïve and PI-experienced patients show that Kaletra maintained viral suppression through 72 weeks. Co-administration of Kaletra is contraindicated with certain drugs, and could cause serious side effects with certain other drugs. Women on Kaletra should not breast-feed. Moderate adverse effects associated with Kaletra include abnormal stools, asthenia, headache, and nausea. The recommended dosage for adults is 400/100 mg twice daily with food. In children 6 months to 12 years of age, the dosage is based on weight.



ALTACE

American Home Products Corporation (Madison, NJ) received approval to market Altace (ramipril) to reduce the risk of myocardial infarction, stroke, and death from cardiovascular (CV) causes in patients 55 years and older, either with a history of coronary artery disease, stroke, peripheral vascular disease, or diabetes that is accompanied by at least 1 other CV risk factor. This expanded indication is based on evidence from the Heart Outcomes Prevention Evaluation (HOPE) study, a multicenter, randomized, placebo-controlled, double-blind study (N = 9297). The HOPE study results showed that Altace 10 mg/day significantly reduced the rate of myocardial infarction, stroke, and death from CV causes to 14%, compared with 17.8% for placebo. The study also evaluated a subset of 81 patients with type 1 and 3496 patients with type 2 diabetes, and demonstrated an overall reduction of CV events in this population by 25%. Altace is contraindicated in patients with a history of angioedema related to previous treatment with an angiotensin-converting-enzyme (ACE) inhibitor. When used in the second and third trimesters of pregnancy, ACE inhibitors can cause fetal and neonatal morbidity and death. Adverse

effects include headache, dizziness, fatigue, and dry cough. The recommended dosage for reduced risk of CV events is 2.5 mg once daily for 1 week, 5 mg once daily for the next 3 weeks, and then increased as tolerated to 10 mg once daily.

NOVANTRONE

Approval was granted to Immunex Corporation (Seattle, WA) to market Novantrone (mitoxantrone for injection concentrate) for reducing neurologic disability and/or the frequency of clinical relapses in patients with secondary (chronic) progressive, progressive relapsing, or worsening relapsing-remitting multiple sclerosis (MS). Two randomized, controlled, multicenter clinical studies assessed the safety and efficacy of Novantrone in MS. Study 1 evaluated patients with secondary progressive or progressive relapsing MS. Patients (N = 188) received placebo, 5 mg/m² Novantrone, or 12 mg/m² Novantrone, administered intravenously (IV) every 3 months. At 24 months, patients on Novantrone experienced significant improvement as measured by the Kurtzke Expanded Disability Status Scale, mean Ambulation Index change, mean number of relapses per patient requiring corticosteroid treatment, and mean Standard Neurological Status change. Study 2 evaluated Novantrone in combination with methylpred-

nisolone (MP) in patients with secondary progressive or worsening relapsing-remitting MS who had residual neurological deficit between relapses. Patients (N = 42) received monthly treatments of 1 g of IV MP alone (n = 21) or ~ 12 mg/m² of IV Novantrone plus 1 g of IV MP (n = 21) (NOV + MP). After 6 months, patients experienced significant improvement on NOV + MP as compared with MP alone, with the primary endpoint being the percentage of patients without new lesions on magnetic resonance imaging (MRI). Novantrone is contraindicated in patients with serious heart problems, liver disease, or certain blood disorders. Women who are pregnant, trying to become pregnant, or breast-feeding should not use Novantrone. Adverse effects include nausea, hair loss, diarrhea, and changes in menstrual cycle. The recommended dosage is 12 mg/m² given as a short IV infusion every 3 months. Novantrone should not be administered to MS patients who have received a cumulative lifetime dose of ≥ 140 mg/m².

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