Drugs recently approved or pending approval

AVELOX

The United States Food and Drug Administration approved marketing of Avelox (moxifloxacin hydrochloride) by Bayer Corporation (West Haven, CT). Avelox is indicated for the treatment of adults with the following infections: acute bacterial sinusitis caused by susceptible strains of *Streptococcus pneumoniae, Haemophilus influenzae,* or *Moraxella catarrhalis;* acute bacterial exacerbations of chronic bronchitis (BECB) caused by susceptible strains of *S. pneumoniae, H. influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Staphylococcus aureus,* or *M. catarrhalis;* and mild to moderate community acquired pneumonia (CAP) caused by susceptible strains of *S. pneumoniae, H. influenzae, Mycoplasma pneumoniae, Chlamydia pneumoniae,* or *M. Catarrhalis*. Effectiveness of Avelox in treating acute BECB was evaluated in a randomized, double-blind, controlled trial. Patients (n = 629) were randomized to Avelox (400 mg/day for 5 days) or clarithromycin (500 mg twice daily for 10 days). The study's primary endpoint was clinical success 7 to 17 days after therapy. The clinical success for both treatment arms was 89%. Drug efficacy in treatment of CAP was evaluated in a randomized, double-blind, controlled trial. Patients (n = 474) with clinically and radiologically documented CAP were randomized to Avelox (400 mg/day) or high-dose clarithromycin (500 mg twice daily). Clinical success for the evaluable patients (n = 382) was 95% for both treatment arms. Efficacy of Avelox in treating acute bacterial sinusitis was evaluated in a controlled double-blind study. Patients (n = 457) were randomized to Avelox (400 mg/day for 10 days) or cefuroxime axetil (250 mg twice daily for 10 days). Clinical success 7 to 21 days after therapy was 90% for the Avelox arm compared with 89% for the cefuroxime arm. Potential adverse events associated with Avelox include nausea, diarrhea, dizziness, headache, and abdominal pain. The recommended dose of Avelox is 400 mg/day; treatment duration is 10 days for acute bacterial sinusitis and CAP and 5 days for acute BECB.

AGGRENOX

Approval was granted to Boehringer Ingelheim (Ridgefield, CT) to market Aggrenox (aspirin/extended-release dipyridamole [ER-DP]). Aggrenox is indicated for the reduction of stroke in patients who have had transient ischemia of the brain or completed ischemic stroke caused by thrombosis. Drug efficacy was evaluated in a double-blind placebo-controlled study of 24 months' duration. Patients (n = 6602) who had experienced an ischemic stroke or a transient ischemic attack in the preceding 3 months were randomized to one of four treatments: Aggrenox (25 mg aspirin/ 200 mg ER-DP), ER-DP alone (200 mg), aspirin alone (25 mg), or placebo, twice daily. Stroke risk was reduced by 22.1% in the Aggrenox arm compared with the aspirin-only arm. Compared with the ER-DP arm and the placebo arm, Aggrenox reduced the risk of stroke by 24.4% and 36.8%, respectively. Potential adverse reactions associated with Aggrenox include headache, dyspepsia, abdominal pain, nausea, and diarrhea. The recommended dose of Aggrenox is one capsule orally twice daily (morning and evening).

KEPPRA

UCB Pharma (Smyrna, GA) received approval to market Keppra (levetiracetam). Keppra is indicated as adjunctive therapy in the treatment of partial onset seizures in adults with epilepsy. Drug efficacy was evaluated in three multicenter, double-blind, placebo-controlled studies. In one study, patients (n = 293) who had refractory partial onset seizures for at least 2 years and had taken two or more antiepileptic drugs were randomized to Keppra 1000 mg/day (n = 97), Keppra 3000 mg/day (n = 101), or placebo (n = 95), administered in equally divided doses twice daily. Treatment duration was 18 weeks. The study's primary endpoint was reduction in weekly frequency of partial onset seizures relative to placebo; the secondary endpoint was incidence of patients with 50% or greater reductions in partial onset seizure frequency from baseline (responder rate). The percent reduction over placebo in weekly frequency of partial onset seizures was 26.1% for the 1000-mg Keppra arm compared with 30.1% for the 3000-mg Keppra arm. The responder rates were 37.1% for the 1000-mg Keppra arm, 39.6% for the 3000-mg Keppra arm, and 7.4% for the placebo arm. Adverse events associated with Keppra may include somnolence, asthenia, infection, and dizziness. The recommended starting dose is 1000 mg/day (500 mg twice daily); dosing may be gradually increased up to a maximum of 3000 mg/day.

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.*