Drugs recently approved or pending approval

SYNERCID

The United States Food and Drug Administration approved marketing of Synercid (quinupristin and dalfopristin) by Rhône-Poulenc Rorer (Collegeville, PA). Synercid is indicated for the treatment of adults with serious or life-threatening infections associated with vancomycin-resistant *Enterococcus faecium* (VREF) bacteremia and complicated skin and skin-structure infections caused by methicillin-susceptible *Staphylococcus aureus* or by *Streptococcus pyogenes*. Drug efficacy in the treatment of VREF bacteremia was evaluated in four noncomparative trials. In evaluable patients (n = 298) treated with Synercid (7.5 mg/kg intravenously [IV] every 8 hours), the overall efficacy rate (defined as clinical success and eradication of the initial pathogen) was 52.3%. Drug efficacy in the treatment of complicated skin and skin structure infections was evaluated in two open-label clinical trials. In one study, evaluable patients (n = 233) were randomized to Synercid (7.5 mg/kg IV every 12 hours) or cefazolin (1 g IV every 8 hours). Vancomycin (1 g IV every 12 hours) was substituted for the cefazolin if the causative pathogen was methicillin-resistant staphylococcus or if the patient was allergic to penicillins, cephalosporins, or carbapenems. The success rate for curing or improving the infections was 66.4% in the Synercid arm compared with 64.2% in the cefazolin or vancomycin arm. Potential adverse reactions associated with Synercid include various infusion site reactions, nausea, arthralgia, and myalgia. The recommended dosage of Synercid is 7.5 mg/kg IV every 8 hours for VREF infection and 7.5 mg/kg IV every 12 hours for a minimum of 7 days for complicated skin and skin structure infections.

RAPAMUNE

Wyeth-Ayerst (Philadelphia, PA) received approval to market Rapamune (sirolimus) for the prophylaxis of organ rejection in patients receiving renal transplants. Drug safety and efficacy were evaluated in two double-blind multicenter trials. In one study, patients (n = 719) were randomized after transplantation to cyclosporine and corticosteroids in combination with Rapamune 2 mg/day (n = 284), Rapamune 5 mg/day (n = 274), or azathioprine 2 to 3 mg/kg/day (n = 161). The primary endpoint of the study was reduction of efficacy failure rates in the first 6 months after transplantation. Efficacy failure was defined as the first occurrence of an acute rejection episode, graft loss, or death. At 6 months, the incidence of efficacy failure was 18.7% in the 2-mg Rapamune arm and 16.8% in the 5-mg Rapamune arm, compared with 32.3% in the azathioprine arm. Adverse reactions associated with Rapamune include peripheral edema, hypertension, hyperlipemia, and hypercholesterolemia. The recommended loading dose for transplant recipients is 6 mg administered as soon as possible after transplantation; the recommended maintenance dose is 2 mg administered orally once daily.

ELLENCE

Approval was granted to Pharmacia & Upjohn (Kalamazoo, MI) to market Ellence (epirubicin hydrochloride injection). Ellence is indicated as a component of adjuvant therapy in patients with evidence of axillary node tumor involvement following resection of primary breast cancer. Drug effectiveness was evaluated in two open-label multicenter studies. In one study, premenopausal and perimenopausal patients (n = 716) with axillary-node-positive breast cancer, no T4 tumors, and no distant metastasis were randomized to a regimen of Ellence 120 mg/m^2 in combination with cyclophosphamide and fluorouracil (CEF-120) or a regimen of cyclophosphamide, methotrexate, and fluorouracil (CMF). The study's primary endpoints were relapse-free survival and overall survival based on Kaplan-Meier estimates. The relapse-free survival rate at 5 years was 62% for the CEF-120 arm compared with 53% for the CMF arm. Overall survival at 5 years was 77% in the CEF-120 arm compared with 70% in the CMF arm. Ellence is contraindicated in patients with baseline neutrophil count less than 1500 cells/mm^3; severe myocardial insufficiency or recent myocardial infarction; previous treatment with anthracyclines up to the maximum cumulative dose; hypersensitivity to epirubicin, other anthracyclines, or anthracenediones; or severe hepatic dysfunction. Acute adverse events associated with Ellence include leukopenia, neutropenia, alopecia, nausea and vomiting, and anemia. The recommended starting dose of Ellence is 60 mg/m^2 IV on days one and eight in combination with cyclophosphamide (75 mg/m^2 orally on days one through 14) and 5-fluorouracil (500 mg/m^2 IV on days one and eight), repeated every 28 days for six cycles; or Ellence (100 mg/m^2 IV) in combination with 5-fluorouracil (500 mg/m^2 IV) and cyclophosphamide (500 mg/m^2 IV), all administered on day one and repeated every 21 days for six cycles.

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.*