Drugs recently approved or pending approval

APTIVUS

The US Food and Drug Administration (FDA) has given approval to Boehringer Ingelheim Pharmaceuticals, Inc. (Ridgefield, CT) to market Aptivus (tipranavir) to be coadministered with ritonavir 200 mg for the treatment of HIV-1–infected adult patients with evidence of viral replication who are highly treatment experienced or have HIV-1 strains resistant to multiple protease inhibitors. Aptivus was evaluated in 2 ongoing, randomized, controlled, open-label, multicenter studies in HIV-positive, triple antiretroviral class–experienced patients. Patients (N = 1159) received 24-week treatment with either Aptivus coadministered with ritonavir 200 mg plus an optimized background regimen (OBR) or a ritonavir-boosted protease inhibitor (ie, lopinavir, amprenavir, saquinavir, or indinavir) plus an OBR. Prior to randomization, the OBR was individually defined for each patient based on genotypic resistance testing and patient history. After 24 weeks, a higher proportion of Aptivus/ritonavir-treated patients had less than 400 copies/mL of HIV-1 RNA compared with the control group (34% versus 16%); also, a higher proportion of Aptivus/ritonavir-treated patients had less than 50 copies/mL of HIV-1 RNA as compared with the control group (23% versus 9%). The median change in CD4+ cell count from baseline to week 24 was +34 cells/mm^3 in the Aptivus group versus +4 cells/mm^3 in the control group. The most common adverse effects associated with Aptivus were diarrhea, nausea, fatigue, headache, and vomiting.

LEVEMIR

The FDA has given approval to Novo Nordisk Inc. (Princeton, NJ) to market Levemir (insulin detemir [rDNA origin] injection) for the treatment of adult patients with type 1 or type 2 diabetes mellitus who require basal (long-acting) insulin for the control of hyperglycemia. The efficacy and safety of Levemir given once daily at bedtime or twice daily (before breakfast and at bedtime, before breakfast and with the evening meal, or at 12-hour intervals) was compared with that of once-daily or twice-daily neutral protamine Hagedorn (NPH) human insulin or once-daily insulin glargine in nonblinded, randomized, parallel studies (3 studies of type 1 diabetes patients [N = 3724], 2 studies of type 2 diabetes patients [N = 2280]). In all studies, patients treated with Levemir achieved levels of glycemic control similar to those treated with neutral protamine NPH or insulin glargine, as measured by glycosylated hemoglobin. The most common adverse effect seen with Levemir was hypoglycemia. Levemir can be administered once or twice daily. The dosage of Levemir should be individualized. For once-daily dosing, Levemir should be administered with the evening meal or at bedtime; for twice-daily dosing, the evening dose can be administered either with the evening meal, at bedtime, or 12 hours after the morning dose.

TYGACIL

Wyeth Pharmaceuticals, Inc. (Philadelphia, PA) has been given FDA approval to market Tygacil (tigecycline) for the treatment of (1) complicated skin and skin structure infections (cSSSI) caused by *Escherichia coli, Enterococcus faecalis* (vancomycin-susceptible isolates only), *Staphylococcus aureus* (methicillin-susceptible/resistant isolates), *Streptococcus agalactiae, Streptococcus anginosus* group (including *Streptococcus anginosus, Streptococcus intermedius,* and *Streptococcus constellatus*), *Streptococcus pyogenes,* and *Bacteroides fragilis*; and (2) complicated intra-abdominal infections (cIAI) caused by *Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Klebsiella oxytoca, K. pneumoniae, Enterococcus faecalis* (vancomycin-susceptible isolates only), *Staphylococcus aureus* (methicillin-susceptible isolates only), *Streptococcus anginosus* group (including *Streptococcus anginosus, Streptococcus intermedius,* and *Streptococcus constellatus*), *B. fragilis, B. thetaiotaomicron, B. uniformis, B. vulgatus, Clostridium perfringens,* and *Peptostreptococcus micros* in patients aged 18 years and older. Tygacil is the first-approved antibiotic in a new class called glycylcyclines. Tygacil (100 mg intravenously [IV] followed by 50 mg IV every 12 h) was compared with vancomycin/aztreonam (1 g IV every 12 h/2 g IV every 12 h) in 2 randomized, double-blind, multicenter, multinational trials involving patients with cSSSI. In cSSSI trials, Tygacil monotherapy provided clinical cure rates comparable with vancomycin/aztreonam combination therapy. Tygacil (100 mg IV followed by 50 mg every 12 h) was also compared with imipenem/cilastatin (500 mg IV every 6 h) in 2 randomized, double-blind, multicenter, multinational trials involving patients with cIAI. In cIAI trials, Tygacil monotherapy provided clinical cure rates comparable with imipenem/cilastatin monotherapy. The most common adverse effects observed with Tygacil were nausea and vomiting.

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