Drugs recently approved or pending approval

BOTOX

The US Food and Drug Administration (FDA) has given approval to Allergan, Inc. (Irvine, CA) to market Botox (botulinum toxin type A) for the treatment of severe primary axillary hyperhidrosis that is inadequately controlled with topical agents. The efficacy of Botox was evaluated in 2 randomized, multicenter, double-blind, placebo-controlled studies (1 in the US and 1 in Europe). In the US study, patients (N = 322) were randomized to either Botox 50 U, Botox 75 U, or placebo (per axilla) and were evaluated at 4-week intervals. 55% of patients treated with Botox 50 U, 49% treated with Botox 75 U, and 6% treated with placebo were considered responders. Study responders were defined as patients who showed at least a 2-grade improvement from baseline value on the Hyperhidrosis Disease Severity Scale 4 weeks after both of the first 2 treatment sessions or had a sustained response after the first treatment and did not receive retreatment during the study. Four weeks after the first treatment, patients treated with Botox 50 U or Botox 75 U experienced a greater than 50% decrease in axillary sweat production as compared with placebo (81% and 86% versus 41%, respectively). The median duration of response was 201 days. The most common adverse effects associated with Botox were injection site pain and hemorrhage, nonaxillary sweating, infection, pharyngitis, flu syndrome, headache, fever, neck or back pain, pruritus, and anxiety. The recommended dose of Botox is 50 U per axilla. Repeat injections should be administered when the clinical effect of the previous injection diminishes. Botox previously was approved for the treatment of cervical dystonia and for the treatment of strabismus and blepharospasm associated with dystonia.

CAMPRAL

The FDA has given Forest Laboratories, Inc. (New York, NY) and Merck KGaA (Darmstadt, Germany) approval to market Campral (acamprosate calcium) for the maintenance of abstinence from alcohol in patients with alcohol dependence who are abstinent at treatment initiation. Campral is the first drug in 9 years to be approved for the treatment of alcohol dependence. The efficacy of Campral was evaluated in 3 double-blind, placebo-controlled studies of alcohol-dependent patients (N = 998) who had undergone inpatient detoxification and were abstinent from alcohol on the day of randomization. Study durations ranged from 90 to 360 days. In all 3 studies, Campral was superior to placebo in maintaining abstinence. In a fourth study evaluating alcoholics, including patients with a history of polysubstance abuse and patients who had not undergone detoxification and were not required to be abstinent at baseline, Campral failed to demonstrate superiority over placebo in maintaining abstinence from alcohol. The most common adverse effects associated with Campral use was diarrhea. Those treated with Campral should have a comprehensive management program that includes psychosocial support.

VYTORIN

Merck Pharmaceuticals (Whitehouse Station, NJ) and Schering-Plough Pharmaceuticals (Kenilworth, NJ) were granted approval by the FDA to market Vytorin (ezetimibe/simvastatin) for the treatment of high levels of low-density lipoprotein (LDL) cholesterol in patients with primary hypercholesterolemia or mixed hyperlipidemia as adjunctive therapy to diet when diet alone is not enough. Vytorin is the first drug approved to treat 2 sources of cholesterol by inhibiting cholesterol production in the liver and blocking cholesterol absorption in the intestine, including cholesterol from food. In 2 trials of 12 and 23 weeks, patients treated with Vytorin or ezetimibe and simvastatin combination (equivalent to Vytorin) at various doses experienced a significant reduction in LDL cholesterol when compared with patients treated with ezetimibe alone (12-week study only), simvastatin alone, or placebo. In a 24-week study comparing 10/10 mg and 10/20 mg ezetimibe/simvastatin combination equivalent to Vytorin and atorvastatin 10 mg, Vytorin lowered LDL cholesterol to a greater degree than atorvastatin. In another 24-week study involving diabetic patients (N = 214) pretreated with thiazolidiones and simvastatin, patients were randomized to receive either simvastatin 40 mg or Vytorin 10/20 mg. Vytorin was significantly more effective at lowering LDL cholesterol than the double dose of simvastatin. The most common adverse effects observed with Vytorin were headache, upper respiratory tract infection, myalgia, influenza, and pain in the extremities. The recommended starting dose of Vytorin is 10/20 mg per day.

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.*