Drugs recently approved or pending approval

LOTRONEX

The United States Food and Drug administration approved marketing of Lotronex (alosetron hydrochloride) by Glaxo Wellcome (Research Triangle Park, NC). Lotronex is indicated for the treatment of irritable bowel syndrome (IBS) in women whose predominant bowel symptom is diarrhea. Drug efficacy was evaluated in two double-blind, placebo-controlled studies involving nonconstipated women with IBS who experienced at least mild pain and whose main bowel symptom was diarrhea. In one study, patients (n = 647) received 1 mg of Lotronex or placebo twice daily for 12 weeks. The study's primary endpoint was patients' weekly assessment of relief of IBS pain and discomfort. Patients in the Lotronex arm experienced significantly more relief of IBS pain and discomfort than patients in the placebo arm. The study's secondary endpoints were percentage of days with urgency and daily assessment of stool frequency and consistency. Patients in the Lotronex arm reported a significant reduction in the percentage of days with urgency and a significant reduction in stool frequency compared with patients in the placebo arm. Patients in the Lotronex arm also reported firmer stool consistency. Potential adverse reactions associated with Lotronex include constipation, nausea, gastrointestinal discomfort and pain, and abdominal discomfort and pain. The recommended dosage is 1 mg taken twice daily with or without food.

ANDROGEL

Approval was granted to Unimed Pharmaceuticals (Buffalo Grove, IL) to market AndroGel 1% (testosterone gel). AndroGel is indicated as replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone, such as congenital or acquired primary hypogonadism and congenital or acquired hypogonadotropic hypogonadism. Drug effectiveness was evaluated in a two-phase, parallel-group, active-controlled study of 180 days' duration. During the initial treatment phase (days 1–90), patients with hypogonadal conditions (n = 227) were randomized to AndroGel 5 g to deliver 50 mg testosterone daily (n = 73), AndroGel 10 g to deliver 100 mg testosterone daily (n = 78), or a nonscrotal testosterone transdermal system (n = 76). During the extended treatment phase (days 91–180), patients in the AndroGel arms who had single-sample serum testosterone levels above or below the normal range on day 60 (n = 40) were titrated to 7.5 g to deliver 75 mg testosterone daily on day 91. In the 5-g and 10-g AndroGel arms, normal testosterone levels were achieved on day one of treatment and were maintained for the duration of the study. Patients in all AndroGel arms experienced significant increases in total body mass and total body lean mass and significant improvement in libido, which were maintained throughout the study. AndroGel is contraindicated in men with breast cancer or known or suspected prostate cancer. Adverse reactions associated with AndroGel may include abnormal laboratory tests, application site reactions, prostate disorders, and acne. The recommended starting dose of AndroGel is 5 g applied to clean, dry, intact skin of the shoulders and upper arms and/or the abdomen once daily.

PREVNAR

Wyeth Lederle Vaccines (Philadelphia, PA) received approval to market Prevnar, Pneumococcal 7-Valent Conjugate Vaccine (diphtheria CRM_{197} protein). Prevnar is indicated for active immunization of infants and toddlers against invasive disease caused by the seven serotypes of *Streptococcus pneumoniae* included in the vaccine. Efficacy was measured in a randomized, double-blind study. Infants (n = 37,816) were randomized to receive Prevnar (n = 18,906) or a control vaccine (n = 18,910) at ages 2, 4, 6, and 12 to 15 months. The study's primary endpoint was effectiveness against invasive pneumococcal disease caused by the vaccine serotypes. Per protocol analysis included cases of pneumococcal disease that occurred 14 days or more after the third dose of vaccine, and intent-to-treat analysis included all cases of invasive pneumococcal disease caused by vaccine serotypes in children who received at least one dose of vaccine. In both the per protocol and the intent-to-treat analyses, Prevnar demonstrated 100% efficacy against the *S. pneumoniae* serotypes included in the vaccine. In analysis of all pneumococcal serotypes, Prevnar demonstrated 90% efficacy in the per protocol group and 88.9% efficacy in the intent-to-treat group. Potential adverse reactions include injection site reactions, irritability, drowsiness, restless sleep, and decreased appetite. The dose of the Prevnar vaccine is 0.5 mL administered intramuscularly; the vaccination schedule depends on the age of the infant or toddler.

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.*