Drugs recently approved or pending approval

DAYTRANA

The US Food and Drug Administration (FDA) has given approval to Shire Pharmaceuticals (Philadelphia, PA) to market Daytrana (methylphenidate transdermal system) for the treatment of attention-deficit/hyperactivity disorder (ADHD). Daytrana is the first and only non-oral medication approved for ADHD. The efficacy of Daytrana was evaluated in 2 randomized, double-blind, placebo-controlled studies involving children aged 6 to 12 years with ADHD as defined by the *Diagnostic Statistical Manual IV*. In study 1, ADHD symptoms were evaluated by teachers and observers in a classroom setting using the Deportment Subscale from the Swanson, Kotkin, Agler, M-Flynn, and Pelham (SKAMP) rating scale. There was a 5-week open-label Daytrana optimization phase, followed by a 2-week treatment phase using the optimal patch dose for each patient or placebo. Mean differences in change from baseline in SKAMP score were statistically significant with Daytrana as compared with placebo. In study 2, Daytrana or placebo was blindly administered as flexible doses to achieve an optimal regimen over 5 weeks, followed by a 2-week maintenance period using optimal doses for each patient. Daytrana was statistically significantly superior to placebo as measured by the mean change from baseline in ADHD Rating Scale-IV total score. The most common adverse effects were decreased appetite, insomnia, nausea, and vomiting. Daytrana should be applied to the hip area 2 hours before an effect is needed and should be removed 9 hours after application.

FLOVENT HFA

GlaxoSmithKline (Research Triangle Park, NC) has been given FDA approval to market Flovent HFA (fluticasone propionate HFA) Inhalation Aerosol for the maintenance treatment of asthma as prophylactic treatment in children aged 4 to 11 years. Flovent HFA was evaluated in a 12-week placebo-controlled trial of 241 children aged 4 to 11 years. Flovent HFA 88 µg twice daily improved peak expiratory flow, reduced daily rescue albuterol use, and reduced nighttime awakenings due to asthma as compared with placebo. Adverse effects in children taking Flovent HFA were similar to those in adult trials and included upper respiratory infection, throat irritation, and headache. The recommended starting dose of Flovent HFA in pediatric patients is 88 µg twice daily. Flovent HFA was previously approved for maintenance treatment of asthma in patients aged 12 years and older, and this current approval is an expanded indication.

PROGRAF

The FDA has given approval to Astellas Pharma US, Inc. (Deerfield, IL) to market Prograf (tacrolimus) for prophylaxis of organ rejection in patients receiving heart transplantation in conjunction with azathioprine or mycophenolate mofetil. The safety and efficacy of Prograf were evaluated in 2 open-label, randomized, comparative studies. In study 1 (a phase 3 European study), 314 patients received antibody induction, corticosteroids, and azathioprine in combination with Prograf or cyclosporine modified for 18 months. Patient/graft survival at 18 months was similar between treatments arms (91.7% in the Prograf group and 89.2% in the cyclosporine group). In study 2 (conducted in the United States), 331 patients received corticosteroids and Prograf plus sirolimus, Prograf plus mycophenolate mofetil, or cyclosporine modified plus mycophenolate mofetil for 1 year. Patient/graft survival at 12 months was similar in the Prograf plus mycophenolate mofetil arm and the cyclosporine modified plus mycophenolate mofetil arm (93.5% and 86.1%, respectively). The Prograf plus sirolimus arm was associated with increased risk of wound healing complications, renal function impairment, and posttransplant insulin-dependent diabetes mellitus and is not recommended. The most common adverse effects in Prograf-treated patients were abnormal renal function, hypertension, diabetes mellitus, cytomegalovirus infection, tremor, hyperglycemia, leukopenia, infection, and hyperlipemia. The recommended starting oral dose of Prograf is 0.075 mg/kg/d administered every 12 hours in 2 divided doses. Initiation of oral Prograf therapy is recommended as soon as it is tolerated. The initial dose of Prograf should be administered no sooner than 6 hours after transplantation. Prograf is also approved for use in patients who received liver or kidney transplantation.

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.*