*Drugs recently approved or pending approval*

## AZILECT

The US Food and Drug Administration (FDA) has given approval to Teva Neuroscience, Inc. (Kansas City, MO) to market Azilect (rasagiline) for the treatment of the signs and symptoms of idiopathic Parkinson's disease as initial monotherapy in early Parkinson's disease and as adjunct therapy to levodopa in moderate-to-advanced disease. The efficacy of Azilect was evaluated in 1 double-blind, randomized, fixed-dose parallel group trial as monotherapy (study 1) and 2 multicenter, randomized, multinational trials in combination with levodopa (studies 2 and 3). In study 1, patients with early Parkinson's disease (N = 404) were randomized to placebo, Azilect 1 mg/day, or Azilect 2 mg/day. The primary efficacy measure was the change from baseline in the total score of the Unified Parkinson's Disease Rating Scale (UPDRS). Azilect-treated patients had significantly less worsening in the UPDRS score compared with placebo-treated patients; the effectiveness of Azilect 1 mg and 2 mg was comparable. Study 2 (N = 472) and study 3 (N = 687) evaluated Azilect or placebo in addition to levodopa (average dose, 700–800 mg) in patients with advanced Parkinson's disease. Patients recorded 1 of 4 conditions in a daily diary: "ON" (defined as a period of relatively good function and mobility) with no dyskinesia or without troublesome dyskinesia, ON with troublesome dyskinesia, "OFF" (defined as period of relatively poor function and mobility), or asleep. The primary efficacy measure was the change in the mean number of hours in the OFF state at baseline compared with the mean number of hours in the OFF state during the treatment period. In both studies 2 and 3, Azilect 1 mg once daily reduced OFF time compared with placebo. The most common adverse effects with Azilect monotherapy were headache, arthralgia, and dyspepsia, and the most common adverse effects with Azilect as adjunct therapy were dyskinesia, accidental injury, nausea, and headache. Products that are rich in tyramine should be avoided to prevent a possible hypertensive crisis during Azilect treatment.

## REMICADE

Centocor, Inc. (Malvern, PA) has been given FDA approval to market Remicade (infliximab) for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients (aged > 6 years) with moderately to severely active Crohn's disease who have had inadequate response to conventional therapy. This is the only biologic therapy approved for use in pediatric patients with Crohn's disease. The safety and efficacy of Remicade were assessed in a randomized, open-label study of 112 pediatric patients with Crohn's disease. All patients received an induction dose of Remicade 5 mg/kg at weeks 0, 2, and 6. At week 10, patients were randomized to a maintenance regimen of Remicade 5 mg/kg administered either every 8 or every 12 weeks. At week 10, 88% of patients had clinical response. At both week 30 and week 54, the proportion of patients in clinical response and clinical remission was greater in the every-8-week group compared with the every-12-week group. For those receiving corticosteroids at baseline, the proportion of patients able to discontinue corticosteroids while in remission was 46% and 33% at week 30 and 46% and 17% at week 54 in the every-8-week group and 12-week group, respectively. The most common adverse effects associated with Remicade were anemia, blood in stool, leukopenia, flushing, viral infection, and neutropenia. Infections were also more commonly reported in pediatric patients as compared with adult patients treated with Remicade (56% versus 50%).

## ZOSTAVAX

The FDA has given approval to Merck & Co., Inc. (Whitehouse Station, NJ) to market Zostavax (zoster vaccine live) for prevention of herpes zoster (shingles) in individuals aged 60 years and older. Zostavax is the first and only medical option for preventing shingles. The efficacy of Zostavax was evaluated in a placebo-controlled, double-blind trial involving 38,546 patients aged 60 years and older. Patients were randomized to a single dose of Zostavax (n = 19,270) or placebo (n = 19,276) and were followed for the development of herpes zoster for a median of 3.1 years (range, 31 days–4.9 years). Compared with placebo, Zostavax reduced the risk of developing shingles by 51%. The efficacy of Zostavax was highest in patients aged 60 to 69 years and declined with increasing age. In those who were vaccinated but developed shingles, Zostavax statistically significantly reduced the incidence of postherpetic neuralgia in patients aged 70 years and older; a statistically significant result was not seen in patients aged 60 to 69 years or in patients older than 80 years. The most common adverse effects associated with Zostavax were headache and injection site reactions, including erythema, pain/tenderness, and swelling.

*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.*