Drugs recently approved or pending approval

EXELON

The US Food and Drug Administration (FDA) has given approval to Novartis Pharmaceuticals Corporation (East Hanover, NJ) to market Exelon (rivastigmine tartrate) for the treatment of mild to moderate dementia associated with Parkinson's disease. Exelon is the first available treatment for this condition. Exelon was evaluated in a randomized, double-blind, placebo-controlled trial involving patients with mild to moderate dementia, with onset at least 2 years after the initial diagnosis of idiopathic Parkinson's disease. Patients enrolled in the study had a Mini-Mental State Examination score between 10 and 24 at entry. Main outcome measures were cognitive performance (as measured by the cognitive subscale of the Alzheimer's Disease Assessment Scale [ADAS-cog]) and overall clinical effect (as measured by the Alzheimer's Disease Cooperative Study–Clinician's Global Impression of Change [ADCS-CGIC]) at baseline and 24 weeks. Patients (N = 541) were randomized to Exelon (3–12 mg) or placebo given in divided doses (16-week titration phase and 8-week maintenance phase). At 24 weeks, there was a statistically significant difference in ADAS-cog scores and ADCS-CGIC scores in Exelon-treated patients as compared with placebo-treated patients (mean difference, 3.8 points and 0.5 points, respectively). The most common adverse effects associated with Exelon were nausea, vomiting, and tremor.

GARDASIL

Merck & Co., Inc. (Whitehouse Station, NJ) has been given FDA approval to market Gardasil (quadrivalent human papillomavirus [types 6, 11, 16, 18] recombinant vaccine), the first treatment for the prevention of cervical cancer, cervical precancers (cervical intraepithelial neoplasia [CIN] grade 2/3 and adenocarcinoma in situ [AIS]), vulvar precancers (vulvar intraepithelial neoplasia [VIN] grade 2/3), and vaginal precancers (vaginal intraepithelial neoplasia [VaIN] grade 2/3) caused by human papillomavirus (HPV) types 16 and 18 in girls and women aged 9 to 26 years. Gardasil is also approved for the prevention of genital warts and low-grade cervical lesions (CIN 1) caused by HPV types 6, 11, 16, and 18. The efficacy of Gardasil was evaluated in 4 placebo-controlled, double-blind, randomized trials. Women received Gardasil or placebo on the day of enrollment and 2 and 6 months after enrollment. Primary analyses were conducted in women who received all 3 vaccinations within 1 year of enrollment, did not have major deviations from the study protocol, and were naïve to relevant HPV type(s) prior to dose 1 and through 1 month after dose 3. Gardasil prevented 100% of HPV 16– and HPV 18–related cervical precancers and noninvasive cervical cancers (CIN 2/3 and/or AIS); 95% of low-grade cervical dysplasia and precancers (CIN 2/3 or AIS) caused by HPV 6, 11, 16, or 18; 99% of genital warts caused by HPV 6 or 11; and 100% of HPV 16– and HPV 18–related vulvar and vaginal precancers (VIN 2/3 or VaIN 2/3) in women not previously exposed to relevant HPV types. Gardasil was approved for use in adolescent girls aged 9 to 15 years based on studies evaluating immunogenicity in girls (age, 9–17 years) and women (age, 18–26 years). The most common adverse effects associated with Gardasil were pain and swelling at the injection site, pyrexia, and fever. Gardasil should be administered as 3 separate intramuscular injections at the elected date, 2 months after the first dose, and 6 months after the first dose.

WELLBUTRIN XL

The FDA has given GlaxoSmithKline (Research Triangle Park, NC) approval to market Wellbutrin XL (bupropion HCl extended-release tablets) for the prevention of seasonal major depressive episodes in patients with a diagnosis of seasonal affective disorder. Wellbutrin XL is the first medication approved for the prevention of this condition. Wellbutrin XL was evaluated in 3 double-blind, placebo-controlled trials in adults with major depressive disorder with an autumn-winter seasonal pattern (as defined by DSM-IV criteria). Patients were randomized to placebo or Wellbutrin XL 150 mg once daily for 1 week followed by up-titration to 300 mg once daily (mean dose, 257–280 mg/day). Treatment was started before onset of symptoms in autumn and discontinued following a 2-week taper in the spring (treatment duration, 4–6 mo). In all 3 trials, a higher percentage of patients were depression-free at the end of treatment in the Wellbutrin XL group as compared with placebo (84.3% versus 72%). The most common adverse effects associated with Wellbutrin XL were headache, dry mouth, insomnia, and nasopharyngitis. Wellbutrin XL has been previously approved for the treatment of major depressive disorder.

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.*