Drugs recently approved or pending approval

CHANTIX

The US Food and Drug Administration (FDA) has given approval to Pfizer Inc. (New York, NY) to market Chantix (varenicline) as an aid to smoking cessation treatment. The efficacy of Chantix was evaluated in 6 trials that involved 3659 cigarette smokers (≥ 10 cigarettes/day), in which abstinence from smoking was determined by patient self-report and verified by measurement of exhaled carbon monoxide at weekly visits. In all studies but studies 1 and 6, patients were treated for 12 weeks and were followed for 40 weeks post-treatment. All patients were provided with an educational booklet on smoking cessation and received 10 minutes of smoking cessation counseling. Patients set a date to stop smoking (ie, target quit date), and dosing started 1 week before this date. Study 1 was a phase II study to confirm the effectiveness of Chantix. Study 6 assessed the effect of Chantix therapy for an additional 12 weeks and the likelihood of abstinence. Study 2 compared Chantix 1 mg/day and 2 mg/day with placebo; study 3 was a flexible-dosing study that compared Chantix at patient-determined doses (0.5 mg 4 times/day to 1 mg twice daily) with placebo; and studies 4 and 5 were identical double-blind studies that compared Chantix 2 mg/day, bupropion sustained release 150 mg twice daily, or placebo. Chantix reduced the urge to smoke compared with placebo in all studies, based on responses to the Brief Questionnaire of Smoking Urges and the Minnesota Withdrawal scale. In studies 2 through 5, a greater percentage of Chantix-treated patients had superior rates of carbon monoxide–confirmed abstinence as compared with either placebo or bupropion (depending on the study). In addition, Chantix-treated patients were more likely to maintain abstinence throughout the follow-up period as compared with placebo-treated patients. The most common adverse effects associated with Chantix were nausea, sleep disturbance, constipation, flatulence, and vomiting. Chantix should be taken after eating and with a full glass of water. The recommended dose of Chantix is 1 mg twice daily following a 1-week titration (days 1–3, 0.5 mg once daily; days 4–7, 0.5 mg twice daily; day 8–end of treatment, 1 mg twice daily).

DACOGEN

The FDA has given approval to MGI PHARMA, INC. (Bloomington, MN) to market Dacogen (decitabine for injection) for the treatment of patients with myelodysplastic syndromes including previously treated and untreated, de novo and secondary myelodysplastic syndromes of all French-American-British subtypes (ie, refractory anemia with or without ringed sideroblasts, excess blasts, or excess blasts in transformation; and chronic myelomonocytic leukemia), and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups. Dacogen was evaluated in a randomized, multicenter, controlled trial involving 170 patients with myelodysplastic syndromes meeting French-American-British classification criteria and International Prognostic Scoring System high-risk, intermediate-2, and intermediate-1 prognostic scores. Patients received either Dacogen intravenous infusion (n = 89) at a dose of 15 mg/m^2 over a 3-hour period every 8 hours for 3 consecutive days or supportive care (n = 81), which consisted of blood and blood product infusions, prophylactic antibiotics, and hematopoietic growth factors. Cycles were repeated every 6 weeks. Primary endpoints were overall response rate (complete response plus partial response) and time to acute myeloid leukemia or death. The overall response rate in Dacogen-treated patients was 17% compared with 0% in the supportive care group. The most common adverse effects associated with Dacogen were neutropenia, thrombocytopenia, anemia not otherwise specified, pyrexia, and nausea.

NEXIUM

AstraZeneca (Wilmington, DE) has been given FDA approval to market Nexium (esomeprazole magnesium) delayed-release capsules for the short-term treatment of gastroesophageal reflux disease (GERD) in children aged 12 to 17 years. The safety and tolerability of Nexium was evaluated in a multicenter, randomized, double-blind, parallel-group study of 149 adolescent patients (age, 12–17 years) with clinically diagnosed GERD. Patients were treated with either Nexium 20 mg or 40 mg once daily for up to 8 weeks. The use of Nexium for short-term treatment of GERD is supported by extrapolation of results already included in the currently approved labeling from adequate and well-controlled studies that supported the use of Nexium in adults and from safety and pharmacokinetic studies performed in adolescent patients. The most common adverse effects reported in this study of adolescents were headache, abdominal pain, diarrhea, and nausea.

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.*