

### Drugs recently approved or pending approval

#### SPIRIVA HANDIHALER

The US Food and Drug Administration (FDA) granted approval to Boehringer Ingelheim Pharmaceuticals, Inc (Ridgefield, CT) to market Spiriva HandiHaler (tiotropium bromide inhalation powder) for the long-term, once-daily maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. Spiriva HandiHaler was evaluated in six phase 3 studies involving 2663 patients with COPD: two 1-year, placebo-controlled studies; two 6-month placebo-controlled studies; and two 1-year, ipratropium-controlled studies. All patients in these studies had a clinical diagnosis of COPD, were aged  $\geq 40$  years, had a  $> 10$  pack-year smoking history, had a forced expiratory volume in 1 second ( $FEV_1$ )  $\leq 60\%$  or  $65\%$  predicted, and a ratio of  $FEV_1$ /forced vital capacity  $\leq 0.7$ . In these studies, Spiriva HandiHaler, administered once daily in the morning, provided improvement in lung function (as measured by  $FEV_1$ ) with peak effect occurring within 3 hours following the first dose. Spiriva HandiHaler demonstrated significant bronchodilation that was sustained over the duration of the study periods. The most common adverse effect associated with Spiriva HandiHaler was dry mouth. Spiriva HandiHaler may potentially worsen symptoms and signs associated with narrow-angle glaucoma, prostatic hyperplasia, or bladder-neck obstruction and should be used with caution in patients with these conditions.



#### ZITHROMAX

Pfizer, Inc., of New York, NY, announced that the FDA has approved Zithromax (azithromycin) as a once-daily, 3-day treatment for acute bacterial sinusitis. Zithromax is the only antibiotic approved as a 3-day treatment regimen for acute bacterial sinusitis. Zithromax (500 mg once-daily for 3 days) was compared with amoxicillin/clavulanate (500/125 mg 3 times/day for 10 days) in a randomized, double-blind, double-dummy, controlled trial. The primary endpoint was defined at the clinical cure rate at day 28. For the 594 patients analyzed at day 10, the clinical cure rate for 3 days of Zithromax was 88% (268/303) compared with 85% (248/291) for 10 days of amoxicillin/clavulanate. For 586 patients analyzed at day 28, the clinical cure rate for 3-day Zithromax was equal to that of 10-day amoxicillin/clavulanate (97.5% confidence interval,  $-8.4$  to  $8.3$ ). The most common treatment-related adverse effects associated with Zithromax were diarrhea and nausea. Zithromax is contraindicated for patients with hypersensitivity

to azithromycin, erythromycin, or any macrolide antibiotic. Zithromax has been previously approved as a once-daily, 5-day treatment for community-acquired respiratory and skin infections; a once-daily, 5-day treatment for otitis media in pediatric patients; and both 1-day and 3-day treatment for acute otitis media in pediatric patients.

#### ZYPREXA

The FDA has given Eli Lilly and Company (Indianapolis, IN) approval to market Zyprexa (olanzapine) for maintenance treatment of bipolar disorder. Zyprexa is the first treatment in 30 years to be recognized by the FDA as a treatment for both acute mania and maintenance of bipolar disorder. Zyprexa was evaluated in a randomized, placebo-controlled, double-blind trial involving patients ( $N = 361$ ) meeting DSM-IV criteria for a manic or mixed episode of bipolar disorder who had responded during an initial open-label treatment phase to Zyprexa 5 mg to 20 mg per day. Patients were randomized to either continuation of Zyprexa at their same dose ( $n = 225$ ) or to placebo ( $n = 136$ ) for observation of relapse. Response was defined as having a decrease in the Young Mania Rating Scale (Y-MRS) total score of  $\leq 12$  or as having a Hamilton Depression Scale (HAM-D 21) score of  $\leq 8$ . Relapse was defined as an increase of Y-MRS or HAM-D 21 total score  $\geq 15$  or being hospitalized for either mania or depression. Approximately 50% of Zyprexa-treated patients had discontinued treatment by day 59, and 50% of placebo-treated patients discontinued treatment by day 23. Zyprexa-treated patients had a significantly lower rate of mania as compared with placebo-treated patients (16.4% versus 41.2%). Patients treated with Zyprexa also had a significantly lower depression relapse rate as compared with placebo-treated patients (34.7% versus 47.8%). The most common adverse effects associated with Zyprexa were weight gain, fatigue, and akathisia. Zyprexa has been previously approved for the treatment of schizophrenia, as acute monotherapy for the treatment of acute mixed or manic episodes associated with bipolar disorder, and as combination therapy for the short-term treatment of acute mania associated with bipolar disorder.

*Compiled from press reports and pharmaceutical company press releases. For more information, contact Tricia Carbone, Hospital Physician, 125 Stauffer Avenue, Suite 220, Wayne, PA 19087-3391.*