Drugs recently approved or pending approval

LANTUS SOLOSTAR

The US Food and Drug Administration (FDA) has given approval to sanofi-aventis (Bridgewater, NJ) to market Lantus Solostar, a prefilled disposable insulin pen for administration of once-daily 24-hour Lantus (insulin glargine) for the treatment of adult patients with type 2 diabetes mellitus (DM) and for adults and children (aged ≥ 6 yr) with type 1 DM who require long-acting insulin for control of hyperglycemia. Solostar is the only disposable insulin pen that allows patients to administer doses from 1 to 80 units in 1 injection. The 3 mL insulin pen contains 300 units of Lantus (100 units/mL). To administer Lantus with Solostar, patients select their required dose using a dial that is adjustable in 1-unit increments. Tests to evaluate the dose accuracy of Lantus Solostar showed that the device accurately and consistently delivered the dialed dose of insulin well within International Organization for Standardization test standards.

LETAIRIS

The FDA has given approval to Gilead Sciences, Inc. (Foster City, CA) to market Letairis (ambrisentan) for the treatment of pulmonary arterial hypertension (PAH; WHO Group 1) in patients with WHO class II or III symptoms to improve exercise capacity and delay clinical worsening. Letairis once daily was evaluated in two 12-week, randomized, double-blind, placebo-controlled, multicenter studies (ARIES-1 [evaluating 5 and 10 mg] and ARIES-2 [evaluating 2.5 and 5 mg]) involving 393 patients with PAH. The primary endpoint was 6-minute walk distance; clinical worsening was also assessed. In both studies, Letairis-treated patients showed significant improvements in 6-minute walk distance at 12 weeks, with placebo-adjusted mean and median changes from baseline of 31 m and 27 m ($P = 0.008$) for Letairis 5 mg and 51 m and 39 m ($P < 0.001$) for Letairis 10 mg in ARIES-1; and placebo-adjusted mean and median changes from baseline of 59 m and 45 m ($P < 0.001$) for Letairis 5 mg in ARIES-2. Letairis-treated patients had a significant delay in the time to clinical worsening as compared with placebo-treated patients (3% versus 10% in ARIES-1; 6% versus 22% in ARIES-2). The most common adverse effects were peripheral edema and nasal congestion.

LYRICA

Pfizer (New York, NY) has been given FDA approval to market Lyrica (pregabalin) for the management of fibromyalgia (FM). Lyrica once-daily was evaluated in a 14-week, double-blind, placebo-controlled, multicenter study (F1) and a 6-month, randomized withdrawal study (F2) involving FM patients who met American College of Rheumatology criteria (a history of widespread pain for 3 mo and pain at ≥ 11 of 18 specific tender point sites). Efficacy of Lyrica was measured using Visual Analog Scale (VAS; reduction in pain), patient global assessment (PGIC), and the Fibromyalgia Impact Questionnaire (FIQ). In F1, patients with a minimum mean baseline pain score of 4 or more on an 11-point scale and a VAS score of 40 mm or more received Lyrica 300, 450, or 600 mg/day or placebo. In F2, patients were titrated to Lyrica 300, 450, or 600 mg once daily for a 6-week open-label dose optimization phase, and those who had at least a 50% reduction in pain (as measured by VAS) and rated their overall improvement as "much improved" or "very much improved" on the PGIC were randomized to either the dose achieved or placebo. Efficacy in F2 was assessed by time to loss of therapeutic response (< 30% reduction in pain from open-label baseline to 2 consecutive visits of the double-blind phase or worsening of FM symptoms requiring an alternative treatment). In both studies, all doses of Lyrica demonstrated improvements in pain compared with placebo. Lyrica-treated patients in F2 had a longer time to loss of response based on the FIQ. The most common adverse effects were dizziness and somnolence.

XYZAL

The FDA has given approval to UCB and sanofi-aventis (Atlanta, GA and Bridgewater, NJ) to comarket Xyzal (levocetirizine dihydrochloride) for the relief of symptoms associated with seasonal allergic rhinitis (SAR) and perennial allergic rhinitis (PAR) in adults and children aged 6 years and older. Xyzal was evaluated in 6 randomized, placebo-controlled, double-blind clinical trials (three 2–4 wk dose-ranging trials, one 2-wk efficacy trial in patients with SAR, and 2 efficacy trials [one 6-wk and one 6-mo] in patients with PAR) involving 2412 adult and adolescent patients (aged, ≥ 12 yr). The primary endpoint was the mean total symptom score (ie, sum of individual symptoms as measured by patients on a 0–3 categorical severity scale) averaged over the first week and over 2 weeks for SAR trials and over 4 weeks for PAR trials. Xyzal 2.5, 5, and 10 mg once daily demonstrated statistically significant decreases in the total symptom score compared with placebo. The most common adverse effects were somnolence and nasopharyngitis.

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