Drugs recently approved or pending approval

DEGARELIX

The US Food and Drug Administration (FDA) has given approval to Ferring Pharmaceuticals (Parsippany, NJ) to market degarelix, an injectable gonadotropin-releasing hormone receptor antagonist, for treatment of advanced prostate cancer. The safety and efficacy of degarelix were evaluated in an open-label, multicenter, randomized, parallel-group study involving 620 patients with prostate cancer. Patients received either degarelix 240 mg subcutaneously followed by monthly doses of degarelix 160 or 80 mg subcutaneously or monthly leuprolide 7.5 mg intramuscularly for 1 year. The primary endpoint was testosterone suppression to castration levels (testosterone ≤ 50 ng/dL) from day 28 to day 364. Degarelix 240/160 mg and 240/80 mg were as effective (98.3% and 97.2%, respectively) as leuprolide (96.4%) in achieving and maintaining testosterone suppression to castration levels during 12 months of treatment. Degarelix also statistically significantly reduced testosterone faster than leuprolide; at days 3 and 14, respectively, 96% and 99% of degarelix-treated patients achieved testosterone suppression as compared with 0% and 18% of leuprolide-treated patients. Prostate-specific antigen levels monitored as a secondary endpoint were lowered by 64% after 2 weeks of treatment with degarelix, 85% after 1 month, 95% after 3 months, and remained suppressed throughout 1 year. The most common adverse effects were injection site reactions, hot flashes, increased weight, and fatigue.

LUSEDRA

The FDA has granted approval to Eisai Corporation of North America (Woodcliff Lake, NJ) to market Lusedra (fospropofol disodium) injection for monitored anesthesia care sedation in adults undergoing diagnostic or therapeutic procedures. Standard and modified Lusedra dosing regimens were evaluated in 2 randomized, blinded, dose-controlled studies for sedation in patients (age > 18 yr) undergoing colonoscopy (study 1) or flexible bronchoscopy (study 2). Patients were randomized to standard or modified Lusedra dosing administered intravenously as an initial bolus dose with up to 3 supplemental doses at 25% of initial bolus dose to sedate patients so that they did not respond readily to their name spoken in a normal tone of voice. The standard dosing regimen was an initial bolus dose of 6.5 mg/kg followed by supplemental doses of 1.6 mg/kg as needed. The modified dosing regimen was 75% of the standard dosing regimen. All patients were given 50 µg of fentanyl citrate intravenously prior to receiving Lusedra. Patients who were inadequately sedated with Lusedra received alternative sedative medication (ie, midazolam). The primary endpoint was the rate of sedation success, defined as the proportion of patients who did not respond readily to their name spoken in a normal tone of voice (≤ 4 on the Modified Observer's Assessment of Alertness/Sedation Scale) on 3 consecutive measurements taken every 2 minutes and who completed the procedure without the use of alternative sedative medication and without the use of manual or mechanical ventilation. The analyses of the 2 dosing regimens were combined. In studies 1 and 2, Lusedra-treated patients had a sedation success rate of 87% and 89%, respectively, and required a mean number of 2.3 (±1.4 SD) and 1.7 (±1.6 SD) supplemental doses, respectively. The most common adverse effects were paresthesia and pruritis.

SAVELLA

Forest Laboratories, Inc. (New York, NY) has received FDA approval to market Savella (milnacipran HCl) for the management of fibromyalgia. The efficacy of Savella was established in 2 multicenter, double-blind, placebo-controlled studies in patients (aged, 18–74 yr) with fibromyalgia. Patients who met the American College of Rheumatology criteria for fibromyalgia (a history of widespread pain for 3 mo and pain present at ≥ 11 of 18 specific tender point sites) received Savella 100 or 200 mg or placebo for 6 months (study 1) or for 3 months (study 2). The primary endpoint was treatment response, as measured by improvement in pain, physical function, and patient global assessment. In both studies, Savella-treated patients experienced at least a 30% reduction in pain from baseline (as measured by the Visual Analog Scale) and considered themselves "much improved" or "very much improved" (as measured by the Patient Global Impression of Change) as compared with placebo-treated patients. Some patients who rated themselves as much or very much improved experienced a decrease in pain as early as week 1 of treatment with Savella. In both studies, Savella 200 mg/day did not provide greater benefit over Savella 100 mg/day. The most common adverse effects were constipation, hot flush, hyperhidrosis, vomiting, palpitations, and tachycardia. Savella is not approved for use in pediatric patients.

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.*