Drugs recently approved or pending approval

TEKTURNA

The US Food and Drug Administration (FDA) has given approval to Novartis Pharmaceuticals Co. (East Hanover, NJ) to market Tekturna (aliskiren) tablets for the treatment of hypertension. The effectiveness of Tekturna was established in 6 randomized, double-blind, placebo-controlled 8-week clinical trials involving 3961 patients with mild to moderate hypertension. Patients were administered doses of 75, 150, 300, or 600 mg of Tekturna or placebo. Although all doses of Tekturna decreased blood pressure, the greatest response was observed with 150 or 300 mg, and a substantial proportion (85%–90%) of the blood pressure–lowering effect was observed within 2 weeks of treatment. Patients continued open-label Tekturna for up to 1 year, which resulted in a statistically significant difference between Tekturna-treated patients and placebo-treated patients. Tekturna was effective across all demographic subgroups; however, African-American patients tended to have smaller reductions in blood pressure as compared with Caucasians and Asians. Tekturna used in combination with other antihypertensive agents (eg, diuretics, valsartan) has been clinically proven to further reduce blood pressure compared with Tekturna alone. The most common adverse effect associated with Tekturna was diarrhea. The recommended starting dose of Tekturna is 150 mg once daily. In patients whose blood pressure is not adequately controlled, the daily dose may be increased to 300 mg.

VAPRISOL

Astellas Pharma US, Inc. (Deerfield, IL) has been given FDA approval to market Vaprisol (conivaptan hydrochloride injection), an arginine vasopressin receptor antagonist, for treatment of hypervolemic hyponatremia in hospitalized patients. Vaprisol was evaluated in a double-blind, placebo-controlled, randomized, multicenter study involving 84 patients with euvolemic or hypervolemic hyponatremia. All patients' daily fluid intake was restricted to 2 L or less. Patients were randomized to receive either placebo (n = 29), Vaprisol 40 mg/day intravenously (IV; n = 29), or Vaprisol 80 mg/day IV (n = 26). Vaprisol was administered as a continuous infusion following a 30 min IV infusion of a 20 mg loading dose on the first treatment day. Serum or plasma sodium concentrations were measured at predose (0 hr) and postdose (4, 6, 10, and 24 hr) on all treatment days. At baseline, the mean serum sodium concentration was 123.3 mEq/L. Following treatment with Vaprisol 40 mg/day, serum sodium concentration increased (≥ 4 mEq/L) in 79% of patients. The mean change in serum sodium concentration from baseline to the end of 2 and 4 days of treatment with Vaprisol was 5.3 mEq/L (mean concentration, 128.6 mEq/L) and 6.5 mEq/L (mean concentration, 129.8 mEq/L), respectively. After 2 and 4 days, 41% and 69% of patients (respectively) achieved an increase of 6 mEq/L or more in serum sodium concentration or normal serum sodium of 135 mEq/L or greater. Vaprisol 80 mg/day was not significantly more effective than 40 mg/day. The most common adverse effects in Vaprisol-treated patients were infusion site reactions. The recommended maximum daily dose of Vaprisol is 40 mg/day. Vaprisol was previously approved for hospitalized patients with euvolemic hyponatremia.

VYVANSE

The FDA has given approval to Shire LLC (Philadelphia, PA) and New River Pharmaceuticals, Inc. (Radford, VA) to comarket Vyvanse (lisdexamfetamine dimesylate) for the treatment of attention-deficit/hyperactivity disorder (ADHD). Vyvanse once daily was evaluated in 2 double-blind, randomized, placebo-controlled trials involving 342 pediatric patients aged 6 to 12 years who met DSM-IV criteria for ADHD. In study 1, patients were randomized to fixed-dose treatment groups receiving final doses of 30, 50, or 70 mg of Vyvanse or placebo in the morning for 4 weeks. In study 2, patients followed a 3-week open-label dose titration with Adderall XR (amphetamine aspartate, amphetamine sulfate, dextroamphetamine saccharate, dextroamphetamine sulfate) and were randomized to continue the same dose of Adderall XR (10, 20, or 30 mg), Vyvanse (30, 50, or 70 mg), or placebo in the morning for 1 week. Vyvanse-treated patients in both clinical trials had significant improvements in ADHD symptoms as compared with placebo-treated patients (as measured by the ADHD Rating Scale in study 1; and the Swanson, Kotkin, Agler, M.Flynn, and Pelham [SKAMP]-Deportment scores in study 2). The most common adverse effects associated with Vyvanse were decreased appetite, insomnia, irritability, weight loss, and upper abdominal pain. The recommended dose of Vyvanse for children aged 6 to 12 years with ADHD is 30 mg once daily in the morning (maximum dose, 70 mg/day).

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.