Drugs recently approved or pending approval

COLAZAL

The US Food and Drug Administration (FDA) has given approval to Salix Pharmaceuticals, Ltd. (Raleigh, NC) to market Colazal (balsalazide disodium) for the treatment of mildly to moderately active ulcerative colitis in children aged 5 to 17 years. Colazal was evaluated in a clinical trial of 68 pediatric patients aged 5 to 17 years. Patients were randomized to either Colazal 6.75 g/day (n = 33) or 2.25 g/day (n = 35). The primary endpoint was the proportion of patients with clinical improvement, defined as a reduction of at least 3 points in the Modified Sutherland Ulcerative Colitis Activity Index (MUCAI) from baseline to 8 weeks. Of patients in the Colazal 6.75 g/day and 2.25 g/day groups, 15 and 13, respectively, demonstrated clinical improvement. In both groups, patients with higher MUCAI total scores at baseline were likely to experience greater improvement. The most common adverse effects were headache, abdominal pain, vomiting, diarrhea, nasopharyngitis, and pyrexia. The recommended dose of Colazal in pediatric patients is either three 750 mg capsules 3 times/day (6.75 g/day) or one 750 mg capsule 3 times/day (2.25 g/day) with or without food for 8 weeks.

CYANOKIT

Dey, LP (Napa, CA) has been given FDA approval to market Cyanokit (hydroxocobalamin for injection) for the treatment of known or suspected cyanide poisoning. Cyanokit was evaluated in 2 studies: a prospective, uncontrolled, open-label study involving 69 patients who had been exposed to smoke inhalation from fires (study 1); and a retrospective uncontrolled study of 14 patients who had been exposed to cyanide either by ingestion or inhalation (study 2). In study 1, 50 of 69 (73%) patients survived following treatment with Cyanokit. Of 42 patients with potentially toxic pretreatment cyanide levels, 28 (67%) survived after treatment with Cyanokit, while 11 of 19 (58%) patients with potentially lethal pretreatment cyanide levels survived after Cyanokit treatment. Nine of 50 patients had neurologic sequelae at hospital discharge. In study 2, 10 of 14 (71%) patients survived following treatment with Cyanokit. Of the 10 patients who survived, 1 had neurologic sequelae at hospital discharge. The most common adverse effects were transient chromaturia, erythema, rash, increased blood pressure, nausea, headache, and injection site reactions. The starting dose of Cyanokit is 5 g (two 2.5-mg vials) administered as an intravenous infusion over 15 minutes. Each 2.5-mg vial should be reconstituted with 100 mL of diluent (0.9% sodium chloride is recommended but not provided with Cyanokit) using the supplied sterile transfer spike. Once reconstituted, each vial should be repeatedly inverted and rocked (not shaken) for 30 seconds and should be inspected for particulate matter and color before infusion. A second dose of 5 g may be administered for a total dose of 10 g depending on the severity of poisoning and clinical response (rate of infusion for second dose, 15 min–2 hr).

INVEGA

The FDA has given approval to Janssen, LP (Titusville, NJ) to market Invega (paliperidone) extended-release tablets, a new atypical antipsychotic, for the treatment of schizophrenia. Invega once-daily was evaluated in 3 placebo- and active-controlled (olanzapine), 6-week, fixed-dose trials in nonelderly adult patients (mean age, 37 yr) with schizophrenia. The doses studied were 3, 6, 9, 12, and 15 mg/day. The efficacy of Invega was measured using the Positive and Negative Syndrome Scale (PANSS), a validated multi-item inventory to evaluate positive and negative symptoms, disorganized thoughts, uncontrolled hostility/excitement, and anxiety/depression; and the Personal and Social Performance (PSP) scale, a validated clinician-rated scale that measures personal and social functioning, personal and social relationships, self-care, and disturbing and aggressive behaviors. In all 3 studies, Invega was superior to placebo on both the PANSS and PSP scale. The most common adverse effects associated with Invega were akathisia and extrapyramidal disorder (eg, involuntary movements, tremors, muscle stiffness). The recommended dose of Invega is 6 mg/day (range, 3–12 mg/day). Invega is not approved for treatment of patients with dementia-related psychosis.

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

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