ORENCIA

The US Food and Drug Administration (FDA) has given approval to Bristol-Myers Squibb Company (Princeton, NJ) to market Orencia (abatacept) for treating rheumatoid arthritis (RA). It is indicated for reducing the signs and symptoms, inducing major clinical response, slowing the progression of structural damage, and improving physical function in adults with moderately to severely active RA who have had an inadequate response to 1 or more disease-modifying antirheumatic drugs (DMARDs). Orencia was evaluated in 5 randomized, double-blind, placebo-controlled studies. The studies included the following patients: study 1, patients with active RA who had failed at least 1 DMARD or etanercept; study 2 and 3, patients with inadequate response to methotrexate (MTX) and who were continued on their stable dose of MTX during the study period; study 4, patients with an inadequate response to a tumor necrosis factor (TNF)—blocking agent (agent was discontinued prior to randomization); and study 5, patients with active RA requiring additional intervention despite current DMARD therapy. Study 1 patients were randomized to either Orencia 0.5, 2, or 10 mg/kg or placebo. Study 2 patients were randomized to Orencia 2 or 10 mg/kg or placebo for 12 months. Patients in studies 3, 4, and 5 were randomized to receive a dose of Orencia based on weight (< 60 kg received 500 mg, 60–100 kg received 750 mg, > 100 kg received 1 g) or placebo for 12 (studies 3 and 4) or 6 (study 5) months. Orencia-treated patients demonstrated significant improvements in signs and symptoms of RA at 6 and 12 months compared with placebo-treated patients. Orencia-treated patients also experienced significant improvements in physical function, and improvements were observed in all 8 domains of the SF-36 as compared with placebo-treated patients. The most common adverse effects were headache, upper respiratory tract infection, nasopharyngitis, and nausea. Orencia should not be administered along with TNF antagonists or anakinra. Orencia should be administered as a 30-minute infusion based on the patient’s weight. Orencia should be given at 2 and 4 weeks after the first infusion and then every 4 weeks thereafter.

REVLMID

Celgene Corporation (Summit, NJ) was granted FDA approval to market Revlimid (lenalidomide) for the treatment of patients with transfusion-dependent anemia caused by low- or intermediate-1-risk myelodysplastic syndromes associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities. Revlimid was evaluated in an open-label, single-arm, multicenter study involving 148 patients with erythrocyte transfusion-dependent anemia. Transfusion independence, defined as the absence of any erythrocyte transfusion during any consecutive “rolling” 56 days during the treatment period, was seen in 99 of 148 (67%) patients. The mean duration from when transfusion independence was declared to when an additional transfusion was received (after the 56-day transfusion-free period) was 44 weeks (range, 0 to > 67 wk). Ninety percent of patients who achieved a transfusion benefit did so by 3 months. The dose of Revlimid was reduced or interrupted at least once due to an adverse event in 118 (79.7%) patients, and a second reduction or interruption was required in 50 (33.8%) patients. The most common adverse effects were thrombocytopenia, neutropenia, diarrhea, pruritus, rash, and fatigue. Revlimid has a black box warning stating that it has the potential to cause human birth defects, hematologic toxicity, and/or deep venous thrombosis and pulmonary embolism.

VAPRISOL

The FDA has given approval to Astellas Pharma US, Inc. (Deerfield, IL) to market Vaprisol (conivaptan hydrochloride injection) for the treatment of euvolemic hyponatremia in hospitalized patients. Vaprisol was evaluated in a double-blind, placebo-controlled, randomized, multicenter study of 56 patients with euvolemic hyponatremia (serum sodium, 115–130 mEq/L). All patients received standard care for hyponatremia (primarily fluid restriction). Patients were randomized to either placebo (n = 21), Vaprisol 40 mg/d (n = 18), or Vaprisol 80 mg/d (n = 17). Vaprisol was administered as a continuous infusion following a 30-minute infusion of a 20-mg loading dose on the first treatment day. Fifty-two percent of patients treated with Vaprisol 40 mg/d achieved an increase in serum sodium concentration of at least 4 mEq/L. After 2 and 4 days of Vaprisol treatment, 39% and 67% of patients achieved an increase in serum sodium concentration of at least 6 mEq/L or a normal serum sodium concentration of at least 135 mEq/L. The most common adverse effects associated with Vaprisol were infusion site reactions, hypokalemia, headache, thirst, and vomiting. The total duration of Vaprisol infusion should not exceed 4 days.

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

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