Drugs recently approved or pending approval

ERBITUX

The US Food and Drug Administration (FDA) gave approval to ImClone Systems Incorporated (New York, NY) and Bristol-Myers Squibb Company (Princeton, NJ) to market Erbitux (cetuximab) for use in combination with irinotecan in the treatment of patients with epidermal growth factor receptor (EGFR)–expressing metastatic colorectal cancer who are refractory to irinotecan-based chemotherapy and for use as a single agent in the treatment of patients with EGFR-expressing metastatic colorectal cancer who are intolerant to irinotecan-based chemotherapy. The efficacy of Erbitux used alone (n = 111) or in combination with irinotecan (n = 218) was studied in a randomized, controlled trial and in combination with irinotecan in an open-label, single arm trial (N = 138). A third trial using Erbitux as a single agent (N = 57) also was performed. A blinded review committee assessed the progression on prior irinotecan and the response to protocol treatment for all patients. Erbitux given in combination with irinotecan (n = 218) was found to have an objective response rate (ORR) of 22.9%, a median duration of response of 5.7 months, and a median time to disease progression of 4.1 months. Erbitux monotherapy (n = 111) showed a 10.8% ORR, a median duration of response of 4.2 months, and a median time to disease progression of 1.5 months. Results of Erbitux/irinotecan combination (N = 138) showed an ORR of 15% and a median duration of response of 6.5 months. Erbitux as a single agent (N = 57) showed a 9% ORR and a median duration of response of 4.2 months. The most common adverse effects observed in both Erbitux monotherapy and combination therapy participants were acneform rash, asthenia/malaise, diarrhea, and nausea.

ORTHOVISC

Ortho Biotech Products LP (Ridgewater, NJ) announced that the FDA has approved Orthovisc High Molecular Weight Hyaluronan for the treatment of pain in osteoarthritis of the knee in patients who have failed to respond adequately to conservative nonpharmacologic therapy and to simple analgesics. The effectiveness of Orthovisc was evaluated in 2 randomized, controlled, double-blind, multicenter studies that involved unilateral treatment and 1 study that involved bilateral treatment. The first unilateral treatment study (N = 164) randomized patients to 3 weekly injections of either Orthovisc or saline. The second unilateral study (N = 294) randomized patients to 1 of 3 treatments: 4 Orthovisc injections, 3 Orthovisc injections and 1 arthrocentesis procedure, or 4 arthrocentesis procedures. Only the unilateral study data were analyzed for effectiveness. The effectiveness analysis was performed to determine the proportion of patients achieving a 20% improvement from baseline in WOMAC Pain Score in conjunction with a minimum absolute improvement of 50 mm from baseline in the WOMAC Pain Score, and a 40% and 50% improvement from baseline in the WOMAC Pain Score at 4 assessment points between weeks 8 and 22 for the index knee. The 4-injection Orthovisc regimen demonstrated effectiveness compared with both saline and arthrocentesis control procedures, and the 3–weekly injection regimen demonstrated effectiveness compared with saline. The most common adverse effects observed with Orthovisc in all 3 studies were arthralgia, back pain, and headache.

SENSIPAR

The FDA has given approval to NPS Pharmaceuticals, Inc. (Salt Lake City, UT) and Amgen, Inc. (Thousand Oaks, CA) to market Sensipar (cinacalcet HCl) for the treatment of secondary hyperparathyroidism in chronic kidney disease (CKD) patients on dialysis and for the treatment of hypercalcemia in patients with parathyroid carcinoma. Sensipar was evaluated in three 6-month, multicenter, randomized, double-blind, placebo-controlled trials involving CKD patients on dialysis. Sensipar (or placebo) was initiated at a dose of 30 mg once daily and titrated every 3 or 4 weeks to a maximum dose of 180 mg once daily to achieve a parathyroid hormone level by radioimmunoassay (iPTH) ≤ 250 pg/mL. The dose was not increased if a patient had an iPTH ≤ 200 pg/mL, serum calcium < 7.8 mg/dL, or had any symptoms of hypocalcemia. Forty percent of Sensipar-treated patients (n = 665) and 5% of placebo-treated patients (n = 471) achieved an iPTH ≤ 250 pg/mL ($P < 0.001$). Sensipar also was evaluated in a 2-phase open-label study involving patients with parathyroid carcinoma (N = 10). The study consisted of a dose-titration phase (range of exposure, 2–16 weeks; n = 10) and a maintenance phase (range of exposure, 16–48 weeks; n = 3). The range of change from baseline to last measurement was –7.5 to 2.7 mg/dL during the titration phase and –7.4 to 0.9 mg/dL during the maintenance phase. No patients maintained a serum calcium level within the normal range. The most common adverse effects seen in Sensipar-treated patients were nausea and vomiting.

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

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