Drugs recently approved or pending approval

JANUMET

The US Food and Drug Administration (FDA) has given approval to Merck & Co., Inc. (Whitehouse Station, NJ) to market Janumet (sitagliptin/metformin) tablets as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes mellitus who are inadequately controlled on metformin or sitagliptin alone or in patients already being treated with a combination of sitagliptin and metformin. No clinical efficacy studies have been conducted with Janumet; however, the bioequivalence of Janumet with coadministered sitagliptin and metformin was evaluated in a 24-week, randomized, double-blind, placebo-controlled study involving 701 patients with type 2 diabetes. Patients on metformin (n = 431; 1500 mg/day) completed a 2-week, single-blind, run-in period with placebo. Patients who were already on metformin and another antihyperglycemic agent (n = 229) and patients not on any antihyperglycemic agents (off therapy for ≥ 8 wk; n = 41) completed a 10-week run-in period on metformin monotherapy (≥ 1500 mg/day). After run-in periods were complete, patients were randomized to the addition of either sitagliptin 100 mg or placebo once daily. Patients who did not meet glycemic goals were treated with pioglitazone rescue therapy. When used in combination with metformin, sitagliptin provided significant improvements in hemoglobin A_{1c} (adjusted mean difference, –0.7% [95% confidence interval {CI}, –0.8% to –0.5%]; $P < 0.001$), fasting plasma glucose (adjusted mean difference, –25 mg/dL [95% CI, –31 to –20 mg/dL]; $P < 0.001$), and 2-hour postprandial glucose (adjusted mean difference, –51 mg/dL [95% CI, –61 to –41 mg/dL]; $P < 0.001$) as compared with metformin alone. The most common adverse effects were nausea, vomiting, abdominal pain, and diarrhea.

RHOPHYLAC

CSL Behring (King of Prussia, PA) has been given FDA approval to market Rhophylac (Rh_0[D] immune globulin intravenous [human]) to raise platelet counts in Rh_0(D)-positive, nonsplenectomized adult patients with chronic immune thrombocytopenic purpura (ITP). Rhophylac was evaluated in an open-label, single-arm, multicenter study involving 98 Rh_0(D)-positive adult patients with chronic ITP and a platelet count of 30×10^9/L or less. Patients were given a single intravenous dose of 250 IU/kg (50 µg/kg) of body weight. The primary efficacy endpoint was the response rate, defined as a platelet count of 30×10^9/L or more and an increase of more than 20×10^9/L, within 15 days after treatment with Rhophylac. Secondary endpoints included the response rate, defined as an increase in platelet counts to 50×10^9/L or more within 15 days after treatment, and hemorrhage regression (defined as any decrease from baseline in the severity of overall bleeding status) in patients who had bleeding at baseline. Of 98 patients, 65 (66.3%) achieved the primary endpoint, and 54 (55.1%) achieved the secondary endpoint at day 15. Of 50 patients who had bleeding at baseline, 44 (88% [95% CI, 76%–94%]) experienced hemorrhage regression. The most common adverse effects in Rhophylac-treated patients were chills, pyrexia/increased body temperature, and headache. Rhophylac has also been approved for suppression of rhesus isoimmunization in nonsensitized Rh_0(D)-negative women with an Rh-incompatible pregnancy.

TYKERB

The FDA has given approval to GlaxoSmithKline (Research Triangle Park, NC) to market Tykerb (lapatinib) to be used in combination with capecitabine for the treatment of patients with advanced or metastatic breast cancer whose tumors are HER2-positive and who have received prior therapy with an anthracycline, a taxane, and trastuzumab. The efficacy and safety of Tykerb in combination with capecitabine were evaluated in a randomized, phase 3 trial involving 399 patients (median age, 53 yr); 97% of patients had stage IV breast cancer, and approximately 95% of patients had prior treatment with anthracyclines, taxanes, and trastuzumab. Patients were randomized to receive either Tykerb 1250 mg/day (continuously) and capecitabine 2000 mg/m^2/day on days 1 to 14 every 21 days or receive capecitabine alone at a dose of 2500 mg/m^2/day on days 1 to 14 every 21 days. The endpoint was time to progression, defined as time from randomization to tumor progression or death related to breast cancer. Patients receiving Tykerb and capecitabine had a statistically significant improvement in time to progression compared with patients receiving capecitabine alone (hazard ratio, 0.57 [95% confidence interval, 0.43–0.77]). The tumor response rate in the Tykerb plus capecitabine group was higher as compared with the capecitabine group (23.7% versus 13.9%). The most common adverse effects were diarrhea, nausea, vomiting, palmar-plantar erythrodysesthesia, and rash.

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.