Drugs recently approved or pending approval

CIMZIA

The US Food and Drug Administration (FDA) has given approval to UCB, Inc. (Smyrna, GA) to market Cimzia (certolizumab pegol) for reducing signs and symptoms of Crohn's disease (CD) and maintaining clinical response in adults with moderately to severely active CD who had inadequately responded to conventional therapy. The efficacy and safety of Cimzia were evaluated in 2 double-blind, randomized, placebo-controlled studies of patients (age, ≥ 18 yr) with active CD (Crohn's Disease Activity Index [CDAI] score, 220–450). In study 1, 662 patients were randomized to Cimzia 400 mg or placebo at weeks 0, 2, and 4 and then every 4 weeks to week 24. In study 2, patients were given Cimzia 400 mg at weeks 0, 2, and 4 and assessed for clinical response at week 6. Clinical responders (n = 425) received Cimzia 400 mg or placebo every 4 weeks starting at week 8 as maintenance therapy through week 24. The primary endpoints for both studies were clinical response (defined as a ≥ 100-point reduction in CDAI score as compared with baseline) and clinical remission (defined as a CDAI score of ≤ 150 points). In study 1, statistically significantly more Cimzia-treated patients had a clinical response at weeks 6 and 26 than placebo-treated patients (23% versus 16%). Clinical remission was not statistically significant at week 6. In study 2, 63% of patients in the Cimzia group had a clinical response and 48% maintained clinical remission at week 26, as compared with 36% and 29%, respectively, of patients in the placebo group. The most common adverse effects were upper respiratory infection, urinary tract infection, and arthralgia.

ROTARIX

GlaxoSmithKline (Research Triangle Park, NC) has received FDA approval to market Rotarix (rotavirus vaccine, live, oral) for the prevention of rotavirus gastroenteritis caused by G1 and non-G1 types (G3, G4, and G9) when administered as a 2-dose series in infants. The efficacy of Rotarix was established in 2 randomized, double-blind, placebo-controlled studies involving 24,163 healthy infants from 17 countries. Patients received Rotarix or placebo as a 2-dose series, with the first dose administered orally from age 6 to 14 weeks in study 1 and 6 to 13 weeks in study 2 followed by 1 additional dose given at least 4 weeks after the first dose. The series was completed by age 24 weeks. The primary endpoint for study 1 was prevention of any grade of severity of rotavirus gastroenteritis (as measured by the Vesikari scale) caused by naturally occurring rotavirus from 2 weeks after the second dose through 1 rotavirus season. The primary endpoint for study 2 was prevention of severe rotavirus gastroenteritis caused by naturally occurring rotavirus from 2 weeks after the second dose through 1 year. In study 1, Rotarix was 87.1% effective against rotavirus gastroenteritis of any severity through 1 rotavirus season (95% confidence interval [CI], 79.6%–92.1%; $P < 0.001$). In study 2, Rotarix was 84.7% effective against severe rotavirus gastroenteritis through 1 year (95% CI, 71.7%–92.4%; $P < 0.001$). The most common adverse effects were fussiness/irritability, cough/runny nose, and fever.

TREXIMET

The FDA has given approval to GlaxoSmithKline (Research Triangle Park, NC) to market Treximet (sumatriptan and naproxen sodium) tablets for the acute treatment of migraine attacks with or without aura in adults. Treximet was evaluated in 2 randomized, double-blind, multicenter, parallel-group trials comparing placebo and active components of Treximet (sumatriptan and naproxen sodium) in patients with moderate to severe migraine pain. Patients were randomized to Treximet, sumatriptan 85 mg, naproxen sodium 500 mg, or placebo. The endpoints were headache relief (defined as a reduction in headache severity from moderate or severe pain to mild or no pain) 2 hours after treatment and sustained pain free. Sustained pain free was defined as a reduction in headache severity from moderate or severe pain to no pain at 2 hours postdose without a return of mild, moderate, or severe pain and no use of rescue medication for 24 hours postdose. Significantly more Treximet-treated patients achieved migraine pain relief at 2 hours as compared with placebo-treated patients (65% versus 28% in study 1 and 57% versus 29% in study 2). More patients in the Treximet group (25% in study 1 and 23% in study 2) remained pain-free without use of other medications through 24 hours postdose as compared with patients treated with placebo (8% in study 1 and 7% in study 2), sumatriptan alone (16% in study 1 and 14% in study 2), or naproxen sodium (10% in both studies) alone. The most common adverse effects were dizziness, nausea, and somnolence.

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.*