Drugs recently approved or pending approval

NPLATE

The US Food and Drug Administration (FDA) has given approval to Amgen Inc. (Thousand Oaks, CA) to market Nplate (romiplostim) for the treatment of thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who insufficiently respond to corticosteroids, immunoglobulins, or splenectomy. The safety and efficacy of Nplate were evaluated in 2 double-blind, placebo-controlled studies involving patients who did not undergo splenectomy (study 1) and patients who underwent splenectomy (study 2) and in 1 open-label extension study. In studies 1 and 2, patients with chronic ITP who had completed at least 1 prior ITP treatment and had a platelet count of 30×10^9/L prior to entry were randomized 2:1 to 24 weeks of Nplate (1 µg/kg subcutaneously once weekly) or placebo. Doses were individually adjusted to maintain platelet counts between 50×10^9/L and 200×10^9/L (median weekly dose, 2 and 3 µg/kg in studies 1 and 2, respectively). In both studies, more Nplate-treated patients achieved overall platelet response than placebo-treated patients (study 1, 88% versus 14%; study 2, 79% versus 0%; $P < 0.05$ for both comparisons). In studies 1 and 2, the Nplate group maintained a platelet count of 50×10^9/L or greater for an average of 15 and 12 weeks, respectively, as compared with an average of 1 and 0 weeks for the placebo group. Patients from studies 1 and 2 whose platelet count decreased to less than 50×10^9/L after withdrawal from study medications entered the extension study and received Nplate for a maximum of 96 weeks. The majority of patients reached a median platelet count of 50×10^9/L after receiving 1 to 3 doses of Nplate and maintained the platelet count throughout the study. The most common adverse effects were arthralgia, dizziness, insomnia, myalgia, pain in extremity, and abdominal pain. Nplate is only available for administration by prescribers or health care providers enrolled in the Nplate NEXUS (Network of Experts Understanding and Supporting Nplate and Patients) Program.

VIREAD

The FDA has given approval to Gilead Sciences, Inc. (Foster City, CA) to market Viread (tenofovir disoproxil fumarate) for the treatment of chronic hepatitis B in adults. Viread was evaluated in 2 phase 3, randomized, double-blind, active-controlled studies involving hepatitis B e antigen (HBeAg)–negative (study 1; n = 375) and HBeAg–positive patients (study 2; n = 266) with chronic hepatitis B and compensated liver function, the majority of whom were nucleoside-naive. Patients were randomized to Viread 300 mg or Hepsera (adefovir dipivoxil) 10 mg for 48 weeks. At baseline, patients in studies 1 and 2 had a mean Knodell necroinflammatory score of 7.8 and 8.4, mean plasma hepatitis B virus DNA level of 6.9 and 8.7 $\log_{10}$ copies/mL, and mean serum alanine aminotransferase level of 140 and 147 U/L, respectively. The primary endpoint for both studies was complete response to treatment, defined as hepatitis B virus DNA levels below 400 copies/mL and Knodell necroinflammatory score improvement of at least 2 points, without worsening in Knodell fibrosis at week 48. In both studies, more Viread-treated patients achieved a complete response as compared with Hepsera-treated patients (study 1, 71% versus 49%; study 2, 67% versus 12%). The most common adverse effect was nausea. The recommended dose of Viread is 300 mg once daily taken orally.

XENAZINE

Prestwick Pharmaceuticals, Inc. (Washington, DC) has received FDA approval to market Xenazine (tetrabenazine) for the treatment of chorea associated with Huntington's disease (HD). The efficacy of Xenazine was established in a randomized, double-blind, placebo-controlled multicenter trial involving 84 patients with HD. Patients received Xenazine (started at 12.5 mg/day and titrated upward at weekly intervals in 12.5-mg increments until control of chorea was achieved, until intolerable side effects occurred, or until a maximum dose of 100 mg/day was reached) or placebo for 12 weeks, including a 7-week dose titration period and a 5-week maintenance period followed by a 1-week washout period. The primary endpoint was the total chorea score (score, 0–4, with 0 representing no chorea, for 7 different parts of the body [total score range, 0–28]). Total chorea scores in the Xenazine group decreased by an estimated 5.0 units during maintenance therapy (average of week 9 and 12 scores versus baseline) as compared with an estimated 1.5 units in the placebo group (treatment effect, 3.5 units; $P < 0.05$). At 13-week follow-up, total chorea scores of Xenazine-treated patients returned to baseline. Of Xenazine-treated patients, 19%, 50%, and 69% achieved 10-point, 6-point, and 3-point improvements, respectively, in total chorea score from baseline as compared with 3%, 7%, and 23% of placebo-treated patients. The most common adverse effects were sedation/somnolence, fatigue, insomnia, depression, akathisia, and nausea.

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.*